Supplement to EyeWorld April 2016

The impact of ocular surface dysfunction on surgical outcomes: Evidence-based insights on diagnostic tools to guide treatments

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The impact of a dysfunctional ocular surface on cataract and refractive outcomes

by Terry Kim, MD

Terry Kim, MD

Point-of-care diagnostics will aid ophthalmologists in the early diagnosis of ocular surface disease

Although the prevalence of dry eye has been reported to range from 8–34%, it tends to be under recognized and under diagnosed (Figure 1).[1,2]

Ocular surface health is critically important to vision quality—particularly after cataract and refractive surgery. Historically, dry eye disease (DED) and ocular surface disease (OSD) were not mainstream topics because our understanding of the pathophysiology of the disease process was limited, as were our diagnostic and treatment modalities.

We hope our new paradigm of point-of-care testing will drive awareness of the importance of DED and OSD and how they relate to the presurgical patient. Moreover, we hope these assessments will help us diagnose this condition even before symptoms develop.

> ***"New point-of-care tests can help identify DED or OSD signs so we can identify cases early and treat them proactively."***
>
> ***–Terry Kim, MD***

Effects of OSD

Because the tear film is the first refractive surface that light encounters, an unstable tear film reduces vision quality and adversely affects preop testing and postop vision quality.

Epitropoulos et al. showed significant variation in average K readings and resulting IOL power calculations in patients with elevated tear osmolarity.[3]

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This monograph is part of a year-long curriculum focused on treatment of ocular surface disease and management.

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This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint providership of the American Society of Cataract & Refractive Surgery (ASCRS) and EyeWorld. ASCRS is accredited by the ACCME to provide continuing medical education for physicians.

Educational Objectives
Ophthalmologists who participate in this activity will:
- Identify the true impact of a dysfunctional ocular surface on cataract and refractive outcomes, identify the consequences that accompany an unstable tear film, and discuss the presentation of symptomatic vs. asymptomatic OSD
- Describe the objective evidence supporting the use of new OSD diagnostic tools, including correlation of symptoms, predictive power, and relationship to outcomes, and develop strategies for incorporating new diagnostic tools into clinical practice, including: inclusion in point-of-care and preoperative testing, use of diagnostic information to guide treatment, and utilization of diagnostics to follow success of interventions or treatment

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Furthermore, Donnenfeld et al. reported differences between patients treated with ocular lubricants before LASIK compared with those who were only treated after LASIK.[4] Patients were more likely to have worse visual outcomes if they had tear hyperosmolarity and were not treated before LASIK.

To obtain optimum results, it is essential to manage the ocular surface before performing preoperative measurements for cataract or refractive surgery, particularly when implanting toric, multifocal, and accommodating intraocular lenses. Figure 2 shows member responses from the 2015 ASCRS Clinical Survey regarding cataract and refractive surgery.

Although patients may be disappointed when surgery is delayed, if surgeons do not address the ocular surface before preoperative measurements are made, it could adversely affect the patient's visual outcome and cause the patient to shift the blame from the disease state to the surgeon.

Diagnosing DED

Although patients with DED may have burning, tearing, or other types of irritation, others are asymptomatic. Furthermore, patients may have anterior basement membrane disease, Salzmann's nodular degeneration, or other ocular surface conditions that may adversely affect outcomes as well.

DED increases with age and is more common in women. In addition, patients may use medications that affect the tear film. For example, glaucoma medications may cause an abnormal ocular surface due to corneal toxicity.

Surgery also can induce DED. Yu et al. reported that both femtosecond laser and conventional cataract surgery increased dry eye after surgery.[5]

New point-of-care tests can help identify DED or OSD signs so we can identify cases early and treat them proactively. These tests are not designed to replace clinicians' diagnostic skills but to provide important supplemental data to help us accurately diagnose the patient. For example, we may not find corneal fluorescein staining or an abnormal tear breakup time during our slit lamp examination, but patients may have positive results on osmolarity or MMP-9 testing that indicate early and even asymptomatic disease.

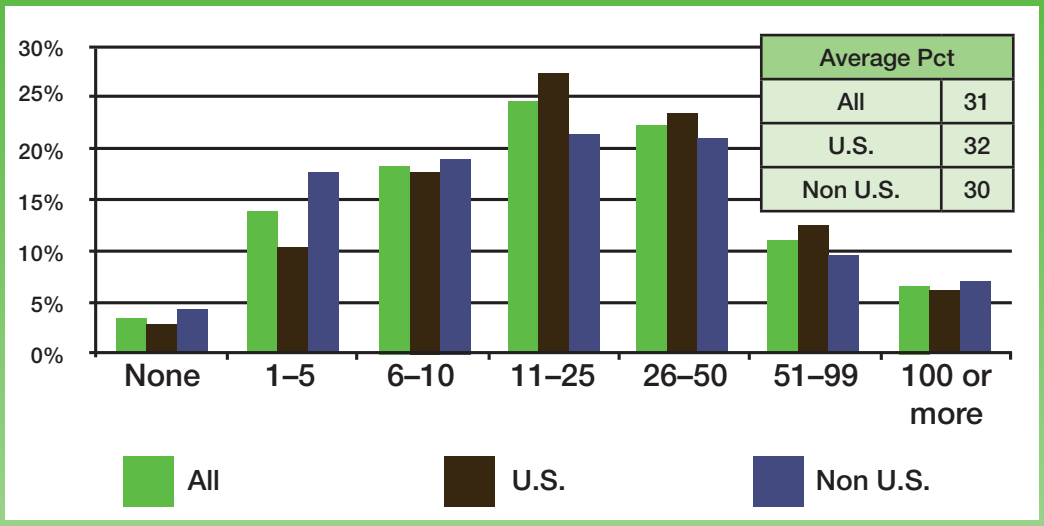

Figure 1. In the 2015 ASCRS Clinical Survey, respondents answered the following question: On average, how many dry eye patients do you see per month who are on a prescription medication for dry eye therapy or have had punctal occlusion (i.e., need more than just tears)?

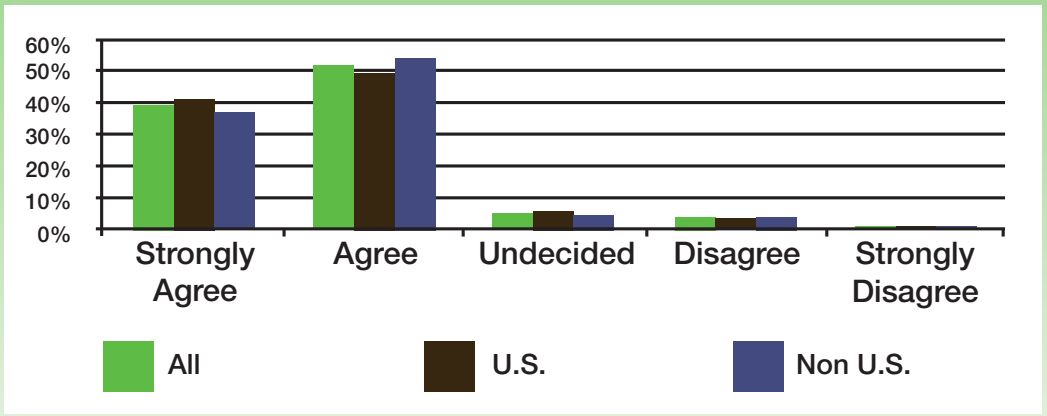

Figure 2. In the 2015 ASCRS Clinical Survey, only 39% of respondents strongly agreed that mild to moderate dry eye significantly impacts satisfaction in postoperative cataract and refractive surgery patients.

Conclusion

In this supplement, our expert faculty will discuss a new algorithm for DED diagnosis and treatment and share their advice for integrating osmolarity, MMP-9 testing, and meibomian gland imaging into their practices.

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Diagnostic tools for OSD: Getting the information you need to make the right treatment decisions

by Christopher Starr, MD, FACS

Christopher Starr, MD, FACS

New tool will guide ophthalmologists and technicians in diagnosing dry eye disease and ocular surface disease

It has been an amazing decade in the realm of ocular surface disease (OSD) and dry eye disease (DED) in particular, with many seminal publications and many new diagnostics and treatments.

Despite these advances, annual ASCRS Clinical Surveys have shown that, in general, clinicians have been slow to adopt the updated guidelines and novel diagnostics (Figures 1).

Although it is exciting to have all of this new information, it can be a bit overwhelming for ophthalmologists to digest it all and apply it in their practices.

To help fill this educational gap, the ASCRS Cornea Clinical Committee is developing a DED and OSD management algorithm to help clinicians easily and more accurately diagnose and treat OSD utilizing the newest technologies.

Algorithm overview

At this writing, the algorithm has not been released, but the following is a brief overview of the process.

Although the workup typically begins with the patient's symptoms, we need to keep in mind that there is often a disconnect between patients' signs and symptoms. Some patients with extreme signs have very few symptoms and vice versa. Therefore, our diagnoses often will be incorrect if we base them on symptoms alone.

We recommend using a validated questionnaire or having technicians ask key questions regarding OSD. In addition to asking about traditional symptoms (dryness, tearing, redness, itching, etc.), it is important to elicit visual symptoms such as aberrations and fluctuations.

If the patient's symptoms suggest DED or OSD, we suggest tear osmolarity as the first test, followed by MMP-9 testing, which are both easy for technicians to perform. The DEWS report in 2007 defined DED as involving both inflammation and hyperosmolarity, so testing for both is reasonable because these tests are inexpensive, easy to use, and reimbursable.

Abnormal results on osmolarity and/or MMP-9 give the clinician a high degree of certainty that DED is present, how severe it is, and whether or not the eye is inflamed.

If osmolarity is high but MMP-9 results are negative, the patient may have early DED without inflammation. In this case, punctal plugs or artificial tears may be warranted.

If results for both are normal in a symptomatic patient, masqueraders may be present; this leads to a new path in the algorithm. However, if osmolarity is normal and MMP-9 results are high, the patient has inflammation but may not have DED, which may direct the user to another path in the algorithm.

When DED is confirmed, we need to differentiate between aqueous deficient and evaporative DED to tailor our treatments. In addition to the traditional examination techniques such as visual tear meniscus height, meibomian gland expression and inspection, Schirmer testing, and dye-based staining and tear breakup time (TBUT), there are many modern diagnostics that are more precise and objective. These can be performed by a technician before the clinician meets the patient. These newer tests include noninvasive TBUT and tear meniscus height/area/volume, lipid interferometry, meibography, tear lactoferrin and

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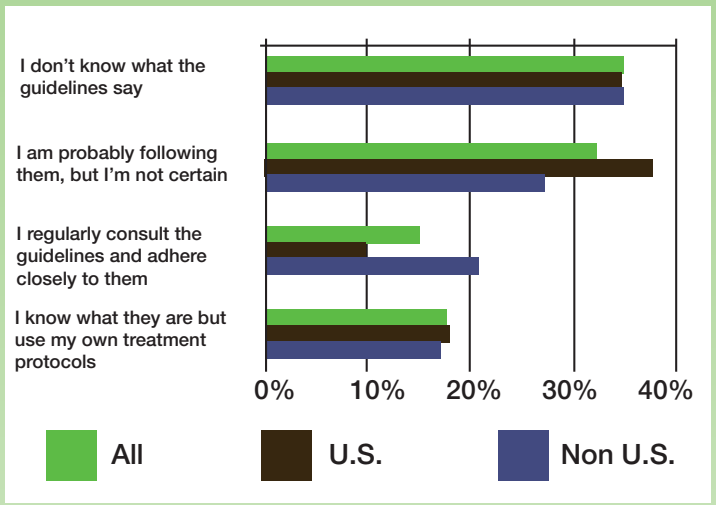

Figure 1. In the 2015 ASCRS Clinical Survey, members responded to the question: "Do you follow the Delphi/DEWS guidelines for treating aqueous deficient dry eye and MGD?"

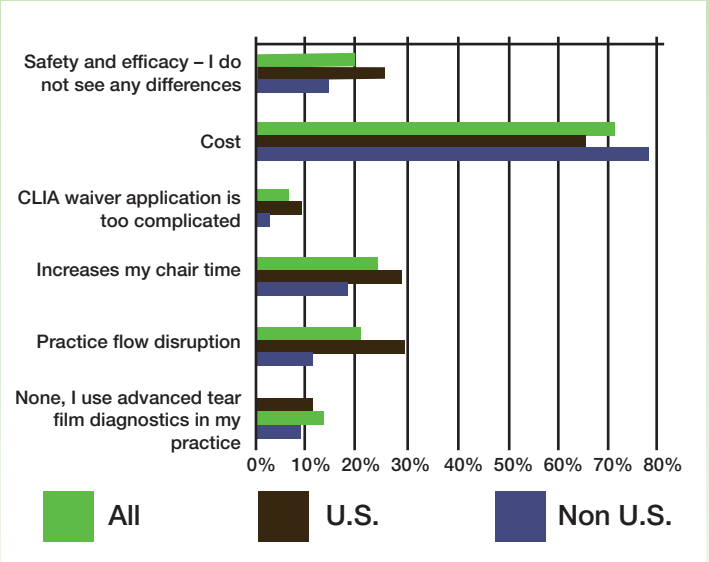

Figure 2. ASCRS survey respondents responded to the following question: "What are the barriers to incorporating advanced tear film diagnostics into your practice? (Select all that apply)

Ocular surface testing insights: Meibomian gland imaging

by Alice Epitropoulos, MD, FACS

Alice Epitropoulos, MD, FACS

Meibomian gland imaging enables early detection of meibomian gland disease and intervention

The prevalence of meibomian gland disease (MGD) has been reported to be as high as 60 to 70%.[1,2] It is increasingly becoming recognized as a chronic progressive disease and the leading cause of dry eye disease (DED), which can adversely affect our refractive cataract surgery outcomes if it is not treated. Furthermore, DED is the leading reason why people stop wearing contact lenses.

Unfortunately, because signs often are not always obvious on examination, MGD is extremely underdiagnosed.

If we can diagnose MGD early and intervene before severe damage occurs, treatment will be more effective and our patients will be more satisfied with their outcomes.

Detection of MGD

Meibography allows clinicians to examine the meibomian glands. Recently, LipiView II, a system with high-definition imaging, was introduced, enabling clinicians to assess the lipid layer and detect structural compromise of the meibomian glands, indicating MGD (Figure 1).

Because symptoms may not correlate with the degree of disease when MGD is in its early stages, meibomian gland imaging should be strongly considered. Furthermore, the degree of structural compromise found can impact the urgency of therapeutic intervention.

Research has shown that if more than 67% of the gland

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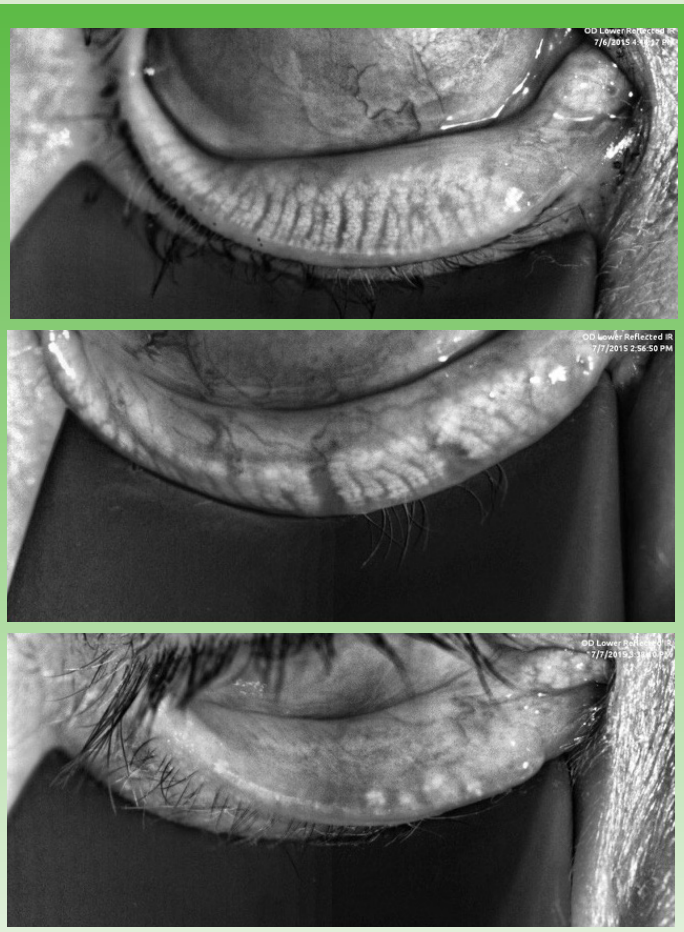

Figure 1. Meibomian gland images showing none to mild, moderate, and severe meibomian gland dysfunction.

Source: TearScience

continued from page 3

IgE, confocal microscopy of meibomian glands, and others.

This basket of test data, in addition to clinical judgment and a careful exam, can save the clinician in the modern practice significant chair time. Although we include every available test in the algorithm, we are not recommending that every practice use every test. The algorithm will help practitioners utilize whichever tests they have available.

Systematic process

This algorithm sheds light on the vast new world of ocular surface disorders, which has been somewhat elusive to the general practitioner in recent years. The novel ASCRS algorithm will be a practical tool to enable ophthalmologists to work more efficiently, save chair time, and make the correct OSD diagnosis more often.

Dr. Starr is associate professor of ophthalmology, director of the refractive surgery service, and director of the cornea, cataract, and refractive surgery fellowship, Weill Cornell Medical Center, New York-Presbyterian Hospital, New York.

Making the most of physician extenders

With the new diagnostics we have at our disposal, much of the workup is driven by physician extenders, and the new algorithm reflects that. However, clinicians can perform as much of the initial workup as they would like.

I find it very useful to have a basket of objective, noninvasive ocular surface data at my fingertips before I see the patient, so I know exactly what I am dealing with from the beginning.

Ocular surface testing insights: Tear osmolarity

by Cynthia Matossian, MD, FACS

Cynthia Matossian, MD, FACS

Tear osmolarity testing provides an important piece of the puzzle in a comprehensive ocular surface assessment

In 2007, the International Dry Eye WorkShop (DEWS) reported that tear hyperosmolarity is a central mechanism in dry eye disease (DED).[1]

Tear hyperosmolarity, which results in ocular cell damage, can only be assessed by laboratory analysis of the tear fluid. With the point-of-care TearLab Osmolarity System, technicians use a pen-like instrument with an attached disposable test card to test osmolarity of the tears in each eye.

Detecting hyperosmolarity

This test can be particularly important in cataract and refractive surgery patients. Epitropoulos et al. reported that patients with tear hyperosmolarity had greater variability in keratometry readings, which could result in less accurate IOL power calculation before cataract surgery.[2]

Researchers have reported a predictive accuracy as great as 88.6% to 98% for tear osmolarity, as well as a sensitivity of 72.8% and specificity of 92%.[3,4] Abnormal results or inter-eye differences greater than 8 mOsm/L indicate tear film instability and the need for further investigation. However, if osmolarity is normal, it does not rule out DED or ocular surface disease. Osmolarity may fluctuate significantly if the tear film is unstable.

Integrating the test

Tear osmolarity is only one piece of the puzzle in our diagnostic process. I also rely on Placido disc imaging (Figure 1) and fluorescein staining (Figure 2). When incorporating tear osmolarity testing, physicians need to establish a protocol determining when it will be used and who will perform the test.

Our screeners ask a set of mandatory questions. Based on their responses, technicians perform tear osmolarity testing before other eye drops are instilled. This test is also performed in all patients considering cataract or refractive surgery. However, insurance only covers this test in patients who have signs or symptoms.

As I examine patients, I ask about their medical history. For example, connective tissue or certain endocrine disorders affect osmolarity and the ocular surface.

I also perform tear breakup time and lissamine green and fluorescein dye staining at the slit lamp so I can examine how the lid margin, conjunctiva, and cornea pick up the dye. I inspect the meibomian gland orifices, the meibomian glands themselves, and the lashes and lash base.

I use all of this information to make the diagnosis, sharing results with the patients. We discuss how we will work together to optimize their ocular surface before preoperative measurements are performed.

After I develop a personalized treatment regimen, I use tear osmolarity in follow-up visits to monitor treatment efficacy.

Tear osmolarity testing is valuable in diagnosing DED and assessing treatment results, whether clinicians are preparing a patient for cataract surgery or fitting contact lenses. Patients are usually grateful when we diagnose and treat their DED because they often have seen other eyecare professionals who have not been able to diagnose their condition.

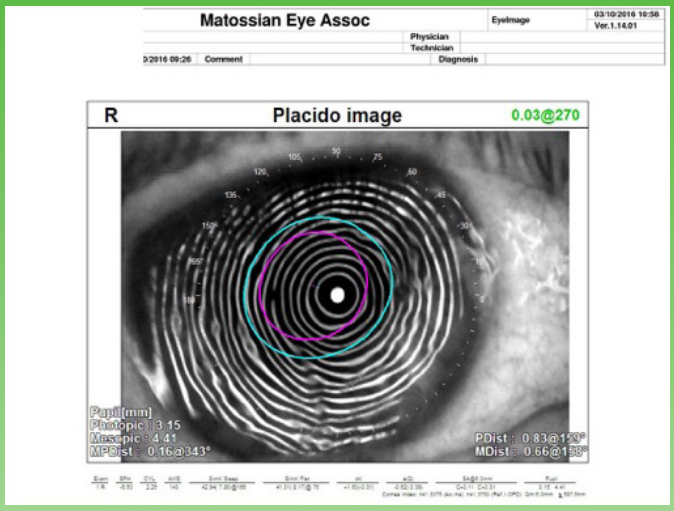

Figure 1. Placido disc image of severe OSD with irregular mires

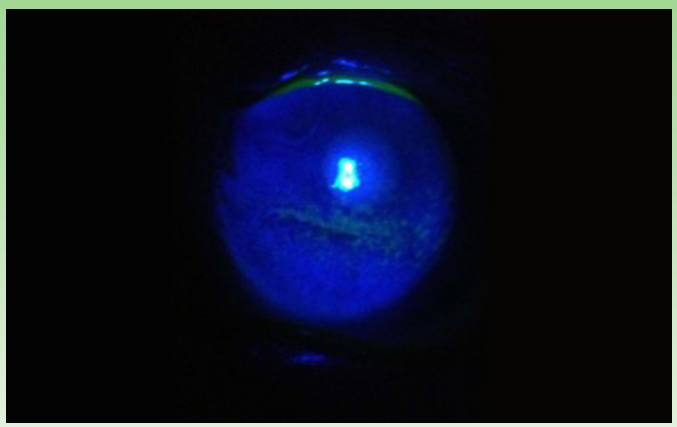

Figure 2. Slit lamp image of same patient as in Figure 1 with fluorescein staining of the cornea

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Ocular surface testing insights: Inflammatory markers

by Kenneth Beckman, MD, FACS

Kenneth Beckman, MD, FACS

MMP-9 testing helps clinicians identify inflammation and monitor treatment results

Although many patients have ocular surface dysfunction, it often remains undetected during eye examinations.

Inflammation is associated with dry eye disease (DED).[1] As part of the diagnostic process, I have found it helpful to test the tear film for the presence of inflammatory biomarkers such as matrix metalloproteinase- 9 (MMP-9). MMP-9 and other inflammatory biomarkers are produced when epithelial cells are under stress, degrading the epithelium and preventing epithelial healing.

Research has shown that MMP-9 testing is highly effective at detecting inflammation and that it is well correlated with other measures of DED. For example, in a study of 237 patients, tear breakup time, Schirmer's, corneal staining, and the Ocular Surface Disease Index (OSDI) test were used to confirm mild DED. When the same subjects were tested with InflammaDry, a tear film test for MMP-9, the positive agreement was 81% and the negative agreement was 98% (Figure 1).[2]

	Positive agreement	Negative agreement
Patients considered to have dry eye with tear breakup time, Schirmer, corneal staining, and OSDI	81%	98%
Patients considered to have dry eye with tear breakup time, Schirmer, and corneal staining, without OSDI	86%	97%

Figure 1. Results of MMP-9 testing from Sambursky et al[2]

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structure is absent or atrophied, a single 12-minute LipiFlow thermal pulsation treatment was less effective compared with results in patients with more than 1/3 of their gland structure remaining.[3] In this study, outcomes were measured as improvement of symptoms and gland function.

Meibography is also an excellent patient education tool and helps guide our discussion with patients, allowing them to see what their glands look like versus what they should look like. If they have advanced damage, I disclose that they may not respond as well to treatment as they would in the early stages. Meibography reveals the current structural integrity of the glands. Treatment for MGD would not be expected to result in regrowth of meibomian glands; it is expected to slow the atrophying process due to obstruction. Thus, meibography is not an effective short-term metric for treatment response.

Incorporating meibomian gland imaging

When deciding whether to incorporate meibomian gland imaging for all patients, we need to ask ourselves why we would wait for patients to report a problem if we could intervene early and prevent progressive damage.[4]

Meibomian gland imaging can be incorporated easily into any workup before the patient sees the ophthalmologist. I have my patients complete a SPEED questionnaire, and if patients are symptomatic with a score greater than 7, the technician performs point-of-care testing, such as tear osmolarity, MMP-9 testing, or meibomian gland imaging.

Patients who are known to be at high risk for meibomian gland disorder and ocular surface disease should be assessed routinely for MGD with gland evaluation and imaging if possible. High-risk patients include cataract and refractive surgery patients, contact lens wearers, and those with glaucoma or DED.

Early detection, early intervention

Meibomian gland imaging offers numerous benefits, enabling early detection of MGD and guiding treatment decisions. These images help patients understand how their meibomian glands function and encourage them to follow through with recommended treatment.

When treating MGD, early intervention is important because ocular surface disease can have a major impact on our surgical outcomes.

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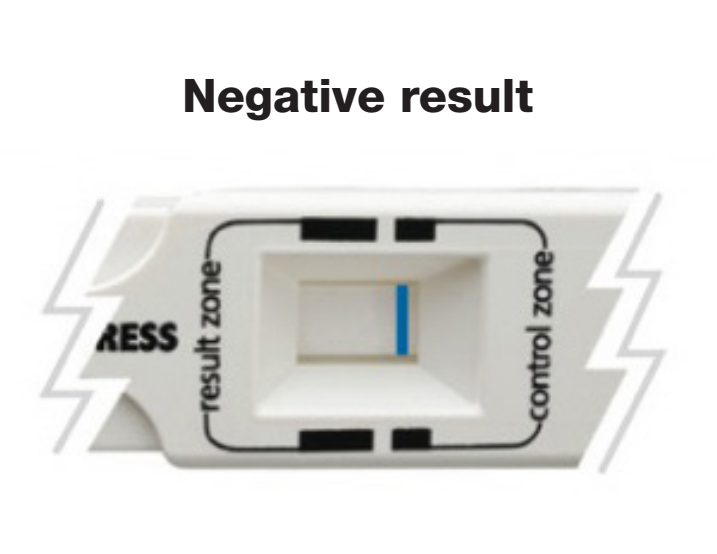

Figure 2. Negative InflammaDry test; note only blue (control) line visible

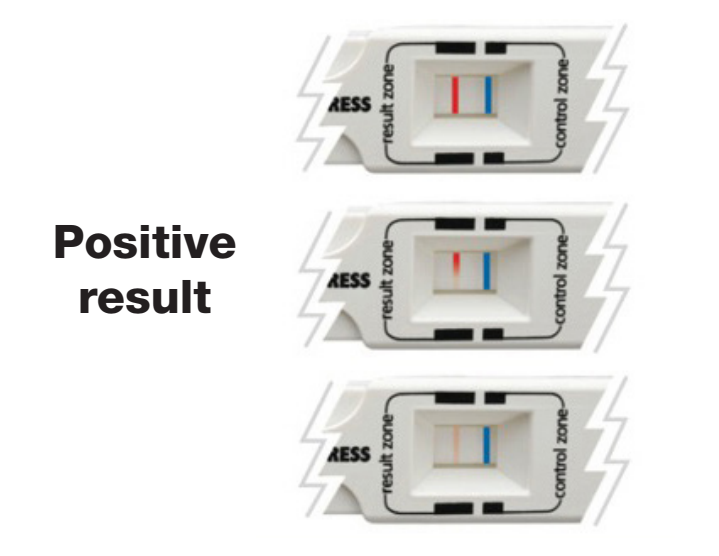

Figure 3. Positive InflammaDry test; note the blue and pink lines visible

With this test, a negative result is a single blue line. A pink line in addition to the blue line is a positive result, indicating the presence of the the inflammatory marker in the tears (Figures 2 and 3). In addition to assisting in diagnosis, MMP-9 testing can help ophthalmologists make treatment decisions. For example, in patients with positive results, we may prescribe steroids or cyclosporine rather than inserting punctal plugs. After we begin treatment, MMP-9 testing is useful in monitoring treatment efficacy.

During dry eye examinations, clinicians may also perform TearScan MicroAssay tests for IgE and lactoferrin to diagnose ocular allergies and dry eye. High IgE levels may indicate allergies, which may cause symptoms mimicking DED or exacerbate symptoms of DED. Lactoferrin levels are used to detect aqueous deficiency. Other biomarkers that may one day assist in our dry eye assessments continue to be evaluated.

Incorporating biomarker testing

In our practice, we evaluate every patient having cataract surgery for DED, which must be treated before we perform preoperative measurements.

When patients return for preoperative measurements, I perform corneal staining, osmolarity, manual K readings, IOLMaster measurements, and topography. If measurements do not correlate well or there is corneal staining, I continue ocular surface treatment.

When integrating point-of-care testing, ophthalmologists need to empower their technicians. As they obtain the patient's history, they need to ask appropriate questions. For example, using a survey, patients should be asked about fluctuating vision and reflex tearing, symptoms patients may not associate with DED.

If symptoms are present, the technician can begin the dry eye workup. In my office, technicians start with osmolarity testing. Subsequently, I perform corneal staining and tear breakup time with fluorescein. If MMP-9 testing is necessary, I may schedule this on the next appointment. Due to obvious time and patient flow issues, it is not practical to perform every dry eye test on the initial visit. Although I perform MMP-9 and Schirmer's early in the course to help me direct treatment, they can also be performed on a follow-up visit.

I do not order MMP-9 testing based specifically on the osmolarity score or any other individual test. Rather, if I find anything that could indicate inflammation, whether it is staining or high osmolarity, or if the symptoms warrant a dry eye evaluation, I order a baseline MMP-9.

MMP-9 testing not only helps us identify inflammation and monitor treatment results, it can have a hidden value. Patients with DED are often dissatisfied because other eyecare professionals have not resolved their problem. If you can effectively manage DED, you will build your reputation among optometrists and patients.

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CME questions (circle the correct answer)

1. If ocular surface disease is not diagnosed and addressed before cataract surgery, it may:
a. Affect preoperative measurements and surgical outcomes
b. Increase the risk of posterior capsular opacification
c. Affect the accuracy of point-of-care testing
d. Increase the risk of infection

2. High MMP-9 results specifically indicate:
a. Aqueous deficient dry eye disease
b. Evaporative dry eye disease
c. Inflammation
d. Meibomian gland dysfunction

3. Tear osmolarity testing has a specificity of:
a. 67%
b. 85%
c. 72%
d. 92%

4. _____ is/are the leading cause of dry eye disease.
a. Glaucoma medications
b. Hormonal deficiencies
c. Meibomian gland disease
d. Connective tissue diseases

5. According to Dr. Starr, after dry eye disease is confirmed, the clinician then needs to:
a. Confirm the presence of visual symptoms, such as aberrations and vision fluctuations
b. Perform meibomian gland expression
c. Insert punctal plugs
d. Differentiate between aqueous deficient and evaporative dry eye

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To claim credit, please fax the test and fully completed form by September 31, 2016 to 703-547-8842, email to GPearson@ascrs.org, or mail to: EyeWorld, 4000 Legato Road, Suite 700, Fairfax, VA 22033, Attn: April 2016 CME Supplement

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