

# MODERN MANAGEMENT OF MGD:

Practical Strategies to Elevate Care

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# Modern Management of MGD: Practical Strategies to Elevate Care

Meibomian gland dysfunction (MGD) has been shown to affect 86% of patients with dry eye.<sup>1</sup> As a chronic, progressive disease, MGD has life-long consequences and requires ongoing care. Whether the patient is a heavy computer user, a contact lens wearer, or a candidate for cataract or refractive surgery, significant attention should be paid to identifying compromised, lost and malfunctioning glands.

Fortunately, our ability to assess gland function and structure has improved significantly with technology like the meibomian gland evaluator and meibography. Furthermore, if a patient has a diagnosis of dry eye disease, we can directly treat the primary causes of the disease as well as manage the ocular surface response (signs and symptoms) to having the disease.

As modern life marches on and patients become increasingly connected to digital devices and interested in refractive surgical procedures, the imperative to optimize ocular surface health should be a top priority. This guide is intended to help you do just that.

## Meet the Panel



**Casey Claypool, OD**  
Empire Eye Physicians  
Spokane, WA



**Marjan Farid, MD**  
Gavin Herbert Eye Institute,  
UC-Irvine  
Irvine, CA



**Paul M. Karpecki, OD, FFAO**  
Kentucky Eye Institute  
Lexington, KY



**Cynthia Matossian, MD, FACS**  
Matossian Eye Associates  
Doylestown, PA



**Tal Raviv, MD**  
New York Eye & Ear Infirmary  
of Mount Sinai  
New York, New York

Drs. Claypool, Farid, Karpecki, Matossian and Raviv are paid consultants of Johnson & Johnson Surgical Vision, Inc.

## DISEASE ASSESSMENT

**Dr. Raviv:** Do you wait for patients to mention symptoms before actively looking for signs of dry eye and MGD?

**Dr. Farid:** We cannot diagnose and treat dry eye based on symptoms alone. It is so much harder to treat disease late in the disease process, particularly MGD since the atrophied glands may not recover. Our job is to identify and treat disease even when patients don't know they have a problem.

**Dr. Karpecki:** Patients with advanced disease often don't complain at all.

**Dr. Claypool:** Many of them start to think that it's normal to be uncomfortable. Then, over time, they become desensitized and don't feel the disease as much, despite the fact that it has progressed.

**Dr. Matossian:** Even in earlier stage disease, many patients avoid mentioning their symptoms, and the signs can be easy to miss. However, these same patients may leave your practice if you don't address the problem they never discussed with you. That's why we need to be proactive by asking the right questions. Patients vote with their feet and switch to another doctor who pays closer attention, takes their disease seriously, and treats them accordingly.



**TIP: Don't wait for symptoms. Proactively look for disease.**

**Dr. Matossian:** Do you use a dry eye survey in your practice?

**Dr. Karpecki:** We begin with several triage questions that we ask all patients age 13 and older. If the responses to these four questions are positive, we give the patient the full SPEED questionnaire.

**Dr. Raviv:** We've created a customized pre-operative questionnaire that incorporates questions from SPEED and OSDI, and also adds other lifestyle

“Our job is to identify and treat disease even when patients don't know they have a problem.” - **Marjan Farid, OD**

## Getting Started

Actively looking for dry eye and MGD should be a part of every doctor's exam.

Begin with the patients that are in your chair. Make it simple. It doesn't need to be time-consuming or affect your clinic schedule.



1. Commit to proactive care; Routinely:

- Incorporate a validated symptom questionnaire
- Evaluate meibomian gland function (use a standardized method e.g., MGE)
- Evaluate meibomian gland structure (e.g., dynamic meibomian imaging)
- Dedicate a work stream to educate patients

2. Treat MGD effectively (include in-office treatment, e.g., LipiFlow®)

3. Set appropriate short- and long-term treatment expectations

questions and visual complaint questions.

**Dr. Farid:** For pre-operative patients, I use the modified SPEED questionnaire recommended by the ASCRS clinical cornea committee. It is easy for patients to understand and easy to complete within a few minutes. It also offers clues as to whether or not the patient may be a candidate for a presbyopia-correcting IOL.

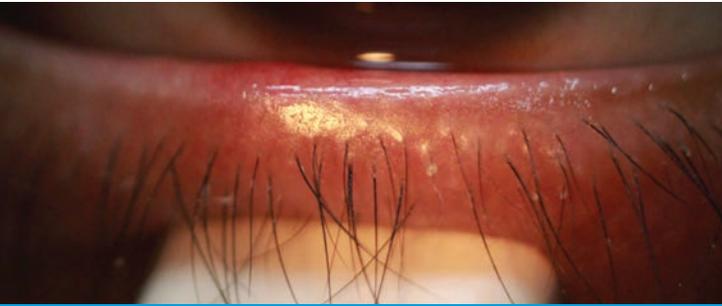
**Dr. Claypool:** Our intake forms include a few questions that trigger basic testing. If a patient indicates any symptoms on the intake form, we automatically perform meibography and the patient will complete a SPEED questionnaire. Based on those findings, the technician will decide whether further point-of-care testing is needed prior to the doctor's exam.



**TIP: Whether you use a standardized questionnaire or create your own, make a detailed survey part of your routine.**

**Dr. Farid:** How has meibography changed your practice?

**Dr. Matossian:** Gland imaging technology has made us newly aware that gland atrophy doesn't only af-



The Meibomian Gland Evaluator provides a standardized method to capture the number of functioning glands consistently across patients. It provides gentle, calibrated pressure that simulates the pressure of a patient's natural blink.

fect older patients. Young patients also experience gland dropout.\* This makes perfect sense when you consider the modern digital lifestyle.

**Dr. Raviv:** Although we don't have all the answers yet, we know a lot more now about the disease than we did 10 years ago or 15 years ago, which is largely due to our ability to visualize the structure and better capture the function of the glands.

**Dr. Claypool:** Looking ahead, I hope one day meibography will become as routine in eye care as x-rays are in dentistry.

**Dr. Raviv:** Logic dictates that the earlier we can diagnose something, the sooner we can study it, intervene, and treat.



**TIP: Consider the additional information that meibography could provide.**

**Dr. Matossian: Do you perform meibomian gland expression on all patients?**

**Dr. Karpecki:** Yes because it's not easy to diagnose MGD simply by looking at the eyelid margins. You really need to express the glands.

“ LipiScan® is a critical component in my patient education. When the patient is in my chair, we project the scans on a very large LCD monitor and use it to help discuss the pathophysiology of the condition. - Tal Raviv, MD

\*The LipiFlow® Thermal Pulsation System, Meibomian Gland Evaluator, LipiScan® Dynamic Meibomian Imager (DMI), and LipiView® II Ocular Surface interferometer are intended for use in adult patients.

**Dr. Raviv:** It is amazing what you start to find when you express every patient's meibomian glands.

**Dr. Farid:** I perform gland expression as a standard diagnostic.

**Dr. Claypool:** It's surprising how many patients tell me they don't have symptoms, yet I find blocked glands. That's why I don't wait for symptoms anymore; I express every patient's glands. Whether or not I find a problem, the information serves as a useful baseline. Also, once you get into the routine, it doesn't take much time.



**TIP: Make gland expression part of your standard routine.**

## MGD, DRY EYE OR BOTH?

**Dr. Matossian: We tend to use the term dry eye interchangeably with MGD. Do you think this has contributed to the confusion about these diseases?**

**Dr. Claypool:** Doctors and patients may mistakenly view MGD as a form of dry eye.

**Dr. Farid:** That's because the two conditions frequently go hand in hand.

**Dr. Karpecki:** But it is important that our colleagues recognize that the two diseases are not the same. MGD is a common contributor to dry eye disease and has been shown to affect 86% of patients with dry eye, but they are two separate conditions.<sup>1</sup> The reason we tend to put them in the same bucket is because when you have decreased oils being expressed from the meibomian glands in an MGD patient, at some point it will likely have an effect on the tear film and ocular surface, leading to evaporative dry eye disease.



**TIP: Dry eye and MGD are two distinct, though often overlapping, diseases.**

**Dr. Claypool:** How do you differentiate the two diseases?

**Dr. Karpecki:** In many cases, MGD precedes dry eye. If the glands are not functioning and they're not distributing oils to the tear film, dry eye is the expected consequence. This is why prompt diagnosis of MGD is so critical. Ideally, we should be doing something to address malfunctioning glands before osmolarity surpasses 308 mOsmol/L.

**Dr. Farid:** Unfortunately, we usually see patients later in the disease process when inflammation is already present. It is critical to assess the rapidity and consistency of the meibomian gland secretions at every visit so that proper treatment can be started.



**TIP: Determine whether the patient has dry eye, MGD or both diseases.**

## PATIENT EDUCATION + MEIBOGRAPHY

**Dr. Karpecki:** What role does meibography have in patient education?

**Dr. Raviv:** LipiScan® is a critical component in my patient education. When the patient is in my chair, we project the scans on a very large LCD monitor and use it to help discuss the pathophysiology of the condition.

**Dr. Claypool:** For several years, we had LipiFlow® but did not have meibography, and it was a lot tougher to talk to patients about their conditions and what we could do about it. Now I can show them. Having meibography has revolutionized the way we're able to talk about and treat MGD. I couldn't imagine practicing without it now.

**Dr. Raviv:** I wish we had something like meibography for every part of our anatomy, including cataracts. It makes it much easier for me to explain. Plus, it has tremendous value for me because it enables me to follow disease progression over the years.



**TIP: Use meibography to help patients understand the importance of their meibomian glands and how atrophy can impact them.**

**Dr. Farid:** When do you discuss MGD and dry eye with your patients?

**Dr. Matossian:** When I meet the patient in the exam room, I already have all of the information at my fingertips and I can use the images and information to educate the patient as I proceed with my clinical exam.

**Dr. Claypool:** In our workup, imaging is performed first, and when I come in the exam room I will do the gland expression. As I'm doing the gland expression I talk to the patient about the disease. This is a big time saver.

**Dr. Farid:** Do you have any standard language that you typically use to explain MGD?

**Dr. Claypool:** I say, "these glands across your eyelid aren't producing the oil as well as they should." If they have atrophy, I'll add, "some of them have died off because they've been clogged for so long." Then I explain that if we don't do anything it's just going to keep getting worse. I don't want to scare them, so I say "you don't go blind from this, but it can impact the quality of your vision and the comfort of your eyes."

**Dr. Matossian:** For cataract patients, I say, "You have two diseases. The cataract I can 'cure' by removing it. But the MGD is progressive and chronic, which I cannot 'cure.' However, we can work together to find therapies to address the lifelong disease."



**TIP: Develop standardized language to explain MGD so opportunities to educate are not missed and the conversation comes easily.**



During your exam, observe the quality of meibum as well as the quantity.

**Dr. Raviv:** How do you make patients understand that MGD isn't going to get better on its own?

**Dr. Claypool:** Patients are a little scared and don't want to lose more glands. I want to give them hope that prevention is possible, even if restoration may not be. My job is to educate so patients understand the condition and respect how we prefer to alleviate it.

**Dr. Karpecki:** We don't want to scare patients but we do need them to take it seriously. I pull up the scan and say, "I'm seeing something here that concerns me." This one sentence changes the energy in the room right away. Then I show them the pathology.

**Dr. Matossian:** Asymptomatic patients present the biggest challenge because it's hard to make them understand that they have a disease that's advanced enough to require lifelong therapy, for which they may need to pay out of pocket. To address this challenge, our messaging needs to be consistent; we need to reinforce it in the reception room, exam room, in emails and in videos. Not everyone will accept it before it starts to effect how they feel or how well they see, but many will let us help them before it advances to that point.

**Dr. Karpecki:** I explain that MGD is chronic like arthritis, and the patient will have the disease for life. As with an arthritis flare-up, there will be times when

dry eye symptoms will be more bothersome and we will need to treat that accordingly.

**Dr. Farid:** I also want patients to understand that dry eye is progressive, meaning it gets worse if the patient doesn't take it seriously and treat it. I want my message to resonate because I worry that if we wait too long, the disease will progress and over time it will likely be harder for me to make the patient comfortable. When this happens it causes a great deal of frustration for me and for the dissatisfied patient.



**TIP: Emphasize that MGD is chronic and will not improve without ongoing treatment.**

## CONTACT LENSES

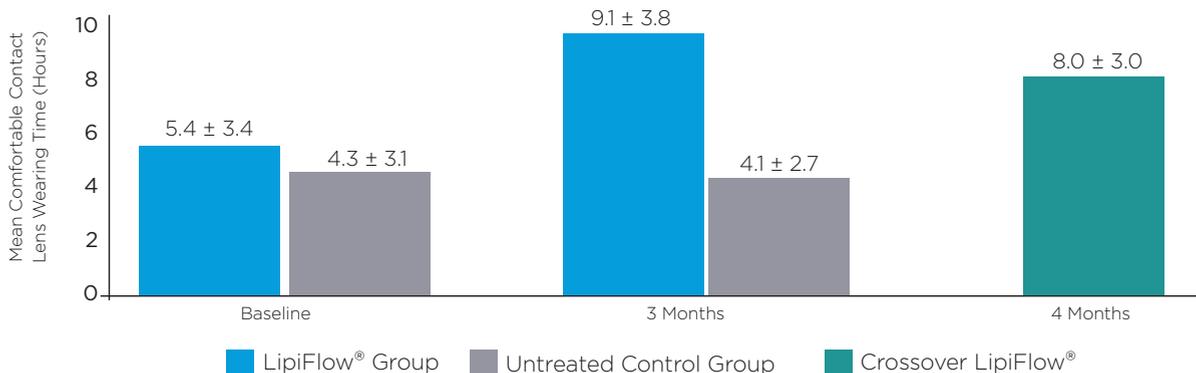
**Dr. Raviv:** The prevalence of MGD in contact lens wearers is reported between 30% and 60%.<sup>3</sup> What role does LipiFlow® have in your contact lens practice?

**Dr. Karpecki:** We see patients every day who have dropped out of lens wear due to discomfort. Often, they are afraid to tell you about symptoms for fear that you'll take them out of their lenses. Other times they don't mention it because they accept discomfort as a normal part of contact lens wear.

**Dr. Claypool:** I'm one of these patients. I stopped wearing contact lenses due to discomfort, but I was

### Comfortable Contact Lens Wear Time<sup>2</sup>

LipiFlow® group had a significantly greater mean increase in comfortable lens wear time than control from baseline to 3 month ( $p < 0.001$ ). LipiFlow® also had significantly ( $p < 0.05$ ) greater improvement in meibomian gland function, tear break-up time, dry eye symptoms, and lid wiper epitheliopathy



## Case Review

By Casey Claypool, OD



*I recently treated a 42-year-old female who presented requesting LASIK. The patient indicated that she had no problems with her contact lenses, but when we performed meibography I could see that she had already lost more than 50% of her glands. Knowing this, I pressed harder to try to tease out whether the patient was truly experiencing any symptoms. After asking the same question multiple ways, the patient finally admitted that her contact lenses drove her crazy at the end of the day. She said she had not shared this previously because she thought that it was perfectly normal.*

*I showed her the images of her glands, explained her condition, and recommended LipiFlow<sup>®</sup>, which she initially refused. However, given the compromised condition of her corneas, the surgeon refused to perform LASIK, so she eventually agreed to LipiFlow<sup>®</sup>.*

*When the patient returned for followup, her exact words were, "I didn't know this is how my eyes were supposed to feel." Furthermore, her SPEED score went from a 20 to a 2. This case was very enlightening for me because I would not have imagined that a patient with a 20 SPEED score would look me in the eye and tell me she was content with her contact lenses.*

*The patient did eventually have LASIK surgery and, before that, she enjoyed end-of-day comfort in her contact lenses.\**

### \* CONTRAINDICATIONS

- Do not use the LipiFlow<sup>®</sup> System in patients with the following conditions. Use of the device in patients with these conditions may cause injury. Safety and effectiveness of the device have not been studied in patients with these conditions.
- Ocular surgery within prior 3 months, including intraocular, oculo-plastic, corneal or refractive surgery procedure.

able to return to wear following LipiFlow<sup>®</sup> treatment.

**Dr. Farid:** I've seen countless patients who have become contact lens intolerant over time due to MGD and have found that, after treating it with LipiFlow<sup>®</sup>, the tear film improved and I was able to get these patients back into their contact lenses.

**Dr. Karpecki:** I used to first try switching solutions, modalities, materials and brands, but now I'm using LipiFlow<sup>®</sup> on patients when they present with MGD and mild to moderate discomfort and many of these patients are back to full day wear.



**TIP: If your contact lens patients experience end-of-day discomfort, check the function of their meibomian glands. LipiFlow<sup>®</sup> can increase comfortable wear time in contact lens patients with MGD.**

## SURGICAL PATIENTS

**Dr. Claypool:** *How important is it to address dry eye preoperatively?*

**Dr. Karpecki:** The stakes are higher with pre-op pa-

tients than they are with a contact lens patient. A contact lens wearer may move in and out of lenses several times in their lifetime, but once you put an IOL in the eye, it's unlikely you're going to replace it.

**Dr. Raviv:** As a refractive cataract surgeon, I take the ocular surface very seriously and consider it key to a successful outcome. I won't go into the OR with a premium lens patient without feeling certain that I have done all I can to treat dry eye and MGD.

**Dr. Farid:** Untreated dry eye disease can affect your preoperative biometry measurements. Research shows that patients who had osmolarity scores within normal limits were within a half diopter of intent, whereas 17% of those with hyperosmolarity would have missed their IOL calculation by more than a diopter.<sup>4</sup>

**Dr. Matossian:** We conducted a pilot study in our practice on 25 eyes.<sup>5</sup> At visit 1, we performed preoperative measurements and based original IOL calculations on these measurements. We then performed LipiFlow<sup>®</sup> on these patients. Six weeks

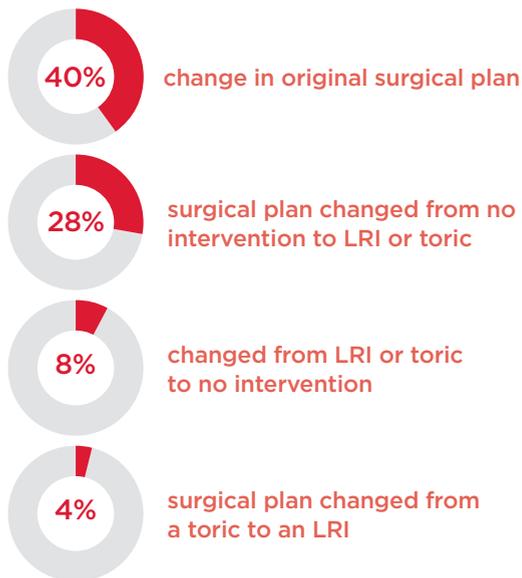
“As a refractive cataract surgeon, I take the ocular surface very seriously and consider it key to a successful outcome. I won’t go into the OR with a premium lens patient without feeling certain that I have done all I can to treat dry eye and MGD.” - **Tal Raviv, MD**

later, at visit 2, measurements were repeated and IOL calculations were performed again based on these new measurements. We found that pre-treatment with LipiFlow® prior to keratometry and topography measurements for cataract surgery correlated with a 40% change in my original surgical plan. Specifically, my surgical plan changed from no intervention to LRI or toric in 28% of cases. It changed from LRI or toric to no intervention in 8% of cases. And, my surgical plan changed from a toric to an LRI in 4% of cases.

 **TIP: Don't take chances. Treat ocular surface disease before cataract surgery.**

### Pretreatment with LipiFlow® prior to keratometry and topography measurements for cataract surgery

*A pilot study conducted at Matossian Eye Associates<sup>5</sup>*



#### **How do you incorporate OSD diagnosis into your pre-op routine?**

**Dr. Raviv:** During my pre-operative exam, I look at the tear film, the topography, the cornea, the conjunctiva and the lids. I then use a cotton swab to express the meibomian glands and evaluate the meibum for consistency and color.

**Dr. Matossian:** I perform a complete ocular surface disease workup in 100% of my cataract consult patients. Every patient completes a variation of the SPEED questionnaire and we perform three tests on every pre-op candidate: tear osmolarity, MMP-9, and meibography.

**Dr. Claypool:** We perform meibography on all of our LASIK and premium IOL patients as well.

 **TIP: Establish a pre-operative dry eye assessment that works for your practice.**

#### **Dr. Farid: Does LipiFlow® have a role post-op in your practice?**

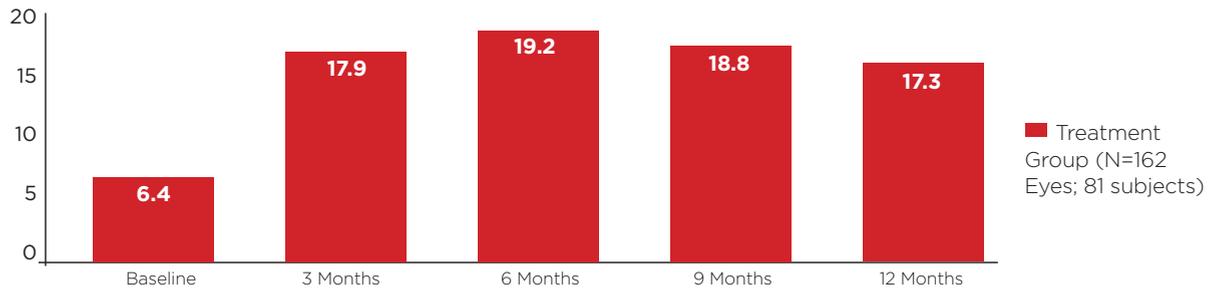
**Dr. Raviv:** Whether or not a patient had LipiFlow® prior to surgery, we sometimes find that it is helpful postoperatively. In fact, we have several patients who have the procedure annually.

**Dr. Matossian:** We frequently use LipiFlow® post-op. Even when you've tuned-up the surface and the patient has an outstanding surgical outcome, nature can take its course. It's not uncommon for patients to stop taking their oral Omega 3s and dry eye medication drops. Before you know it, the patient comes back complaining of fluctuating vision. I always check for posterior capsular opacification (PCO); at times I find the visual change is strictly related to the ocular surface. When this happens, I go back to square one and recommend LipiFlow® as well as additional treatments for MGD.

**Dr. Karpecki:** There are also some patients who go

## Mean Meibomian Gland Secretion Score<sup>6</sup>: 12-Month Cohort with One LipiFlow<sup>®</sup> Treatment

For the 86% of Treatment group Subjects who received on LipiFlow<sup>®</sup> treatment, a **sustained mean improvement in MG Function** was observed from Baseline (6.4 ± 3.7) to 12 Months (17.3 ± 9.1) (p<0.0001)



into surgery without any signs or symptoms of dry eye, but the surgical procedure pushes them over the edge and they are symptomatic post operatively. In these cases, I have found LipiFlow<sup>®</sup> to be very useful to achieve satisfaction with the surgery.

**Dr. Claypool:** We recently saw a patient who had blurry vision following cataract surgery. She assumed the problem was due to the cataract surgery and said she wanted the new IOL removed. After a comprehensive exam, I explained to her that there wasn't a problem with the IOL; she had MGD and it was ocular surface disease that was causing her blurry vision. We performed LipiFlow<sup>®</sup> and two weeks later she came back in tears, and she hugged me and told me that I changed her life.

## TREATMENT

**Dr. Karpecki:** *Where do you think some doctors go wrong when treating dry eye and MGD?*

**Dr. Raviv:** All of us have been faced with patients later in the disease spectrum, many of whom present with visual signs and lifestyle-disabling symptoms. That's why we need to treat this as early as possible.

**Dr. Claypool:** In some ways, eye care is where dentistry was many years ago, before we knew that you have to brush your teeth to prevent problems. Consider how often we wait until there are symptoms of burning, watering, redness and

irritation to treat MGD or dry eye disease. I wish there was a greater focus on prevention. I prefer a natural approach to treatment when possible and LipiFlow<sup>®</sup> gets the glands pumping to help introduce the eye's natural oils.



**TIP: Don't wait too long to initiate MGD treatment.**

**Dr. Farid:** *What are the key benefits of LipiFlow<sup>®</sup> in your practice?*

**Dr. Raviv:** A primary benefit to LipiFlow<sup>®</sup> is the

**Remember! MGD is a chronic disease with a high prevalence that interferes with patient lifestyle choices.**



- 1 Choose a diagnostic and treatment process that is routine, consistent, ready for high volume. This should be a pleasant, informative experience for your patients, your staff, and yourself. Don't be afraid to involve your staff and educate them on power of the disease and how technology can be used to address it.
- 2 Choose a patient education process that is consistent and efficient, with multiple touchpoints in the patient pathway. These touchpoints should address the disease state, why it needs to be treated, and why your recommended treatment is the best approach.

longevity of efficacy from one treatment. For 86% of patients who received only a single LipiFlow® treatment over 12 months, mean improvement in meibomian gland function and dry eye symptoms was sustained from 1 to 12 months.<sup>6</sup>

**Dr. Matossian:** LipiFlow® is versatile, meaning it allows you to treat both the upper and lower lids simultaneously. Plus, it's automated and user-friendly and doesn't require you to manually express the glands after heating them up.



**TIP: Consider the unique benefits of LipiFlow® and weigh them alongside other available treatments.**

**Dr. Matossian:** *Until recently, there weren't as many treatment options. Now, all of a sudden, the market is crowded and a lot of doctors don't know where to start. What is your treatment protocol?*

**Dr. Karpecki:** Once you have your diagnosis, you really need to know the type of disease because the treatments are different. Is it aqueous deficient or evaporative? Before osmolarity surpasses 308, my recommendation is LipiFlow®, warm compresses at night, and omega fatty acids. I also address any biofilm that might be present. But, if the patient already has tipped into dry eye, I usually also add an anti-inflammatory drop and blepharoexfoliation.

**Dr. Farid:** It is so important to dispel the myths surrounding ocular surface disease. For example, there is a common misconception that MGD leads to a dry surface, and therefore if you wet it, your problem will be solved. But MGD is multifactorial and much more complex. You don't need every single treatment for every patient. Instead, simply target the treatment to the unique presentation and use products that have a proven track record and are grounded in science.

**Dr. Claypool:** I'm a big proponent of treating the root cause first and then adding on, if needed, to knock out any secondary issues. For example, if a patient has MGD, my first objective is to treat the glands and get the oil flowing. If that's not enough

“LipiFlow® has always been one of the first treatments in our hierarchy of options for ocular surface disease and MGD.” - **Tal Raviv, MD**

to knock out tear quality or inflammation, I may add a prescription drop. I wouldn't choose to treat MGD the other way around because, even if I reduce some symptoms with an anti-inflammatory, the patient will still be left with obstructed glands.

**Dr. Raviv:** LipiFlow® has always been one of the first treatments in our hierarchy of options for ocular surface disease and MGD. I wish it could be the first for every MGD patient because the treatment makes perfect sense in terms of directly addressing the cause. ■



**TIP: Don't be overwhelmed by all the new treatments for ocular surface disease. Start with one that directly addresses your patient's specific condition.**

1. Lemp MA, Crews LA, Bron AJ, Foulks GN, Sullivan BD. Distribution of aqueous deficient and evaporative dry eye in a clinic based patient cohort: a retrospective study. *Cornea*. 2012; 31(5):472-478.
2. Blackie C. A single vectored thermal pulsation treatment for meibomian gland dysfunction increases mean comfortable contact lens wearing time by approximately 4 hours per day. *Clinical Ophthalmology* 2018; 12:169-83.
3. Schaumberg DA, Nichols JJ, Papas EB, et al. The international workshop on Meibomian gland dysfunction: report of the subcommittee on the epidemiology of, and associated risk factors for, MGD. *Invest Ophthalmol Vis Sci*. 2011;52(4):1994-2005.
4. Epitropoulos AT, Matossian C, Berdy GJ, et al. Effect of tear osmolarity on repeatability of keratometry for cataract surgery planning. *Journal Cataract Refract Surg*. 2015 Aug;41(8):1672-7.
5. Matossian C. Data on file.
6. Blackie CA, Coleman CA, Holland EJ. The sustained effect (12 months) of a single-dose vectored thermal pulsation procedure for Meibomian gland dysfunction and evaporative dry eye. *Clin Ophthalmol*. 2016;10:1385-96.

## INDICATIONS AND IMPORTANT SAFETY INFORMATION for LIPIFLOW® Thermal Pulsation System

### Rx Only

#### INDICATIONS

The LipiFlow® Thermal Pulsation 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. Use of the device in patients with these conditions may cause injury. Safety and effectiveness of the device 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** (e.g., viral, bacterial, mycobacterial, protozoan, or fungal infection of the cornea, conjunctiva, lacrimal gland, lacrimal sac, or eyelids including a hordeolum or styte)
- **Active ocular inflammation or history of chronic, recurrent ocular inflammation within prior 3 months** (e.g., retinitis, macular inflammation, choroiditis, uveitis, iritis, scleritis, episcleritis, keratitis)
- **Eyelid abnormalities that affect lid function** (e.g., entropion, ectropion, tumor, edema, blepharospasm, lagophthalmos, severe trichiasis, severe ptosis)
- **Ocular surface abnormality that may compromise corneal integrity** (e.g., prior chemical burn, recurrent corneal erosion, corneal epithelial defect, Grade 3 corneal fluorescein staining, or map dot fingerprint dystrophy)

#### PRECAUTIONS

The Activator or Activator II (Disposable) may not fit all eyes, such as eyes with small palpebral fornices.

Use of the LipiFlow® System in patients with the following conditions may result in reduced treatment effectiveness because these conditions may cause ocular symptoms unrelated to cystic meibomian glands and require other medical management. Safety and effectiveness of the device have not been studied in patients with these conditions.

- **Moderate to severe (Grade 2-4) allergic, vernal or giant papillary conjunctivitis**
- **Severe (Grade 3 or 4) eyelid inflammation** (e.g., 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** (e.g., Stevens-Johnson syndrome, vitamin A deficiency, rheumatoid arthritis, Wegener's granulomatosis, sarcoidosis, leukemia, Riley-Day syndrome, systemic lupus erythematosus, Sjögren's syndrome)
- **Taking medications known to cause dryness** (e.g., isotretinoin (Accutane®) and systemic antihistamines)
- **Esthetic eyelid and eyelash procedures** (e.g., blepharoplasty, lash extensions, eyelid tattooing)

In addition, the treatment procedure may loosen previously inserted punctal plugs, which may worsen the patient's dry eye symptoms.

#### ADVERSE EFFECTS

Potential adverse effects that may occur 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 (e.g., edema, bruising, blood blister, dermatitis, hordeolum or chalazion);
- Ocular surface irritation or inflammation (e.g., corneal abrasion, conjunctival edema or conjunctival injection (hyperemia)); and
- Ocular symptoms (e.g., burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance, sensitivity to light).

Potential serious adverse events (defined as permanent impairment or damage to a body structure or function or necessitates medical or surgical intervention to preclude permanent impairment or damage to a body structure or function) that are not anticipated because of the device mitigations to prevent occurrence include:

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

#### ATTENTION

Reference the LipiFlow Thermal Pulsation System Instructions for Use for a complete listing of indications, warnings, and precautions.

## INDICATIONS AND IMPORTANT SAFETY INFORMATION for LIPISCAN™ Dy-

## namic Meibomian Imager

### Rx Only

#### INDICATIONS

LipiScan™ Dynamic Meibomian Imager (DMI) is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands.

#### CONTRAINDICATIONS

No contraindications have been identified for the LipiScan™.

#### PRECAUTIONS

Caution: Disinfect the surfaces of the chin rest, forehead rest and Handheld Near Infrared (IR) Lid Everter with isopropyl alcohol immediately prior to use and prior to storage to prevent cross-contamination and patient infection.

#### WARNINGS

Warnings include any potential hazards for adverse events to the patient or user. Review the warnings in Table 1 of the *LipiScan Dynamic Meibomian Imager Instructions for Use* prior to using LipiScan™.

#### ADVERSE EFFECTS

There are no known or anticipated adverse effects associated with use of this device.

#### ATTENTION

Reference the *LipiScan Dynamic Meibomian Imager Instructions for Use* for a complete listing of indications, warnings, and precautions.

## INDICATIONS AND IMPORTANT SAFETY INFORMATION for MEIBOMIAN GLAND EVALUATOR (MGE)

### Rx Only

#### INDICATIONS

The Meibomian Gland Evaluator is a hand-held instrument used by a physician to evaluate Meibomian gland secretions in adult patients during a routine eye examination. The instrument provides a standardized method to apply consistent, gentle pressure to the outer skin of the lower eyelid while visualizing the secretions from the Meibomian gland orifices through a slit lamp biomicroscope.

#### CONTRAINDICATIONS

No contraindications are known.

#### PRECAUTIONS

- Do not depress the shaft to the endpoint of the spring. Do not apply any additional force after the shaft has been depressed approximately 6 mm. Applying additional force negates the benefit of using the instrument to apply standard force.
- Familiarity with use of a slit lamp biomicroscope is required to use Meibomian Gland Evaluator for assessment of the meibomian gland secretions.

#### WARNINGS

To ensure proper use of the Meibomian Gland Evaluator, review the warnings below.

- Do not use Meibomian Gland Evaluator if the package is open or broken. Do not use Meibomian Gland Evaluator if it appears broken or has sharp edges or rough surfaces upon initial inspection.
- Maintain proper infection control procedures including cleaning hands before handling the device and before evaluation of each patient. Disinfect the instrument with alcohol after each use and between patients.
- Avoid contact of the devices with the eye. Instruct the patient to look up and away to avoid injury to the cornea in the event the contact surface inadvertently touches the eye.

#### ADVERSE EFFECTS

Potential adverse effects that are unlikely but may occur with use of the Meibomian Gland Evaluator include but are not limited to:

- Skin abrasion (e.g., from a rough surface on the device)
- Eye abrasion (e.g., from improper contact of the instrument with the eye)
- Infection of the skin or eye (e.g., from improper or lack of disinfection after use and between patients)
- Allergic or toxic reaction (e.g., from exposure to any residue on device during user handling)

#### ATTENTION

Reference the Meibomian Gland Evaluator Package Insert for a complete listing of indications, warnings, and precautions.

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