

MARCH 2016

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Creating a Dry Eye Center of Excellence

Highlights from our 2nd annual Dry Eye
seminar held during AAO in Las Vegas



John Sheppard, MD, MMSc
Moderator



Mitchell A. Jackson, MD



Patti Barkey, CEO, COE



Kendall Donaldson, MD, MS



Sheetal Shah, MD



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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RESTASIS® (Cyclosporine Ophthalmic Emulsion) 0.05%

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

INDICATION AND USAGE

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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 mL) 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 mL) 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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Creating a Dry Eye Center of Excellence

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Table of Contents

MARCH 2016

Overview of a Successful Dry Eye Center of Excellence 06

Deciphering the Dry Eye Code 08

What You Need to Get Started 12

Taking Ocular Surface Treatment to the Next Level 14

Our Unique Approach to Dry Eye in Rural Georgia 18

Dry Eye Q&A 20



Special thanks to program

coordinator **Lauren Levine**, who works closely with the Florida Society of Ophthalmic Administrators and is a contributor to *Ophthalmic Professional*. This is her second year spearheading the Dry Eye breakfast seminar.

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Overview of a Successful Dry Eye Center of Excellence

Myths and realities from the management perspective

At our growing practice, which consists of 17 providers and 195 employees working in four offices, we long ago stopped asking whether we should establish ourselves as a dry eye center of excellence. We felt that if we were to remain committed to clinical leadership in our community, the answer had to be “yes.”

Dry eye is a ubiquitous disease that affects a patient’s quality of life and vision as well as our surgical outcomes. This is so important that we market dry eye care as much as we market cataract surgery in our practice — and the dry eye ads, particularly for clinical research, often bring in more patients.

When other practices consider this way of thinking about dry eye care, three objections tend to arise: 1) It will slow us down; 2) It will distract us from our surgical focus; and 3) The profit margins are low. Our practice is proof that these objections are myths and not reality.

Dry Eye Care Won’t Slow Down a Practice

Quality dry eye care adds elements to the exam and patient education, but none of it has to stress patient flow. Use of physician extenders speeds up the process. These key staff members may include a scribe, a physician assistant, an excellent optometrist, a mover who runs patients back and forth between rooms, the personnel at checkout,

and an astute counselor who clearly describes the diagnoses and treatment choices to patients.

Dry Eye Care Enhances the Surgical Focus

Cataract surgery is known to add one severity step to a patient’s dry eye as classified by DEWS, and LASIK is known to add two steps¹ (Figure 1). Therefore, at our practice, we have zero tolerance for preoperative intraocular inflammation or posterior segment inflammation, and we find punctate keratopathy, particularly in the visual axis, as well as topographic aberrations intolerable.

In the multifocal IOL and refractive cataract surgery era, where our outcomes must be ultra satisfying, no surgeon should risk a patient with a bad outcome who says, “You gave me dry eye. I didn’t have it before my surgery.” We must be proactive.

Dry Eye Care Generates Revenue

In order to adequately treat dry eye and to maximize our surgical outcomes, we’re expanding our procedural services. Today, a wide variety of excellent practice-building treatments are available, including traditional punctal occlusion. In our practice in 2014, collagen and silicone punctal plugs and punctal cautery brought in six figures in collections and markedly improved the lives of our patients.

We use LipiFlow thermal pulsation therapy (TearScience) for our patients who have meibomian gland dysfunction/evaporative dry eye. We motivate our patients and our practitioners to recommend this at every opportunity because of the dramatic, sometimes life-changing, results we achieve. We’ve been able to

John Sheppard, MD, MMSc
Virginia Eye Consultants
Norfolk, Va.



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)		

Figure 1: 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.

continuously decrease our fee, thanks in part to recent pricing reductions from TearScience. We can easily gross more than \$100,000 per year for our practice by offering this treatment.

Using the Prokera biologic corneal bandage (Bio-Tissue) to control the inflammatory process and accelerate healing on the ocular surface in a variety of dry eye-related conditions and to accelerate preparation for surgery, we can add more than \$300,000 to our collections.

In addition, we recommend nutritional supplements to our patients, including HydroEye (ScienceBased Health), as part of our retail sales segment. We also sell other adjunct therapies, such as lid wipes, lid compresses, and humidifying masks, through MyEyeStore.com and at the checkout counter in our four clinics. By offering these retail products to our patients, we can earn an additional \$300,000-plus yearly. Our combined revenue derived from dry eye therapeutics tops \$1 million each year.

Furthermore, we've found that dry eye treatments, whether insurance-based or cash-based, are often a better use of physician time in terms of the dollars per minute they generate. For example, on this measure, Prokera Slim outperforms cataract surgery with monofocal IOL implantation (\$120 vs. \$40), and LipiFlow outperforms LASIK (\$180 vs. \$150 OU). These efficiencies are highly dependent on a well-trained technical and counseling staff.

Diagnostic testing for dry eye is

an expanding area. We can perform a variety of tests, including imaging, which I consider complementary. For example, in our practice, we utilize tear osmolarity testing (TearLab) for a host of indications — new dry eye patients, all surgical patients, punctal plug decision analysis, lipid or aqueous prioritization, monitoring treatment effectiveness, neurotrophic assessment, post-LASIK hyperesthesia syndrome, contact lens decision analysis — which legitimately generates high six-figure billings annually. Other diagnostic tests we use contribute to vital decisions for each patient and limit erroneous therapeutic recommendations.

The tests that generate important annual revenue for our practice from our 17 providers follows:

- InflammADry (RPS)
- TearLab Osmolarity test
- LipiView interferometry (TearScience)
- LipiView Dynamic Meibomian Imaging (TearScience)
- Doctor's Allergy Formula (Bausch + Lomb)

Taken together, the dry eye-related diagnostic testing and imaging we perform in our practice results in significant revenues. Combining that with our dry eye therapeutics revenue, we are generating more than \$3 million toward better patient care, the equivalent of three providers, yet superior decision making saves society an estimated \$1 million per year. These fiscal bottom-line benefits come logically by making the correct

diagnosis the first time around and prescribing the appropriate therapy, thereby saving tremendously on unnecessary topical prescriptions, oral prescriptions, over-the-counter medications, unpredictable refractive and cataract surgical outcomes, and unnecessary time and travel costs with fewer patient visits to providers to clean up previously empirical therapeutic decisions. Everyone wins.

Everyone Benefits from Dry Eye Care

No one loses when a practice commits to providing quality dry eye care. Patients win because their needs are identified and taken care of; insurers win because diagnosis is accurate and therapy is correctly targeted the first time; doctors win because their own practice grows; and the entire practice wins because income is diversified.

We look forward to continuing on our positive dry eye trajectory with the eventual help of several new therapies that are on the horizon. These include a multidose vial of cyclosporine (Restasis, Allergan), the secretagogue clinical candidate tavilermide (Allergan), electrostimulation (Allergan), liftegrast (Shire), and the antibacterial, antiviral topical surface treatment (Shire) that has the potential to revolutionize the way we treat dry eye and secondary infections. ■

Reference

1. Behrens A, Doyle JJ, Stern L, et al. Dysfunctional tear syndrome: a Delphi approach to treatment recommendations. *Cornea*. 2006;25(8):900-907.

Deciphering the Dry Eye Code

A framework for diagnostic and treatment protocols

The tear film is the most important refracting surface of the eye, and this is very important in our practice where we've performed more than 30,000 laser vision correction procedures and more than 20,000 cataract surgeries and have approximately 90% conversion to femtosecond laser-assisted cataract surgery and 53% conversion to premium IOLs. Our success is based on our active management of ocular surface disease, i.e., dry eye, along with astigmatism, macular pathology, posterior capsular opacification, and IOL calculations, all of which factor into our overall patient satisfaction.

Dry eye is a complex disease, but our understanding of it as a profession has been improving. As a result, it's

possible to distill what is currently known down to key points we can use to create and guide our diagnostic and treatment protocols.

Dry Eye Facts, Simplified

► Dry eye is a multifactorial disease accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.¹

► The disease classification developed by the International Dry Eye Workshop (DEWS)¹ is a way to stage dry eye severity in the clinical setting. I think of it like this: Level 1 is conjunctival staining; Level 2 is corneal and conjunctival staining; Level 3 additionally involves filamentary signs on the cornea; and Level 4 additionally involves conjunctival scarring.

► Meibomian gland dysfunction

(MGD), a progressive disease that can lead to meibomian gland atrophy,² is present in 86% of cases of dry eye.³

► Dry eye risk factors include the following:

- Age
- Female gender (postmenopause)
- Poor diet (low in omega-3 fatty acids, high in bad omega-6 fatty acids)
- Autoimmune disease (thyroid, lupus, rheumatoid arthritis, diabetes)
- Sjögren's Syndrome
- Low blink rate (due to systemic disease, e.g., Parkinson's, or digital device use)
- Medications (antihistamines, diuretics, antidepressants/antianxiety)

My Personal Approach

With the key dry eye facts and risk factors in mind, I approach the care of each patient in the following manner:

► **Review patient questionnaire.**

We have our patients complete the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire. I've modified it to include allergy-related questions as a first step toward determining the precise causes of their symptoms.

► **Analyze results of point-of-care diagnostic testing.** There are many clinical measures for evaluating and monitoring dry eye, including:

- Tear secretion (Schirmer's test)
- Corneal/conjunctival vital dye stains
- Tear breakup time
- Lipid layer imaging (LipiView, TearScience)
- Meibomian gland structure imaging (LipiView II/Dynamic Meibomian Imaging [DMI], Tear Science)
- Impression cytology (goblet cell analysis)
- Tear osmolarity (TearLab)
- MMP-9 activity (InflammaDry, RPS)
- Sjögren's syndrome test (Sjö, Valeant)
- Ocular allergy testing

Mitchell A. Jackson, MD

Jacksoneye
Lake Villa, Ill.





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MMP-9 and Dry Eye Severity¹

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

Figure 1: MMP-9 levels in the tear film help to identify dry eye severity.

(Doctor's Allergy Formula, Bausch + Lomb)

I don't have every available diagnostic test and device in my practice, but in addition to vital dye staining, I've found InflammDry, TearLab osmolarity testing, LipiView, and Doctor's Allergy Formula to be very useful in assessing the overall ocular surface status.

InflammDry is a rapid point-of-care test. Our technicians have no problems performing it. The test identifies elevated levels of the inflammatory biomarker matrix metalloproteinase 9 (MMP-9) in the tear film with high sensitivity and specificity. Inflammation isn't a factor in every patient's dry eye, so it's important to know when it is so we can treat it. A positive result is MMP-9 ≥ 40 ng/ml, and it indicates, based on the DEWS classification, at least Level 2 severity (See Figure 1). InflammDry is a useful way to monitor the effects of treatment as well.

Several studies have shown that a significant number of patients, including those coming in for cataract or refractive surgery, have signs of ocular surface disease but are asymptomatic.^{4,5} It's up to the doctor to look for the signs.

Tear osmolarity testing is an excellent predictor of disease severity.⁶ Two numbers are crucial in

identifying abnormal osmolarity: 1) If the highest reading of the two eyes is >308 mOsm/L, it indicates loss of homeostasis and pathogenesis for ocular surface disease; and 2). An intereye difference of >8 mOsm/L is a hallmark of tear instability. It's important that patients don't use drops for at least 1 to 2 hours before the osmolarity test.

The LipiView II interferometer for detecting MGD is also part of our dry eye workup, and we're in the process of implementing the new DMI capability. This instrument quantifies the lipid layer of the tear film with sub-micron precision and also shows if patients are partial blinkers,

which we can help them to change. DMI improves assessment of gland structure. Seeing the degree of gland dropout is essential to knowing the extent of MGD progression so expectations can be set.

Finally, we also utilize the Doctor's Allergy Formula point-of-care skin test, which takes the guesswork out of determining whether allergy is or isn't playing a role in a patient's ocular surface disease. Also, positive skin testing helps validate any prior authorization that is needed for prescribed topical antihistamine and/or steroid eye medications.

During a patient's initial evaluation, I like to prescribe at least one treatment to move the health of the ocular surface in the right direction. I typically follow up 6 weeks later to see how he or she is doing, and tear osmolarity is my main objective test at that visit.

► **Prescribe, titrate treatment based on the diagnostic testing.**

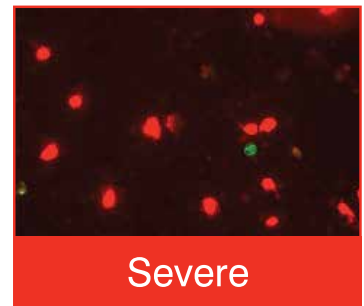
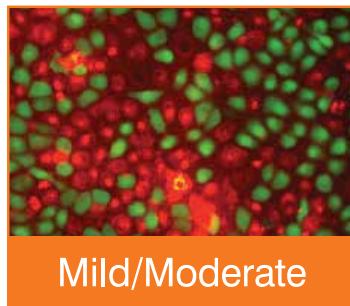
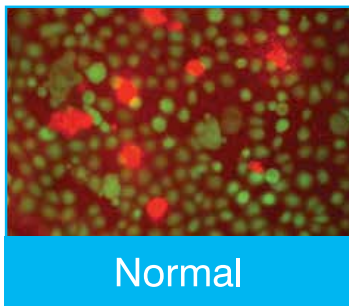
- For patients who need ocular allergy treatment, I prescribe an H1 receptor-specific topical medication, such as Lastacast (alcaftadine ophthalmic solution 0.25%, Allergan) or Bepreve (bepotastine besilate ophthalmic solution 1.5%, Bausch + Lomb), which have a lower dry eye side effect than others that are non-specific.

CONTINUED ON PAGE 22



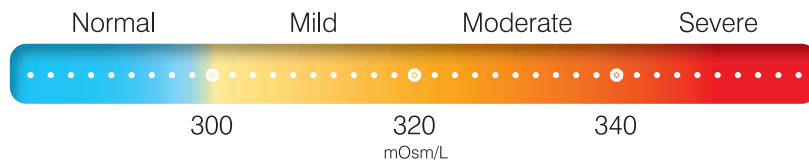
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Increasing osmolarity leads to an unhealthy tear film



Increasing osmolarity leads to an increase in human corneal epithelial cell apoptosis.

Hyperosmolarity and inter-eye variability indicate unstable tear film and evidence of pathogenic changes on the ocular surface.



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What You Need to Get Started

Implementation of dry eye care into today's busy practice

At Bowden Eye & Associates, we provide a range of premium services, but we don't consider our dry eye care to be a premium service. We consider it a necessary medical service, provided in a premium manner. While we've grown into quite a large practice, even the smallest practice should have a dry eye component. You don't need to be a full-service specialty dry eye office that offers comprehensive diagnostics, treatments, and products. You could choose to share care by diagnosing dry eye and offering related products but referring out for treatments. Or, you could choose to be purely referral-based by recognizing the condition and referring out for treatments and products. Whichever type of dry eye practice you choose to be, ensuring that your patients receive the dry eye care they deserve is of the utmost importance.

So, how should you begin? The good news is you already have the necessary first component: the patients. They walk through your door every day.

Use the Five Ps as Your Road Map

In order to truly treat dry eye in your practice, you have to look beyond the patients who present with red eyes. Not all cases of dry eye involve red eyes, or any symptoms at all for that matter. Every patient is a person potentially in need of dry eye treatment, and to identify and help them you need to have in place your people, products and diagnostics, procedures, process, and payment process (**Figure 1**).

PEOPLE

For a practice to successfully treat dry eye, its leaders need to develop clinical protocols, i.e., a standard of care. All staff members need to be trained and engaged in that standard of care. It helps to have an administrator who can make things happen. As our practice's CEO/administrator, I'm quite strict in this regard. I expect that if we put a protocol in place, everybody on the team is going to learn the protocol, and everybody on the team is going to follow the protocol. Otherwise, patients aren't being fully cared for and revenue and outcomes become subpar.

It's important to appoint someone to the role of implementer of the dry eye program. This person should direct the dry eye services by making sure all of the parts are in place and running as intended. When anything new is added to the standard of care, he or she shares the message with the rest of the staff and ensures that the patients are receiving the right messages, too. If something isn't working smoothly or as intended, the implementer is the one to figure out how to change it. A counselor should be part of a practice's dry eye culture as well. A cataract counselor can take on this role. It isn't difficult for someone in that position to learn how to educate patients about dry eye.

It's worth repeating that staff buy-in and education are crucial, and training needs to be ongoing. All of the vendors who have dry eye products on the market offer training and related resources. Take advantage of that. If you're making a purchase with them,

Patti Barkey, CEO, COE
Bowden Eye & Associates
Jacksonville, Fla.



rely on them to help make it work for you.

PRODUCTS AND PROCEDURES

Comprehensive dry eye care requires a practice to adopt a portfolio of products, not just one, in order to accurately diagnose dry eye and treat it in all its forms.

Having a nutritional supplement to recommend in order to address the root of the condition is important. We chose HydroEye (ScienceBased Health) for our practice and have utilized all of the training, webinars, and so forth, the company provides to help staff members understand the product.

Your providers must be prepared to address blepharitis and meibomian gland dysfunction (MGD), and for that purpose we find BlephEx (Rysurg) effective for lid exfoliation and discouraging demodex and easy to incorporate. We also consider the in-office Cliradex Complete Advanced Lid Hygiene Kit (Bio-Tissue) to be essential for managing demodex as well as blepharitis, MGD, rosacea, dry eye, chalazia, and other lid margin diseases. Each kit comes with eyelid and eyelash cleansing wipes for patients to take home. And one of the most effective therapies for MGD is LipiFlow thermal pulsation therapy (TearScience), which we use in our practice as well. Punctal plugs are a proven treatment for dry eye and we've also added to our arsenal the Prokera Slim biologic corneal bandage (Bio-Tissue). This cryopreserved amniotic membrane device contains hormones, growth factors, and anti-microbials that work together to expedite healing of a damaged corneal surface.

On the diagnostic side, in addition to osmolarity testing (TearLab), we find meibography to be an indispensable tool. The LipiView II device with Dynamic Meibomian Imaging (DMI) (TearScience) not only gives our doctors a way to quickly assess meibomian gland structure and function, but also has been amazing for helping us to demonstrate for



Figure 1: In order to treat dry eye in your practice, you need the 5 Ps: people, products and diagnostics, procedures, process, and payment.

patients why they need treatment and opt to have it.

PROCESS

In our practice, the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire begins the dry eye standard of care process. The technicians fill it out with the patient. From that, they glean what to do next. For example, does the patient need an InflammDry test (RPS)? Does the patient need DMI?

Other advice I give about the dry eye care process is that it's necessary to decide how you'll inventory the products you'd like patients to use. Along with that, you don't have to limit the items you offer to just one per category. For example, we sell several types of eye masks (Eyeeco; Bruder; or Fire and Ice, Rhein Medical) because our patients like to choose which type they want. Furthermore, you can package certain products, such as lid wipes or gauze pads, and send them home with patients so they have everything they need to begin their at-home therapy. You can tie this into your marketing by creating a branded bag to use as your packaging.

PAYMENT

Being paid for the dry eye services and products you offer is, of course, crucial. Some are patient-pay and others are covered by insurance. I encourage any practice that is serious about dry eye care to not worry about that.

Don't avoid using a product or treatment you feel would benefit your patients only because insurance isn't covering it. Set your standard of care and set your fee structure and get started.

File what you can with the carriers, know what you can't file, educate patients about the importance of the test or therapy, have them sign advance beneficiary notices when necessary, and collect your fees.

Be Ready to Greet the Future

At our practice, we feel strongly that eventually everyone in the community will soon recognize the importance and benefits of providing real dry eye care.

In the meantime, we're happy to have our strategy already in place as an early adopter so our patients are getting the care they need and we're expanding as a result. ■

Taking Ocular Surface Treatment to the Next Level

What's working at our academic dry eye center

More than 25 million Americans suffer from dry eye, the disease state most frequently encountered by eyecare professionals, and they spend \$3.8 billion annually on symptom relief.¹ Some people have dry eye so chronic and/or so severe it adversely affects their daily lives. It's not unheard of, as we see in Internet chat rooms for example, for it to cause people to contemplate suicide. We've been caring for dry eye patients for years at the Bascom Palmer Eye Institute in Miami, and we now have a facility in Plantation, Fla., where we've centered all of our ocular surface functions.

In Plantation, we see many patients for whom initial dry eye treatments, perhaps artificial tears, punctal occlusion, or warm compresses that work very well for others, simply haven't been effective enough. Our approach for these patients begins with helping them to understand that dry eye is a chronic condition, and we aim to forge a supportive relationship to help them achieve the best outcomes. Thankfully, we have some newer treatments we can use to help us.

Omega Supplements

I'm a believer in omega dietary supplementation, and I recommend it for all of my dry eye patients. We do have unanswered questions about optimal omega supplementation, including what balance of omega-3 and omega-6 fatty acids is best, so further study is needed. But two recent clinical studies are notable.

A multicenter, randomized, prospective, controlled study by Sheppard, et al. compared the effects

of HydroEye (ScienceBased Health) omega-GLA supplements with placebo in post-menopausal women.² Only the supplements improved dry eye symptoms. In addition, the supplement group experienced no progression of ocular surface inflammation based upon conjunctival impression cytology T cell and HLA marker expression,

Allergan) can be considered as a first-line treatment for dry eye with an inflammatory component, which we can now better direct using MMP-9 point-of-care testing, and it's also been shown to be effective in very complicated cases.

In a systematic review and meta-analysis by Zhou and Wei, even



Kendall Donaldson, MD, MS
Bascom Palmer Eye Institute
Plantation, Fla.

while inflammation worsened in the placebo group. Corneal topographic smoothness was maintained with supplement use, but surface irregularity progressed in the patients taking placebo.

Another study, a multicenter, double-masked, randomized, placebo-controlled trial by Donnenfeld et al. compared placebo with supplementation with Dry Eye Omega Benefits (PRN), which contains 1,680 mg EPA and 580 mg DHA. By 12 weeks, the treatment was effective, resulting in statistically significant improvement in tear osmolarity, corneal staining, ocular surface disease index (OSDI) symptom scores, and omega-index levels.³ This study is continuing.

Restasis

Certainly Restasis (cyclosporine,

patients with systemic immune dysfunction exhibited statistically significant improvement in tear break-up time (TBUT) and Schirmer's test scores with use of Restasis.⁴

Serum Tears

There haven't been many well-controlled appropriately randomized studies of serum tears, but last year a retrospective study of 50% concentration autologous serum tears by Hussain et al. found them to be safe and effective. Improvements in corneal fluorescein staining and Schirmer's test scores were sustained with long-term use.⁵ I'm very interested in serum tears, and we're having great success using them for our patients at Bascom Palmer. We've seen how this therapy can be life-changing for even the sickest of patients. We started out using primarily

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UNCOVER HIDDEN DRY EYE



20% serum tears and now we're using 40% to 50% in many patients with very good results.

We're in the process of running our own trial. As we're looking at our data, we're finding improvement in OSDI, corneal staining, TBUT, tear osmolarity, and Schirmer's testing. Our objective biomicroscopic findings indicate that 26% have full resolution of signs, 42% have partial resolution, and in 32% we're unable to distinguish an improvement.

When we asked our patients for their perspective on serum tears, 26% reported, "This has fully cured my problem." These are patients who were refractory to all other treatments. In addition, the treatment isn't covered by insurance, yet patients are motivated to spend \$120 a month year after year to have it.

Lid Treatments

Cliradex for Demodex

As we now know, a substantial percentage of the dry eye cases we see are driven by eyelid and meibomian gland problems. One such problem that we've become more aware of is demodex. When these little mites multiply out of control, they contribute to a number of ocular surface-drying conditions, including blepharitis, meibomian gland dysfunction (MGD), and conjunctival inflammation.

Although tea tree oil is an effective treatment for demodex, it's toxic to the ocular surface and eyelids. Our new demodex treatment of choice is Cliradex cleansing towelettes (Bio-Tissue). Cliradex towelettes contain the component of tea tree oil, 4-Terpineol, that has the greatest effectiveness at the lowest concentration. Therefore, when patients use these at home, they're highly effective but don't cause the reactions we would see with tea tree oil. Many of our staff members who don't have demodex use Cliradex as part of their daily skin care regimen.

Meibomian Gland Therapies

We have a full lid clinic at our facility,

SHIRE'S PRODUCT PIPELINE

Currently, Shire's ophthalmic unit is working to bring to market lifitegrast, a new dry eye product. Shire has completed its Phase 3 trial of the investigational drug, which is designed to treat the signs and symptoms of dry eye disease in adults.

In January, Shire announced it had resubmitted the New Drug Application (NDA) to the FDA for lifitegrast after receiving a request for an additional study in October 2015. To address the request, Shire included added data from OPUS-3, a Phase 3 efficacy and safety trial with a primary endpoint of patient-reported symptom improvement.

The FDA has granted Shire a Prescription Drug User Fee Act (PDUFA) date of July 22, 2016.

where we perform all of our manual meibomian gland expression and MiBoFlo and LipiFlow (TearScience) treatments. MiBoFlo is relatively new to us, but we're pleased with our results so far, and LipiFlow has been very successful for us. Somewhat unexpectedly, our patients who have benefitted the most from LipiFlow are those with the greatest degree of corneal staining, not necessarily those with the highest degree of MGD or most inflamed eyelids. Many of our patients return to our lid clinic for monthly or bimonthly manual expression and are choosing to return for MiBoFlo and LipiFlow treatments when necessary as well.

Scleral Contact Lens

The PROSE (prosthetic replacement of the ocular surface ecosystem) scleral

contact lens (BostonSight) is a very important solution we offer to our severe dry eye patients. It's designed for use in a variety of conditions, such as irregular astigmatism, corneal dystrophies, and scarring, but it has served as the missing link for many of our patients who are refractory to every other available ocular surface disease treatment.

Amniotic Membrane

Several different types of amniotic membrane are available and can be used to relieve the symptoms of chronic dry eye. The Prokera amniotic membrane (Bio-Tissue) is differentiated by the fact that it's cryopreserved with a proprietary method that maintains the effectiveness of the components of the membrane that are necessary for regenerative healing. That means it does more than protect the surface of the eye — it rejuvenates it.

The newest version of Prokera, the Prokera Slim, is a game-changer due to its ease of use and enhanced tolerability for patients. In a case where a patient has trouble keeping the membrane in the eye, tape tarsorrhaphy is an easy, effective solution.

Utilizing novel, advanced treatments to help patients who weren't able to find help elsewhere tends to turn challenging dry eye cases into some of the most rewarding. ■

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

Our Unique Approach to Dry Eye in Rural Georgia

Addressing an unmet need with motivation, organization, and delegation

Throughout the past 6 months, we've developed a dry eye clinic within our established practice. (See "North Georgia Eye at a Glance.") We decided to do this for several reasons: 1) We know that patients want to see 20/20 or better, and quality vision requires a healthy ocular surface; 2) 50% to 75% of our patients have dry eye symptoms, so by treating them, we can, in theory, have happier and more satisfied patients; and 3) it's a great way to step into an under-represented area of ophthalmology, improve surgical outcomes, generate revenue, and establish a niche and a referral base.

We accomplished this by performing scheduled dry eye evaluations 2 days per week. We see 20 to 25 patients each day, and approximately 25% of them undergo a treatment at that visit. Approximately 80% of our dry eye clinic patients are in-office referrals, meaning they were already our patients. Around 10% are self-referrals, and 10% are referred by outside eye doctors or primary care physicians. I currently work 2 days per week, and 75% of my practice is ocular surface disease. We have three technicians who rotate in and out of the clinic and one financial counselor. This approach is unique because we're a small-scale yet full-service dry eye clinic with separate scheduled evaluation appointments, and most of our patients are internal referrals.

We have five parts to our dry eye management algorithm:

1) Identify dry eye disease

- SPEED questionnaire
- InflammDry (RPS)

2) Diagnose dry eye disease

- LipiView (TearScience)
- Schirmer's test
- Diagnostic expression/Korb Meibomian Gland Evaluator (TearScience)

3) Educate the patient

4) Provide financial counseling (if needed)

5) Perform treatment; establish follow-up care

- BlephEx (Rysurg)
- LipiFlow (TearScience)
- Prokera biologic corneal bandage (Bio-Tissue)
- Dry eye medications
- Dry eye product basket

The first step to carrying out the algorithm is getting patients scheduled for the dry eye evaluation. Patients being seen in our comprehensive, cornea, or retina clinics who have dry eye symptoms and are motivated to find a solution are scheduled for a dry eye evaluation during our dedicated dry eye clinic days. The dry eye appointment is a 25- to 30-minute slot. Prior to the appointment, staff call patients to advise them not to use eye drops, eye cream, or makeup in the 24 hours before testing.

During the appointment, patients have three main stops: the front desk, the diagnostic room, and the exam room. At the front desk, patients check in and out, make their payment, and, if necessary, purchase a basket of dry eye products. At check in, they receive a packet containing the SPEED questionnaire, which they begin filling out in the waiting room, explanations of dry eye disease, LipiView and LipiFlow, and a LipiFlow agreement sheet. If they sign the sheet, they receive the LipiView evaluation prior to seeing the physician. Of all the diagnostic tests we use, LipiView has been the most important because of how it helps with patient education. We don't need to say much because they can see firsthand the damage to

NORTH GEORGIA EYE AT A GLANCE

• Location

Gainesville, Ga., approximately 60 miles north of Atlanta, near the Blue Ridge Mountains

• Population

35,533

• Median Household Income

\$32,928

• The Practice

- 3 offices
- 1 ASC
- 3 ophthalmologists
- 1 optometrist
- Optical shop
- Hearing specialist
- Aesthetic center
- 25-30 staff members
- 1,100 patients per month at main clinic

• Services

- Premium cataract surgery
- Retina
- Pediatrics
- Aesthetics
- Contact lens fitting
- External disease

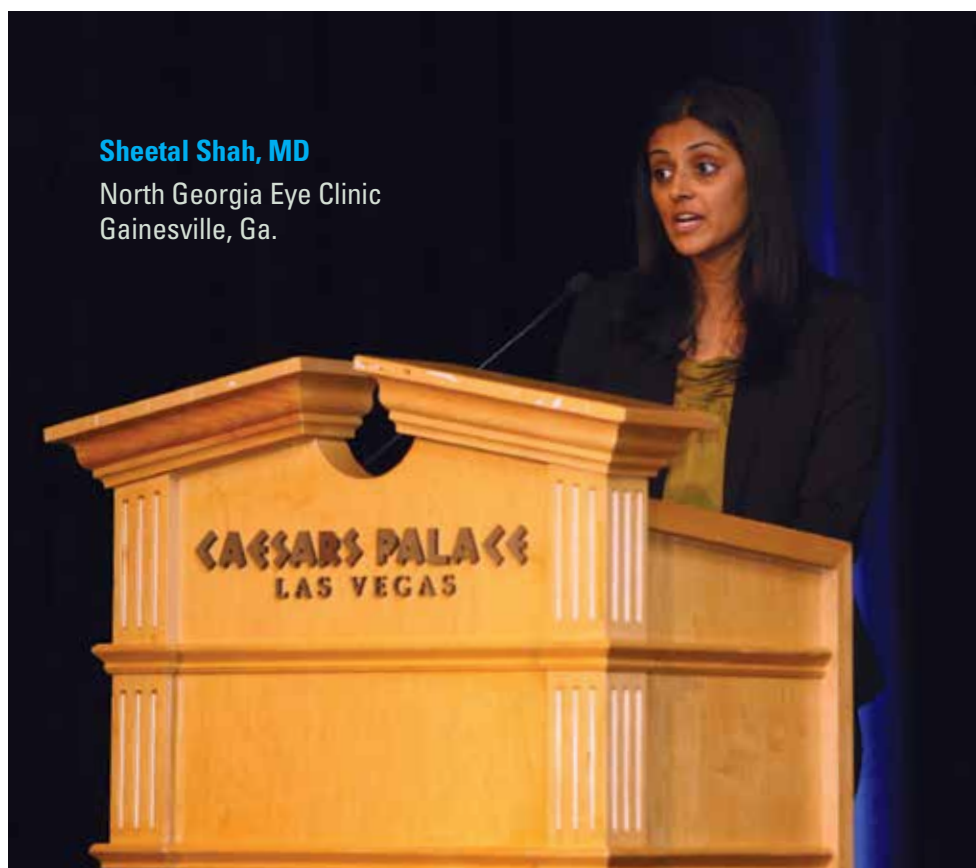
their meibomian glands. Also, we've integrated the LipiView into our electronic medical records system so we can view the results in the exam room and not have to bring patients back to the diagnostic room.

We perform the majority of the testing in the diagnostic room. When testing is complete, we usher patients to the exam room. There, they meet with the physician and undergo diagnostic gland expression. Patient education about treatment options, follow-up care, and financial counseling also take place in the exam room.

At checkout, we sell a variety of products that are packaged in our dry eye basket, including artificial tears and lid hygiene items. This helps to ensure patients use recommended treatments. Our patients like this because in our small town, the products may not be available in all pharmacies and stores.

Three Key Points

One of the aspects of our dry eye clinic that has proved to be very important is teamwork. The technician's contribution to the dry eye appointment is as important as the physician's. Our technicians spend 15 to 20 minutes with each patient during which time they're responsible for most of the diagnostic testing and starting the education process. I spend 5 to



Sheetal Shah, MD

North Georgia Eye Clinic
Gainesville, Ga.

7 minutes with each patient, and am responsible for diagnostic meibomian gland expression, reviewing test results, discussing treatment options, and continuing the education.

The financial counselor is a key member of the team because she

removes the doctor from the financial discussion, which we prefer.

Whenever we deal with services that aren't covered by insurance, the question that arises is whether patients will pay out of pocket. We've learned the answer is "yes," and we should never assume it will be "no." Today's patients want reason-based answers and they want the latest technology. I believe it's my ethical responsibility to offer them the most relevant and up-to-date treatments regardless of what my perception of cost is.

Finally, we've learned that to start a dry eye practice, you don't need a lot of personnel, resources, or materials. What you need is motivation, organization, and delegation. (See "Starting a Dry Eye Clinic.")

If you address dry eye needs in your practice, use the resources you already have to institute a system that works for you and create a team. You can establish dry eye care, just as we did in the "Poultry Capital of the World." ■

STARTING A DRY EYE CLINIC

Five Steps	Example: North Georgia Eye Clinic
1. Identify a need	75% of patients have dry eye disease
2. Appoint one person to take charge	Eyecare provider
3. Create a patient base	Referral system (mostly internal)
4. Decide what diagnostic tests and treatments to offer	InflammaDry, LipiView, LipiFlow, BlephEx, Prokera, dry eye medications
5. Create a team; educate and train	Eye care provider, technician, financial counselor, scheduler; utilized vendor resources and other established practices.

(Left to right) John Sheppard, MD, MMSc,
Mitchell A. Jackson, MD, Patti Barkey, CEO, COE,
Kendall Donaldson, MD, MS, and Sheetal Shah, MD



Dry Eye Q&A

Experts field questions regarding dry eye care

Q: Do you find that addressing dry eye has improved your patients' satisfaction with refractive cataract surgery?

Mitchell A. Jackson, MD: Yes. Refractive cataract surgery patients need a pristine ocular surface so that preoperative diagnostic measurements, including keratometry and corneal topography, are accurate. Otherwise, the IOL power calculation and femtosecond laser astigmatism-correcting incisions can be inaccurate as well, which for premium surgery patients in particular is a disaster. As the PHACO study¹ showed, the majority of cataract surgery patients do not have symptoms of dry eye even though they have the disease. In other words, they're not going to tell you they have dry eye, you have to look for it. Satisfaction has gone way up in terms of my outcomes because we're paying attention to the ocular surface much more closely than we had in the past.

Kendall Donaldson, MD, MS: I agree completely. Also, patients need to understand their dry eye is a preexisting condition (identified and acknowledged before surgery), not a complication we diagnosed after surgery and potentially created with our surgical intervention.

Q: How do you motivate the recalcitrant surgeon to adopt a dry eye mentality?

Patti Barkey: We developed a standard of care that all of the doctors agreed upon. We have a provider meeting about it once a month. Doctors can voice their opinions about certain aspects of it, but at the end of the day, we do what we have agreed to do. I do a great deal of record auditing. I check to what extent the doctors are following our standard of care, for example, whether they use the SPEED questionnaire, whether they evaluate the meibomian glands, and if they are abnormal, whether something is done for the patient to take care of it. Our doctors are on board. We eliminated a doctor from the practice who wasn't on board.

Q: Can you explain the difference between the HydroEye (ScienceBased Health) and the Dry Eye Omega Benefits (PRN) nutritional supplements? We'd like to be able to offer just one in our practice.

John Sheppard, MD, MMSc: Each of these companies has taken to heart the problem of the horrible American

diet. ScienceBased health has created a carefully formulated combination gamma linolenic acid (GLA) and omega-3 product. PRN offers a patented formulation of 3:1 re-esterified EPA and DHA only. They both work beautifully. There are, however, idiosyncratic responses such as seen with glaucoma medications. We have dozens of glaucoma drops we can use, but not every one works for every patient. If HydroEye isn't effective for a patient, Dry Eye Omega Benefits might be, and vice versa. Both are great products and address the problem for the vast majority of patients.

Dr. Jackson: Because some patients tolerate one better than the other, it's good to have access to both products.

Dr. Donaldson: We also need to encourage patients to stick with the supplements for at least a couple of months. They shouldn't expect instant relief. We recommend they get a supply that gives them a 3-month trial.

Q: TearScience recently changed its business model and decreased the cost of LipiFlow thermal pulsation system hardware and the treatment activators. How has that affected your pricing structure?

Dr. Sheppard: We reduced our fee by about half.

Dr. Jackson: We decreased our fee, and if a second treatment is needed within a year, the patient will get a discount. We want to make sure patients have access to the technology.

Barkey: We're not planning to change our fee. We've treated a great deal of patients at our current price level and feel it would be a disservice to them. We use the treatment on 48 to 60 eyes a month. We're going to use the extra profit for more marketing.

Dr. Donaldson: We cut our LipiFlow fee in half and we may cut it further. There were many patients who we felt could benefit from treatment but were unable to do so because of financial limitations. Now with price reductions, we can offer LipiFlow to a larger population of patients who could potentially benefit from this treatment modality.

Dr. Sheppard: We were a beta test site for the lower price and our volume shot up immediately. If this were covered by insurance, really, who wouldn't you recommend it for? Because it's a cash-based procedure, we look upon it just as we do refractive surgery. It's a premium service. The counselor provides a full disclosure about what to expect. If a patient needs a second treatment in 6 to 18 months, we discount that a bit.

Q: What's the incentive for patients to adopt the LipiFlow treatment? What's the endpoint they're trying to avoid in 95% of meibomian gland dysfunction cases?

Dr. Sheppard: Patients fall into one of three categories. Category one: the symptomatic patients. They're a slam dunk because they want to feel better. Category two: the

perioperative patients. They need to optimize their ocular surface for better results and safety. Category three: everyone else. When they look at the meibomian gland images you can capture with LipiView Dynamic Meibomian Imaging (DMI) (TearScience), don't be surprised if you have a doubling or tripling of your conversion rate. And truly, the patients with damaged glands will be more motivated despite a lack of self-awareness.

Q: Do you bring patients back for the dry eye evaluation or see them within the regular flow of the clinic?

Dr. Sheppard: I try to address the dry eye in at least one way at every visit. So, I may recommend an artificial tear or a nutritional supplement, for example, during the regular visit and then bring them back for a more detailed evaluation. We have a separate schedule block for the ocular surface imaging studies, just as we do for OCT, topography, or fields, which greatly facilitates patient flow.

Sheetal Shah, MD: We try to do the same. However, it can be challenging to accommodate the necessary dry eye education during a visit that wasn't scheduled as such, or to accurately perform some of the dry eye testing after the patient has had drops instilled. Therefore, while we try to start the patient off with something for the dry eye, we prefer separate evaluations.

Dr. Jackson: It helps to educate staff so they can identify the dry eye problem in the beginning of the workup and know what testing should be done. If we can't accomplish everything we'd like to at that visit, we try to at least initiate some type of helpful therapy and give it about 6 weeks to work. Then we have the patient back for another diagnostic test, perhaps InflammDry (RPS) or tear osmolarity (TearLab). When the objective test results indicate improvement, patients become more motivated to continue the existing therapy and/or use additional therapy.

Dr. Donaldson: We try to customize what we do by taking the dry eye care one step further than a patient has had elsewhere and creating a supportive partnership through the use of physician extenders, so patients feel we have spent the time and are invested in their care. Often, they are very frustrated and suffering from a lack of support and incomplete treatment of their symptoms. Dry eye is a chronic disease, so we must consider both the physiological as well as the psychological aspects of the disease process.

Barkey: Keep in mind that once you've been doing this for a while, you'll have so many patients you're working with that it's difficult to find a schedule block to fit them all. Access is important to the patient. ■

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- To lower tear osmolarity, I recommend a hypotonic artificial tear, such as Blink Tears (Abbott Medical Optics), Refresh Optive (Allergan), or TheraTears (Akorn).
- To control inflammation, I prescribe pulsed topical steroids or Restasis (cyclosporine ophthalmic emulsion 0.05%, Allergan), which inhibits T-cell activation and decreases MMP-9 activity.⁷ Restasis has also been shown, with continued use, to increase tear production regardless of when in the disease process it's initiated.⁸ Topical lifitegrast (Shire) may also be available in the near future to control inflammation based on the recent OPUS-3 clinical studies.
- For MGD, I've found that warm compresses, lid scrubs, and low-dose doxycycline can be beneficial. We also use LipiFlow thermal pulsation therapy in

our practice, the effects of which have been shown to last for up to 1 year.⁹

- I add nutritional supplementation where needed. While many good products are available, my preference is HydroEye (ScienceBased Health) due to the research behind it.¹⁰ Also, many patients prefer it and report that it does not have a fish taste.

Our attention to the ocular surface in this manner has been one of the most significant contributors to patient satisfaction in our busy surgical practice. ■

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A Program for Ophthalmologists

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TIME: 5:30 RECEPTION | 6:30 PANEL DISCUSSION



Kendall Donaldson, MD



Marguerite McDonald, MD



Cynthia Matossian, MD



Alice Epitropoulos, MD

PANEL:

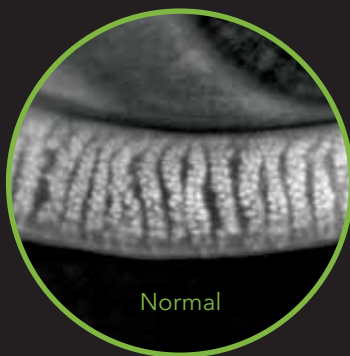
Kendall Donaldson, MD (*Moderator*), Marguerite McDonald, MD,
 Cynthia Matossian, MD, Alice Epitropoulos, MD



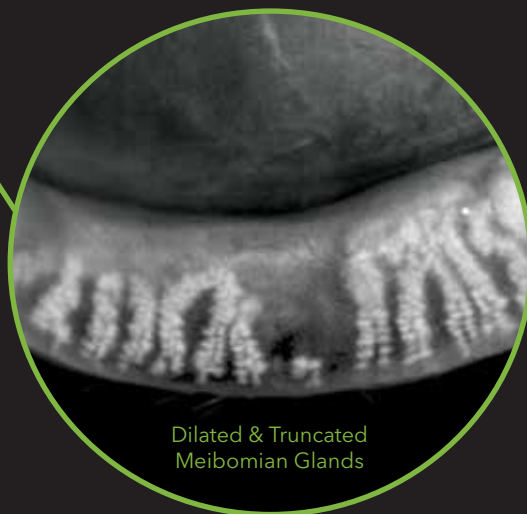
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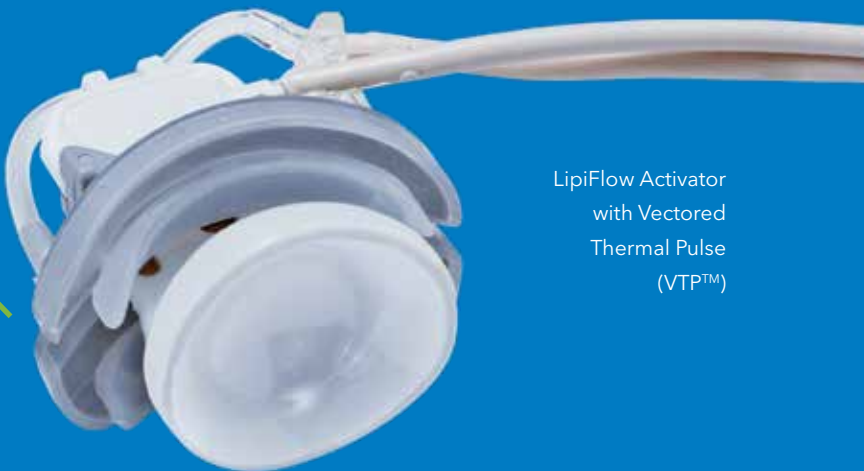
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