



Building a Successful Dry Eye Practice

A consensus document
drawn from a meeting of
experienced practitioners

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Preparing the Practice for the TearScience® System

Educate to Build Enthusiasm

Success with the TearScience® System (which consists of the LipiView® Ocular Surface Interferometer, the LipiFlow® Thermal Pulsation System, and the Meibomian Gland Evaluator [MGE]) requires the understanding and support of the entire eyecare practice. A critical first step before incorporating the TearScience® System is to inform everyone in the practice—from the front-desk staff to the surgeons—about the system and what it will mean to patients and practice. Chances of success are maximized with an informed and enthusiastic team.

The TearScience® System is, indeed, something to be excited about. LipiFlow® treatment improves patients' lives. Its efficacy in reducing dry eye signs and symptoms is supported by scientific study and practitioner experience. Making sure everyone on staff understands this requires a process of education best begun *before* the technology arrives.

The practice surgeons, in particular, must believe in the technology and be ready to recommend it without reservation. Dry eye is a chronic, progressive disease that diminishes quality of life.¹ Dry eye treatment should therefore be considered as important a part of the practice as glaucoma treatment or cataract surgery. If the physician partners understand the importance of dry eye to patients and take the lead in recommending the TearScience® System, success will follow.

Find the Pent-up Demand

Within virtually every eyecare practice, there exists a group of patients struggling with dry eye. These patients may be on artificial tears, doxycycline, steroid drops, topical cyclosporine, lid hygiene, or some other therapy. These may be LASIK candidates whose surgery

has been put on hold due to ocular dryness, or contact lens patients who are experiencing dryness and becoming contact lens intolerant. Any of these patients may be prime candidates for treatment with LipiFlow®, and a chart review can help find eligible patients and get the practice into using the TearScience® System quickly.

Within the Practice

The TearScience® System represents a completely new approach to dry eye treatment. For this to be successful, *everyone* in the practice must understand what the technology is and why it is effective. The TearScience® System is based on three core ideas:

1. Most dry eye is the result of meibomian gland dysfunction (MGD);²
2. MGD is chiefly the result of meibomian gland *obstruction*;³ and
3. This obstructive condition is best treated with the warmth and gentle, pulsatile pressure of the LipiFlow® Thermal Pulsation System.⁴

This new paradigm is exciting because it enables clinicians, for the first time, to treat the root problem in evaporative dry eye: obstructed meibomian glands.

Using this knowledge to create a successful dry eye practice requires that the practice's ophthalmologists pay attention to the ocular surface in every patient they see. Whenever a patient presents with signs or symptoms of dry eye, the examining ophthalmologist should do two simple things: recommend a dry eye work-up, and let patients know that, if evaporative dry eye is present, LipiFlow® can help. The follow-up exam and treatment can often be delegated to others—the key point is that all patients with dry eye be identified, informed of their condition, and told that the practice has an effective means to treat it.

In Practice

Don't Let Dry Eye Patients Slip By

Dry eye disease is highly prevalent, particularly among older people (the population that most ophthalmologists see).⁵⁻⁷ Estimates suggest that in the US alone there are more than 20 million patients with dry eye.⁸ Because it is so prevalent, many patients who present for something else—a glaucoma check, glasses, or cataract consultation—will be troubled by dry eye; but they may not take the time to mention it. Patients often ignore dry eye symptoms, thinking of them as an inevitable consequence of aging. But fortunately, they are wrong: today, dry eye is a treatable condition, and these patients can be helped.

Dry eye is typically progressive,¹ and early treatment may help slow its progression. Furthermore, dry eye disturbs the tear film, which affects the quality of the optical image the eye can form; treating dry eye should improve the quality and stability of the patient's vision. But while treating dry eye is clearly beneficial, patients may not recognize or mention their own symptoms. It is therefore essential to be proactive in looking for dry eye.

The Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire is quick, simple, and provides a reliable estimate of the patient's symptom level. A small amount of time invested in administering the SPEED questionnaire will uncover many patients with dry eye symptoms.

Technicians can play an important role here. Whenever they hear patients mention dry eye symptoms—eg, excess tearing, burning, foreign body sensation, fluctuating vision—it is essential to flag the chart so that action can be taken. These patients can either be worked up during their visit (if time permits) or scheduled to come back for a more complete dry eye evaluation. These

patients should not leave the practice without learning that they very likely have a treatable problem.

Because dry eye is highly prevalent, practices will find numerous cases—if they look for them. In the past, there may have been little reason to look for dry eye patients because, when found, there was little to be done for them. But today there is excellent reason to screen

be evaluated for dry eye; but with a little discussion, they may come to realize why they have difficulty reading for long periods, or why windy days bother them. Not all of these patients will be sufficiently troubled by their symptoms to want treatment, but many will.

Whether or not they are ready for treatment, education early in the disease process is helpful because it increases

START OUT CONFIDENT

Those who have experience with LipiFlow[®] treatment know it works. They find it extremely satisfying to be able to tell dry eye sufferers that there is now a simple, safe procedure that can help them. Here's why they are confident:

Dry eye very often has a significant MGD component;² and LipiFlow[®] is the first treatment to deal safely, effectively, and directly with MGD.⁴

The learning curve for the LipiView[®] Ocular Surface Interferometer is fairly short, and it is satisfying to have a tool that effectively shows patients why they are experiencing dry eye symptoms.

LipiFlow[®] treatment is applicable at all stages of dry eye. It is not just for patients with severe disease.

Eyecare practitioners have long recommended warm compresses and massage because they believe in their efficacy. LipiFlow[®] treatment works on the same principles, but is vastly more effective. Because of its demonstrated safety and efficacy, LipiFlow[®] should be the first line of treatment for dry eye, not the last resort.⁴

Every indicator points to the TearScience[®] System becoming the new standard of care for evaporative dry eye. Now is the time to get involved.

for dry eye: appropriate treatment can help affected patients lead happier, more comfortable lives.

Catch Early-stage Patients with SPEED

The SPEED questionnaire is short and easy enough to be administered to every patient—either in advance of the visit, or while they wait in the office. Some patients may be surprised if the questionnaire indicates that they should

the chance that patients will take steps to treat their dry eye. The SPEED survey is a great way to start: it creates awareness among patients that ocular dryness and discomfort late in the day or after computer work can be part of an underlying, treatable disease. Patients may not act on it immediately, but this awareness is the first step toward seeking effective treatment.

THE OPHTHALMOLOGIST'S RECOMMENDATION IS KEY

If the dry eye practice is going to thrive, one thing is critical: the full support of the practice's ophthalmologists. In practices where optometrists diagnose and treat dry eye, all an ophthalmologist has to do is identify dry eye patients and recommend that they have a full dry eye evaluation, with a LipiFlow® procedure if the examination indicates that it will be of value.

The ophthalmologist does not have to recommend LipiFlow®—that would be inappropriate without a full evaluation—but he or she can say words to the effect of: “Based on what you have told me and what I see of your ocular surface, you appear to have a dry eye condition. We have the new TearScience® System, which has been enormously helpful for many patients with dry eye. I recommend that you see Dr. X [a colleague in the practice] for further evaluation and to determine whether you are a candidate. If you are, the LipiFlow®

procedure could be very beneficial for you.”

Two things are key:

- That the ophthalmologist's recommendation be clear and strong, and
- That it be given to every appropriate patient.

If the patient's candidacy needs to be confirmed through a more complete examination (which may be done by a practice OD), the ophthalmologist can still deliver a clear endorsement of the technology.

Even the retina and glaucoma specialists in the practice will see many patients each day with dry eye. Like their cataract surgeon, cornea specialist, and comprehensive ophthalmologist colleagues, retina and glaucoma subspecialists can recommend that a dry eye condition be evaluated and tell the patient that LipiFlow® treatment has been extremely helpful for dry eye sufferers.

The Advantages of LipiView®

Incomplete Blink The only commercial device that can accurately measure the thickness of the tear film lipid layer, the LipiView® Ocular Surface Interferometer enables the noninvasive, quantitative evaluation of patients' lipid layer.

LipiView® is also excellent for demonstrating blink dynamics. Patients do not always take the doctor seriously (or even understand what is meant) when they are told during the slit lamp exam that they are “incomplete” blinkers. But the effect of seeing their own partial blink on the LipiView® screen can be striking, and it can help patients realize that their lids may not be spreading tears properly.

This realization helps patients understand both their condition and the limits of therapeutic intervention. That is, LipiView® examination helps patients recognize that, while

improving the meibomian glands with a LipiFlow® procedure will help, if they also have incomplete blink, MGD is not their only impediment to a normally functioning ocular surface.

LipiView® and Physician Peers

LipiView® impresses more than patients. Displaying it at continuing education meetings and giving attending optometrists and ophthalmologists a chance to have their lipid layers and blink

processes examined can generate great interest. The technology is as fascinating to professionals as it is to patients.

Get a Good Reading Since eyedrops have a significant effect on the tear film, any drop taken just prior to a LipiView® examination can affect the results. Getting an accurate determination of tear film status requires that patients refrain from drop use for at least 4 hours before their visit. Patients should stop the use of lipid-based drops (eg, SYSTANE® BALANCE; Restasis®, etc.) for at least 12 hours prior to their visit; and ointments should be stopped for at least 24 hours. In general, the longer patients can be off drops prior to the LipiView® examination, the better. Patients should be told this when scheduling their evaluation and be reminded by text message or email the day before they come in.



Gland Expression: A Critical Step in MGD Diagnosis

Of the patients who pass through an eyecare practice each day, only a small percentage have glaucoma, yet virtually every patient has his or her intraocular pressure (IOP) checked. Far more patients are at risk for dry eye than glaucoma, but unless a patient has a specific complaint, few practices will screen for dry eye.

The majority of dry eye disease is evaporative dry eye caused by MGD, and meibomian gland expression is a key test for determining the presence of MGD.² We suggest testing proceed in three steps. For patients whose SPEED score indicates potential dry eye condition, the LipiView® Ocular Surface Interferometer can determine the status of the tear film lipid layer. Then, a gland evaluation can be performed with the MGE. The three assessment steps can be remembered by the acronym SOG: for

Symptoms, Oils, Glands.

As a direct indicator of meibomian gland function, gland expression is an excellent gauge of whether LipiFlow® treatment will be of value to a patient. Gland expression is particularly useful because early-stage patients may have gland blockage without symptoms, and expression may discover evidence of diminished meibomian gland function in these patients. While asymptomatic patients may not wish to be treated, counseling will heighten their awareness. If and when they become symptomatic, they will have an idea of what is wrong and will know that effective treatment is available. If doctors take time to perform gland expression, the number of dry eye patients they discover—and help—will increase dramatically.

Dry Eye = MGD

Before the recent increase in research and focus on the meibomian glands and

their function, it was generally assumed that most dry eye conditions were caused by aqueous deficiency resulting from reduced lacrimal gland secretion. With that mindset, evaporative dry eye caused by MGD was thought to be of limited clinical importance.

Today, however, we know that precisely the opposite is true: the majority of dry eye is the result of evaporation secondary to MGD.² A multisite clinical study by Lemp and colleagues found that 86% of dry eye patients demonstrated signs of MGD.³ MGD has a primary role in most dry eye disease, and this has two critical corollaries:

- Meibomian gland expression is a valuable test for determining the presence of dry eye disease², and
- LipiFlow® treatment of the meibomian glands will benefit patients with an MGD component to their dry eye.⁴ As Lemp and coworkers have shown, this group comprises the

DEDICATED DRY EYE TIME

A little planning on the front end will help ensure successful integration of the TearScience® System into practice routines. Because dry eye patients require extra testing and extra teaching, their visits take longer. One very helpful way to organize their treatment so that it does not disrupt normal patient flow is with dedicated “dry eye clinic” time. For example, all or part of one or two days each week can be set aside for dry eye evaluation and treatment, with patients given longer appointment times to accommodate the necessary testing and education.

When a dry eye condition is discovered in the course of a visit for something else—a glaucoma check, for example—rather than work the dry eye evaluation in immediately, it is advantageous to schedule a second visit for a complete dry eye work-up. Attempting to add a dry eye evaluation to the glaucoma check can play havoc with the schedule in a busy practice. It is much more efficient to have these patients come back on “dry eye clinic day,” with an appointment long enough for the necessary testing and patient education.

Patients who are referred in specifically for a dry eye

evaluation, or patients who self-refer specifically because they have heard about a practice’s dry eye expertise, should likewise be scheduled for an appointment on “dry eye clinic day.”

While dedicated dry eye time is useful, there will always be situations—eg, the out-of-town patient who can only come on a certain day—that demand flexibility.

Not all dry eye appointments need to be done during a special clinic. Follow-up appointments after a LipiFlow® procedure, for example, are usually quick and can be scheduled for a regular slot on a normal workday.

There are benefits beyond efficiency to having “dry eye clinic” time. It can make some patients feel as if they are going to a specialist. (In a sense, of course, they are.) It also differentiates the practice and supports referrals from both patients and other practitioners.

In some practices, the room where the LipiFlow® procedure is performed can be set up with plants, a comfortable chair, and light music—creating a relaxed atmosphere that gives these fee-for-service patients the sense of receiving first-class medical treatment.

great majority of dry eye sufferers.³

Treat the Comorbidities

Incomplete blinking—which is readily spotted on examination

with the LipiView® Ocular Surface Interferometer—may be helped by specific blink exercises.⁹ Underlying allergic, infectious, or inflammatory conditions can be treated medically,

and conjunctivochalasis can, if serious enough, be treated surgically. Patients should be told how these conditions impact their dry eye and the potential results of treatment with LipiFlow®.

Practice Hints

Patient Selection

Treating patients with dry eye disease has multiple benefits. After a LipiFlow® treatment, these patients typically experience symptom improvement,⁴ and they say so—to their friends as well as to their doctors. Treating mild-to-moderate disease relieves patients' symptoms, builds the practice, and is satisfying for practitioners.



And because the great majority of dry eye is either caused by MGD or has a significant MGD component, we can be confident that LipiFlow® treatment will help the great majority of dry eye patients.

The High Costs of Inaction

Patients using a large volume of expensive drops or paying out of pocket for costly medications may have some economic incentive to have a LipiFlow® treatment, as it is likely to

reduce the need for some of their other treatments. But the true “costs” of dry eye are not monetary. In evaluating the LipiFlow® procedure, patients need to consider not just costs and savings but the convenience and value of being rid of their discomfort: what is it worth to be able to read comfortably or work at a computer without having to stop frequently to instill drops?

Patients weighing the cost of a procedure should ask themselves how much of their lives they are losing to dry eye and what it is worth to get it back.

A number of people today come in fully educated about their condition. For these people, explaining the value of a LipiFlow® treatment is relatively easy. These patients are typically knowledgeable about the disease and the procedure. For them, the doctor's role is to explain why the particular patient is or is

not a good candidate. These patients typically have significant disease and have already sold themselves on the procedure. Cost is not a major issue for them.

But patients with mild to moderate disease are often uninformed about dry eye. So proactively explaining their condition and the available alternatives for treating it—particularly the LipiFlow® option—is important. The more a patient knows about the condition, the less significant the price becomes.

The practice can bolster the

PUTTING IT ALL TOGETHER

Attention to a few key points will ensure successful integration of dry eye treatment with the TearScience® System.

- Believe the TearScience® System is important and valuable for your practice because:
 - Dry eye is pervasive, chronic, and progressive¹
 - Most dry eye is the product of MGD²
 - MGD is caused by meibomian gland obstruction³
 - Gentle thermal pulsation is the most effective way to clear meibomian gland obstruction and relieve associated dry eye symptoms⁴
 - The TearScience® System makes the evaluation and treatment of MGD straightforward and clear
- Educate, excite, and involve the entire practice
- Accept LipiFlow® as the first-line treatment for dry eye at all severity levels
- Make sure *all* the practice ophthalmologists look for dry eye and, where appropriate, make a strong recommendation that it be evaluated and treated
- Have dedicated “dry eye clinic” time with longer patient appointments

educational effort by sending out educational material—or directing patients to that information on their website—whenever a new patient calls to schedule a dry eye visit.

It is important to remember that medical practices exist to treat disease—not to give economic advice. The role of the practice is to recommend the best treatment possible for the patient’s medical condition. Patients can decide for themselves whether they can pay for it. And for patients who may need to pay over time, many practices offer financing.

Finding Patients in Your Practice

Many dry eye patients will visit an eyecare practice, often for problems quite distinct from dry eye. Success with the dry eye practice requires spotting these patients and bringing them back for a dry eye evaluation and treatment.

TALKING ABOUT MONEY

Refractive surgeons have learned to talk with patients about money, but many other healthcare professionals find it difficult discuss out-of-pocket costs. If the doctor is uncomfortable in a discussion, his or her body language will communicate that discomfort. Patients may misconstrue a doctor’s discomfort, interpreting it as a lack of confidence in the procedure, rather than as shyness over talking about money. Conveying confidence in both the procedure and in its value is critical when talking to patients. If a doctor has difficulty discussing money, that discussion should be delegated to an appropriate staff member.

For this, it helps to have technicians identify and make note of patients who describe dry eye symptoms. When patients mention ocular itching, burning (especially in the morning), foreign body sensation, excess tearing, or fluctuating vision, this should be noted for follow-

up. Technicians should ask patients to complete a SPEED questionnaire to begin the dry eye evaluation process. Physicians can then talk to identified patients and, where appropriate, instruct them to return for a full dry eye work-up.

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Indications, Contraindications, and Precautions

The LipiView® Ocular Surface

Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate, and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

- No contraindications have been identified for the LipiView® Interferometer.

- The following patient conditions may affect the interferometry assessment of a patient’s tear film using the LipiView® Interferometer:
 - Use of ophthalmic drops such as artificial tear lubricants, ointments, and medications. Patients should not instill oil-based ophthalmic drops for at least 12 hours prior to device use, and should not instill ointments for at least 24 hours prior to device use. Patients should be instructed not to instill any other ophthalmic drop within 4 hours prior to device use.

- Soft or rigid contact lens wear. Patients should remove contact lenses at least 4 hours prior to device use.
- Use of oil-based facial cosmetics around the eye.
- Eye rubbing.
- Swimming in a chlorinated pool. Patients should not to swim for at least 12 hours prior to device use.
- Any ocular surface condition that affects the stability of the tear film. These conditions include disease, dystrophy, trauma, scarring, surgery, or abnormality.

- There are no known or anticipated adverse effects associated with use of the LipiView® Ocular Surface Interferometer. The device does not physically touch the eye, and light exposure is at safe levels for observation of the tear film and image capture.

The LipiFlow® System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.

- **Contraindications:** Do not use the LipiFlow® System in patients with the following conditions, as use of the device in patients with these conditions may cause injury, and its safety and efficacy have not been studied in patients with these conditions.
 - Ocular surgery within prior 3 months, including intraocular, oculo-plastic, corneal, or refractive surgery procedure
 - Ocular injury within prior 3 months
 - Ocular herpes of eye or eyelid within prior 3 months
 - Active ocular infection (eg, viral, bacterial, mycobacterial, protozoan, or fungal infection of the cornea, conjunctiva, lacrimal gland, lacrimal sac, or eyelids, including a hordeolum or sty))
 - Active ocular inflammation or history of chronic, recurrent ocular inflammation within prior 3 months (eg, retinitis, macular inflammation, choroiditis, uveitis, iritis, scleritis, episcleritis, keratitis)
 - Eyelid abnormalities that affect lid function (eg, entropion, ectropion, tumor, edema, blepharospasm, lagophthalmos, severe trichiasis, severe ptosis)
 - Ocular surface abnormality that may compromise corneal integrity (eg, prior chemical burn, recurrent corneal erosion, corneal epithelial defect, Grade 3 corneal fluorescein staining, or map dot fingerprint dystrophy)

- **Precautions:** The Disposable may not fit all eyes, such as eyes with small palpebral fornices. Use of the LipiFlow® System is not recommended in patients with the following conditions. Patients with these conditions may have reduced treatment effectiveness due to ocular symptoms unrelated to cystic meibomian glands. The safety and effectiveness of the device have not been studied in patients with these conditions.
 - Moderate to severe (Grade 2 to 4) allergic, vernal, or giant papillary conjunctivitis
 - Severe (Grade 3 or 4) eyelid inflammation (eg, blepharochalasis, staphylococcal blepharitis, or seborrheic blepharitis). Patients with severe eyelid inflammation should be treated medically prior to device use.
 - Systemic disease conditions that cause dry eye (eg, Stevens-Johnson syndrome, vitamin A deficiency, rheumatoid arthritis, Wegener’s granulomatosis, sarcoidosis, leukemia, Riley-Day syndrome, systemic lupus erythematosus, or Sjögren’s syndrome)
 - Taking medications known to cause dryness (eg, isotretinoin [Accutane®] and systemic antihistamines)
- In addition, the treatment procedure may loosen previously inserted punctal plugs, which may worsen the patient’s dry eye symptoms.
- **Potential Adverse Effects:** In the randomized controlled clinical study, there were no serious adverse events related to the use of the LipiFlow® System. The non-serious device-related adverse events for the LipiFlow® System included moderate eyelid pain and moderate conjunctival hyperemia or vascular injection. Other slit lamp findings included: eyelid hyperemia, eyelid edema, conjunctival petechial hemorrhages, conjunctival chemosis or edema, superficial punctate epithelial keratopathy, ocular surface staining, and discharge or mucus in the tear film. These

non-serious adverse events and slit lamp findings were temporary and resolved during the 4-week study without any permanent effect or need for medical treatment.

Potential adverse effects occurring as a result of the procedure include, but are not limited to, the onset or increase in:

- Eyelid/eye pain requiring discontinuation of the treatment procedure;
- Eyelid irritation or inflammation (eg, edema, dermatitis, hordeolum, or chalazion);
- Ocular surface irritation or inflammation (eg, corneal abrasion, conjunctival edema or conjunctival injection (hyperemia)); and
- Ocular symptoms (eg, burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance, sensitivity to light).

Potential serious adverse events that are not anticipated, due to device mitigations in place to prevent their occurrence, include:

- Thermal injury to the eyelid or eye, including conjunctiva, cornea, or lens;
- Physical pressure-induced injury to the eyelid;
- Ocular surface infection.

The Meibomian Gland Evaluator is a handheld instrument used by a physician to evaluate meibomian gland secretions during routine eye examination. The instrument provides a standardized method to apply consistent, gentle pressure, between 0.8 g/mm² and 1.2 g/mm², to the outer skin of the lower eyelid. The presence of liquid from a meibomian gland orifice (visualized through a slit lamp biomicroscope), during expression with the MGE, indicates the meibomian gland is not obstructed.

For full product and safety information, visit www.tearscience.com/physician/breakthroughtechnology/labeling-and-safety/.