Supplement to

Cataract & Refractive Surgery TODAY

September 2014

CME ACTIVITY

TODAY'S OCULAR SURFACE DISEASE

Optimizing Your Diagnosis, Diagnostics, and Therapeutic Approach

THE DULANEY FOUNDATION

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STATEMENT OF NEED

According to several key articles published in 2004 by the Eye Diseases Prevalence Research Group, the number of persons in the United States with cataracts is projected to rise dramatically by the year 2020 to more than 30 million, and the number of open-angle glaucoma cases will increase by 50%.[1,2] Ocular surface disease continues to be an issue for many patients, especially in older individuals who may have additional needs for ocular surgery for cataracts or retinal degenerative disease.[3]

The landscape of new diagnostic techniques and technologies available to help ophthalmologists diagnose ocular surface disease in their patients continues to rapidly develop. New diagnostic devices using tear film video and image analysis are providing additional means to quantify baseline tear film function and the monitoring of prescribed therapeutics over time. Accompanying therapeutic methods of eyelid disease to improve the production of tear film components is also allowing clinicians to address ocular surface disease in new ways.[4]

Point-of-care laboratory technologies can now provide new means of uncovering subclinical and overt dry eye, including tear osmolarity analysis, which in turn can allow ophthalmologists to better address patient needs before long-term ocular surface disease symptoms develop.[5] Educating ophthalmologists on the latest developments in new patient diagnosis methods, such as the in-office detection of matrix metalloproteinase 9 (MMP-9), an inflammatory component of dry eye disease, is directly linked to bridging the gaps in clinical diagnostic patterns and treatment decision making.[6]

In August 2011, a poll by *Review of Ophthalmology* discussed how improved familiarity with clinical trials reporting and critical analysis of outcomes should improve the implementation of new techniques into clinical practice.[7] Understanding the available and near-to-market ocular surface disease therapeutics in the pipeline is a key element of coordinating the needs of a patient with the available clinical strategies. Possession of this knowledge can have a direct impact on ophthalmologists' ability to more effectively communicate with patients and address their expectations.

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TARGET AUDIENCE

This certified CME activity is designed for ophthalmologists and general eye care professionals.

LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

- Diagnose acute dry eye conditions and chronic ocular surface disease
- Identify patient groups at risk for ocular surface disease in the practice
- Recognize the chronic nature and inflammatory processes in ocular surface disease
- Understand new ocular surface disease diagnostic technologies
- Differentiate palliative versus therapeutic treatment of ocular surface disease
- Discuss the impact of ocular surface disease on surgical outcomes

METHOD OF INSTRUCTION

Participants should read the CME activity in its entirety. After reviewing the material, please complete the self-assessment test, which consists of a series of multiple-choice questions. To answer these questions online and receive real-time results, please visit http://www.eyetube.net/cme-center/ and click on the icon with this activity's title. You will be redirected to http://www.dulaneyfoundation.org where you will log in and complete the activity.

Upon completing the activity and achieving a passing score of over 70% on the self-assessment test, you may print out a CME credit letter awarding 1 AMA PRA Category 1 Credit.™ The estimated time to complete this activity is 1 hour.

ACCREDITATION AND DESIGNATION

This activity has been planned and implemented in accordance with the Essential Areas and Policies

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FACULTY CREDENTIALS

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FACULTY/STAFF DISCLOSURES

Christopher E. Starr, MD, has had a financial agreement or affiliation during the past year with the following commercial interests: Alcon Laboratories, Inc.; Allergan, Inc.; Bausch & Lomb Incorporated; Merck & Co. Inc.; Rapid Pathogen Screening, Inc.; and TearLab Corporation.

Terry Kim, MD, has had a financial agreement or affiliation during the past year with the following commercial interest: Alcon Laboratories, Inc.; Bausch & Lomb Incorporated; Ocular Systems Inc.; Ocular Therapeutix, Inc.; Omerus; PowerVision, Inc.; Shire; and TearScience, Inc.

Marguerite B. McDonald, MD, has had a financial agreement or affiliation during the past year with the following commercial interests: Abbott Medical Optics Inc.; Allergan, Inc.; Bausch & Lomb Incorporated; Nexis Vision Group; OCuSOFT; TearLab Corporation; and TearScience, Inc.

William B. Trattler, MD, has had a financial agreement or affiliation during the past year with the following commercial interests: Abbott Medical Optics Inc.; Allergan, Inc.; Bausch & Lomb Incorporated; and CXL Ophthalmolics, LLC.

Darrell E. White, MD, has had a financial agreement or affiliation during the past year with the following commercial interests: Allergan, Inc.; Bausch & Lomb Incorporated; Eyemaginations, Inc.; and Nicox, Inc.

All of those involved in the planning, editing, and peer review of this educational activity report no relevant financial relationships.

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Today's Ocular Surface Disease: Optimizing Your Diagnosis, Diagnostics, and Therapeutic Approach

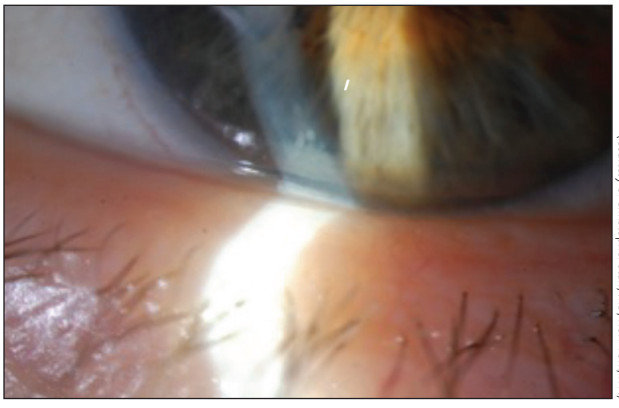
SUPPORTED BY AN UNRESTRICTED EDUCATIONAL GRANT FROM ALLERGAN, INC.

Dr. Starr: In the American Society of Cataract & Refractive Surgery (ASCRS) Clinical Survey 2013, physicians were asked whether dry eye disease takes up too much time in their practice.[1] Although 87% of the respondents said yes, interestingly, younger respondents—those who had been in practice for 10 years or less—did not have a problem with the time involved in managing dry eye disease. So, let me pose the same question to you practitioners: When you need to manage dry eye patients in your practice, is it a nuisance, or do you embrace it?

Dr. White: I have been in practice for 25 years, and I certainly do not find treating dry eye to be a nuisance. I admit that early in my career, dry eye was described as the "crab grass that grows on the lawn of ophthalmology." For my group, however, it was a great opportunity. There is an unmet need out there for dry eye management. When cataract or glaucoma patients in my office present with dry eye syndrome, my staff and I treat them with a regular protocol. This does not seem to add chair time or complicate the preoperative assessment. It took us some forethought to design this protocol, but managing dry eye sufferers feels no different than managing patients with other problems.

Dr. McDonald: I have always embraced dry eye, especially recently because of the new diagnostic and therapeutic modalities we have at our disposal. Treating dry eye builds one's medical and surgical practice, offers little medicolegal exposure, adds significantly to the bottom line, and improves one's surgical outcomes. As they say, if you tell preoperative patients about their dry eye in advance of surgery, it is their problem. If you tell them after surgery, it is your problem.

Dr. Kim: I admit that I used to be a bit reluctant to manage dry eye patients, largely because we had limited treatment therapeutic options. Now, however, new diagnostic modalities like tear osmolarity testing are allowing us to recognize and diagnose dry eye disease sooner so that we can manage these patients at an earlier stage before the disease state progresses. We are also much more aware of the very high prevalence of evaporative types of dry eye disease caused by meibomian gland dysfunction (MGD) (Figure 1). This understanding has opened the door to more diagnostic and therapeutic modalities, such as lipid layer analysis and thermal pulsation for this disease, which has led to a much higher satisfaction level for both the patient as well as the clinician.



(Courtesy of Christopher Starr, MD, New York, NY.)

Figure 1. Slit-lamp examination of an eye reveals meibomian gland dysfunction and telangiectasias, with thick meibum upon gland expression.

Dr. Starr: I agree. New diagnostic tools are making the treatment of dry eye disease more exciting, more accurate, and more relevant. For example, tear osmolarity tests are able to tell us whether the patient has dry eye disease and how severe it is, often before we even see the patient. Such tests make the conversation with the patient much shorter and easier to deliver. Patients can easily understand and

relate to a number (Figure 2). In this modern era, these new diagnostic tests can help bridge the traditional gap between patient and doctor in the context of the often-difficult dry eye realm.

Dr. Kim: Yes, being able to correlate a numerical value to a patient's dry eye symptoms helps them accept the diagnosis, which has been one frustrating part of trying to manage this syndrome. Patients cannot see what we see on a slit-lamp examination (unless we have a slit-lamp camera to show them), so having a qualitative and quantitative reading to share with them has been a welcome change.

Dr. McDonald: My patients understand the osmolarity score on a basic level, and they are excited when it lowers in response to therapy. The osmolarity score enhances compliance, and it certainly shortens the discussion on the first visit.

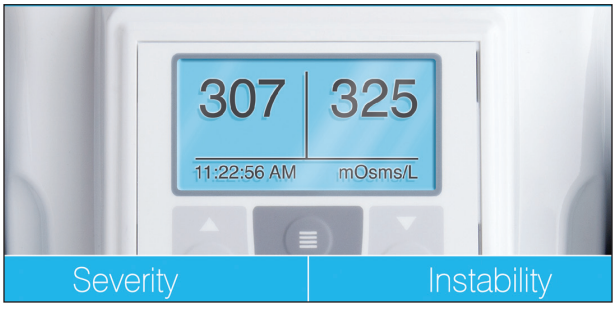
Dr. White: Diagnosing ocular surface disease was almost mystical before these diagnostic tests. For example, a patient would present with tearing, which we all know is a classic symptom of dry eye. And then, after no other testing, the ophthalmologist would look at the slit lamp and say, "Well, of course you have tearing, because you have dry eye." That was the first toe into the quicksand of the long and arduous conversation of how the patient could possibly have dry eye if he or she is tearing. Tear osmolarity testing has alleviated this issue, and I think it might be the difference between ophthalmologists who do not find dry eye to be a nuisance and those who do. Those practitioners who feel that dry eye is a nuisance may still be using an older model of diagnosis by examining patients' eyes, making an educated guess about their condition, and then deciding what tests to perform to confirm the diagnosis.

By contrast, when I enter the examination room at my practice, the patient has already undergone a test for tear film osmolarity and one to detect for matrix metalloproteinase-9 (MMP-9; an inflammatory marker for epithelial cells[2]) (Figure 3). If the patient has an acute red eye, he or she has already undergone a point-of-care test for adenovirus. If the technician deems it appropriate, the patient has also had a Schirmer's test. All of these tests compose a preordered data set for us.

Dr. McDonald: To your point, Dr. White, when patients ask me how they could possibly have dry eye when they are tearing, I tell them that their dry eyes recover overnight while the eyes are closed, but the dry spots start to accumulate again as soon as they open their eyes in the morning. By mid to late afternoon, a critical number of dry spots have collected on their corneas (Figure 4). The brain then senses that the corneas have been injured, and sends in the "emergency tears," hence the paradox.

Dr. Starr: Interestingly, when the ASCRS 2013 Clinical Survey asked respondents questions about traditional testing methods—Schirmer's testing, corneal and conjunctival staining, and tear film breakup time testing—almost 100% of the respondents still use all three of those methods and still feel that they are all clinically useful.[1] I too feel that these tests are still useful, although I no longer perform Schirmer's testing as often, simply because I feel that the newer diagnostics give me as much or more information in a faster way.

When questioned whether they are using the newer diagnostic tests (Table 1), respondents to the survey cited a fairly low adoption rate in general, which surprised me.



(Courtesy of TearLab.)

Figure 2. A point-of-care osmolarity test gives a numerical value to the severity of aqueous deficiency, which gives patients a reference point for understanding the disease.

(Courtesy of Rapid Pathogen Screening.)

Figure 3. A positive MMP-9 assay (left) shows a positive red result line and a positive blue control line. The negative test (right) shows the blue control line only, indicating that the test was valid and run correctly.

TABLE 1. DRY EYE DIAGNOSTIC TESTS CURRENTLY ON THE MARKET			
Diagnostic Test	**Manufacturer**	**Condition**	**CMS Reimbursement?**
AdenoPlus	Nicox, Inc.	Adenoviral conjunctivitis	Yes
TearLab Osmolarity Test	TearLab Corporation	Dry eye disease	Yes
Inflammadry	RPS Detectors	Dry eye disease	Yes
LipiView	TearScience	Dry eye disease	No
Sjö	Nicox, Inc.	Sjögren syndrome	No

Yet, 17% of the respondents said they were using osmolarity testing, and more than 50% of those who were not using it think it has clinical utility. With that high level of interest, I anticipate its adoption rate will grow significantly in the near future.

It also surprised me that just over 10% of ophthalmologists were using the interferometric tear film lipid test, and even fewer thought it had clinical utility. The least popular of the three, however, was the point-of-care test for acute conjunctivitis. Only 10% of the respondents had used it, and most of them said it was not clinically useful. Perhaps this response means that clinicians think they can diagnose viral or adenoviral conjunctivitis clinically.

Dr. McDonald: My staff and I find the point-of-care test for acute conjunctivitis to be very useful. If the patient has a positive test, he or she is spared unnecessary topical antibiotics and is given a topical antiviral of ganciclovir ophthalmic gel in an off-label use. If it is negative, and allergic conjunctivitis has been ruled out by the patient's history and slit-lamp examination, then I prescribe a topical fluoroquinolone. As ophthalmologists become more familiar with its utility, I think the adoption rate of this point-of-care test will increase.

Dr. White: The responses to that survey were fascinating. Also, there are data on a subset of surgeons who were asked whether red eye was acute, viral, or bacterial. The participants were anterior segment ocular surface disease specialists with more than 10 years of training. In clear cases where most clinicians would look at the ocular surface and say this is unquestionably adenovirus, the participants in this survey were right 50% of the time. In cases where they said there was clearly no adenoviral infection, they were right 20% of the time.[3]

Dr. Trattler: I am not surprised by the results of the ASCRS survey, as they match what I am seeing in my own practice, which includes 14 ophthalmologists. Doctors are typically using one or more of the traditional tests (Schirmer's testing, fluorescein eye stain, and tear film breakup time) to evaluate the ocular surface. Many of the doctors in my group have expressed an interest in starting with the newer point-of-care technologies to help enhance their ocular surface disease workups.

ISSUES OF COST

Dr. Kim: Are there cost issues associated with the newer diagnostic tests for dry eye?

Dr. Trattler: Yes, but many of them are reimbursable.

Dr. White: The test to detect MMP-9 recently received a reimbursement number from Medicare of $15.50 per eye, so Medicare carriers will begin reimbursing roughly $3 more than the full retail cost of the test once they add a new billing code in July of 2014.

Dr. Kim: The challenge is that managed care may or may not accept that code or the exact amount, so a practice may get $11 or $9 in reimbursement. Some doctors prefer to wait to see that the commercial insurances will accept a code before they start utilizing a test in dry eye patients.

Dr. White: True, although that does not explain why the tear osmolarity test has had less penetration. It has been reimbursed from the time it was waived by the Clinical Laboratory Improvement Amendment (CLIA), and the median reimbursement exceeds the median cost of the test.

Dr. Starr: Although some insurers do not cover the tear osmolarity test, the manufacturer will, in most cases of zero reimbursement, provide makeup cards so that there is minimal to no financial risk to adopting the test.

Dr. McDonald: We have used tear osmolarity testing in our practice for several years, and the adoption rate is definitely increasing, but I think that there is still confusion about how to interpret the osmolarity readings. When the two eyes have very different readings—298 and 321, for instance—the clinician may interpret this to mean that the test is not accurate, when actually an inter-eye difference of 8 mOsm/L or greater is the hallmark of dry eye. The tear film becomes unstable as the dry eye becomes

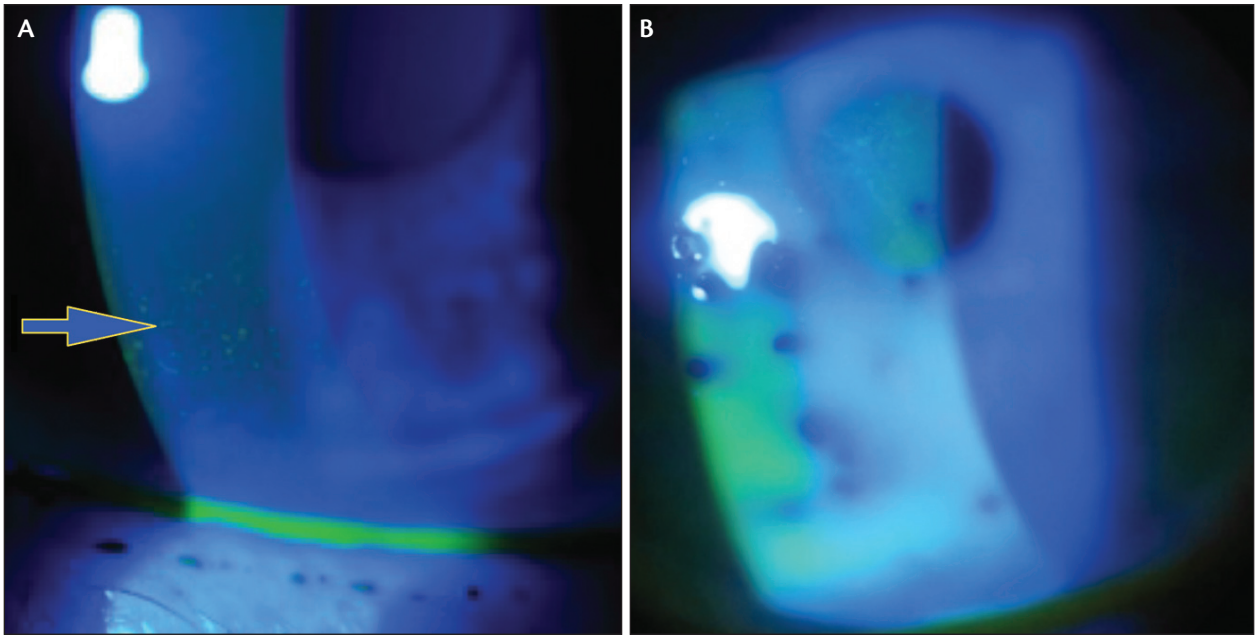


Figure 4. This patient was interested in a premium IOL, but her eyes showed corneal staining (A and B), a rapid tear breakup time, and an irregular topography map—all indications of corneal dryness that precluded her from immediate surgery.

more hyperosmolar, with ever-wilder swings in osmolarity from moment to moment. In other words, the osmolarity readings do increase as dry eye progresses, of course, but the inter-eye difference is at least as important as the higher of the two readings. Once this is understood by the clinician, he or she appreciates the great value that tear osmolarity testing brings to the practice (ie, that it is very useful in diagnosing dry eye and tracking response to treatment).

A NEW LANDSCAPE FOR DRY EYE TESTING

Dr. White: What do you think about the role of traditional tests for dry eye disease? If you perform point-of-service diagnostic testing up front, are you still administering the traditional tests, and what impact are they having on your next steps?

Dr. Starr: I still test for tear film breakup time and corneal staining on every eye. I cannot remember the last time I did a Schirmer's test, however.

Also, I feel the physical examination is critical, not so much for diagnosing dry eye, but for differentiating between evaporative disease versus aqueous deficiency. Neither osmolarity nor MMP-9 differentiates between these entities; therefore, it is useful to examine and express the meibomian glands and assess tear film breakup time and other signs of tear instability and evaporation. Lipid interferometry, of course, is a very useful tool for diagnosing evaporative dry eye, however.

Dr. Trattler: Corneal staining and tear film breakup time tests are easy tests to perform, and they identify patients with epithelial breakdown due to dry eye as well as an unstable tear film that can affect visual quality. Newer point-of-care tests can help identify dry eye patients even earlier, however.

Dr. McDonald: I couldn't agree more. Once the fluorescein is instilled, it takes only a few seconds to evaluate tear film breakup time and corneal staining. It takes only another few seconds to press with one's index finger or thumb on the middle third of both lower lids to express the meibomian glands.

CHAIR TIME WITH DRY EYE PATIENTS

Dr. Trattler: The other issue regarding cost is the chair time that we spend with dry eye patients monitoring the impact of therapy on their disease. New point-of-care testing can help us quantitatively measure patients' responses to therapy and help guide us and them toward selecting therapies that are most effective for their condition.

Dr. Kim: That is a good point. I, too, rarely perform Schirmer's test on my patients; however, I do perform corneal staining and tear film breakup time testing, and express the meibomian glands on all of my patients. These three tests can be performed at the slit lamp in a very short period of time. I recently adopted point-of-care diagnostics for my dry eye patients, which has required a change in the work-up sequence and regimen of my practice. Before this, my technicians provided me with limited information (eg, the patient's symptoms, medical/ocular history, and medications) prior to my evaluation.

Now, my staff are being trained to administer osmolar-

(Courtesy of TearScience, Morrisville, NC.)

SPEED Questionnaire

Name: _____, _____ Date: ___/___/_____
(Last) (First)

DOB: ___/___/_____ **Sex:** M F

Report the type of **SYMPTOMS** you experience and when they occur:

SYMPTOMS	AT THIS VISIT		WITHIN PAST 72 HRS		WITHIN PAST 3 MONTHS	
	YES	NO	YES	NO	YES	NO
Dryness, Grittiness or Scratchiness						
Soreness or Irritation						
Burning or Watering						
Eye Fatigue						

Report the **FREQUENCY** of the above-checked symptoms as Never, Sometimes, Often or Constant using the numbering system below:

SYMPTOMS	0	1	2	3
Dryness, Grittiness or Scratchiness				
Soreness or Irritation				
Burning or Watering				
Eye Fatigue				

0 = Never, 1 = Sometimes, 2 = Often, 3 = Constant

Report the **SEVERITY** of your Symptoms using the rating list below:

SYMPTOMS	0	1	2	3	4
Dryness, Grittiness or Scratchiness					
Soreness or Irritation					
Burning or Watering					
Eye Fatigue					

0 = No problems
1 = Tolerable – not perfect but not uncomfortable
2 = Uncomfortable – irritating but does not interfere with my day
3 = Bothersome – irritating and interferes with my day
4 = Intolerable – unable to perform my daily tasks

Do you use drops and/or ointment? _____ What drops do you use?_____

Figure 5. A short patient questionnaire about the signs and symptoms of dry eye, such as this Standard Patient Evaluation of Eye Dryness, can be added to the medical history.

ity testing (and at times, MMP-9 and lipid layer testing) based on a patient's symptoms and responses on his or her questionnaire prior to seeing me. This is analogous to performing the biometry and keratometry testing prior to evaluating cataract patients. In both scenarios, it is extremely valuable for the clinician to have this information available before examining the patient in order to educate the patient about his or her condition and guide his or her decision-making process regarding the therapeutic options.

The success of point-of-care diagnostic testing for patients does require a commitment by the entire staff, in my experience.

Dr. Starr: Exactly. Although these tests are easy for technicians to perform, I think many practices do not want to change their routines. I recommend using a short patient questionnaire on paper that you include in the medical record (Figure 5). If the patient indicates he or she has at least a couple of the symptoms listed on the questionnaire, the technician then has the green light to administer a dry eye test. In my practice, the osmolarity test is located right next to the patient's chair, and it takes a seasoned technician about 30 seconds or so to test both eyes.

Dr. White: My staff and I have had the same issue with the MMP-9 test. We just started using it and are struggling to figure out where it fits in our protocol. I know that it is an important test, but we are still learning for which patients and at what point to administer it. Our protocol is predicated on making it possible for the last doctor who sees the patient to go in the room only once. We are pushing all routine testing "upstream and offshore" so that we do not waste time for either the patient or the examining doctor.

Dr. Starr: I just started using the MMP-9 test as well. Like osmolarity testing, it is technician-driven, but is important to administer before any other test or procedure that may disturb the natural milieu of the ocular surface. My technicians became adept at administering this test very quickly, as it is very similar in design to the adenovirus detector test we have been using for years. Our protocol is to administer the tear osmolarity test first, followed by the MMP-9 test. Anyone who meets the historical criteria for osmolarity also meets the criteria for MMP-9.

After conducting these tests, the technician takes the patient's refraction, checks the IOP, and dilates his or her eyes. By the time I see the patient, which is usually about 20 minutes later, the results of the two dry eye tests are in the chart and ready for me to review.

Dr. McDonald: We just started using the MMP-9 test in our practice as well. At first, we used it on every patient who had positive responses on the questionnaire; basically the same patients who were receiving a tear osmolarity test. Now, I am testing a regimen where we do the tear osmolarity test on everyone with a history of dry eyes and/or a positive symptom on our questionnaire, but we reserve the MMP-9 test for patients with ocular surface complaints but normal tear osmolarity scores. If they have normal osmolarity scores but a positive MMP-9 test result, then they have an ocular surface disease or condition, but it is not dry eye.

USE OF VARIOUS DRY EYE TESTS

Dr. White: Would you still give a patient the MMP-9 test if his or her osmolarity reading were normal?

Dr. Starr: That is a great question, and I think that we are sorting that out now. I am using both tests currently, because the MMP-9 test is brand new, and I want to evaluate it. We know from the Dry Eye Workshop report that ocular surface hyperosmolarity can lead to ocular surface inflammation, and vice versa,[4] so one could make a broad assumption that any positive result on osmolarity testing

would also have a positive MMP-9 test result. But, I can tell you from my own experience, that this is not always the case, and therefore, I find both tests to be complementary and equally useful in not only identifying dry eye disease but also in guiding my treatment strategies.

Dr. Trattler: The only issue with that reasoning is that evaporative dry eye disease caused by MGD is very common. Can a patient with MGD have hyperosmolar tears on the osmolarity test without elevated MMP-9s as measured on the MMP-9 test?

Dr. McDonald: Dr. Trattler is right in that 86% of patients with dry eye in a study by Michael A. Lemp, MD, had an evaporative component.[5] Recently, published work by Kelly Nichols, MD, indicates that it may be as high as 92%.[6] Many dry eye researchers feel as Dr. Starr and I do; however, that there is an inflammatory component to both aqueous deficient and evaporative dry eye.

Dr. Starr: I agree that sometimes one test result is positive and the other is negative, or vice versa. I think osmolarity is great for confirming the presence of dry eye and its severity. In my opinion, the MMP-9 test is useful as an adjunct for guiding treatment, because anyone with a positive reading has significant inflammation on the ocular surface and thus deserves treatment with an anti-inflammatory medication.

Dr. Kim: Dr. Trattler, are you saying that patients with MGD and rapid tear film breakup time may not show much inflammation on their ocular surface?

Dr. Trattler: Yes, it is possible in that scenario that they may not. I have not had enough experience with the MMP-9 test to evaluate it, but I think there is value in doing the test, even if the osmolarity readings are elevated.

Dr. Starr: Or, even if osmolarity is normal.

Dr. White: We have all seen patients who come in with classic dry eye symptoms and a tear osmolarity of 280. They have a big, voluptuous tear film, and yet it breaks up in 3 seconds. They may or may not have staining, but we know there is some dysfunction going on. We have confirmed that elevated levels of MMP-9 in the meibomian glands deposited on the surface of the eye create that pro-inflammatory milieu. That's why azithromycin ophthalmic solution 1% (Akorn, Inc.), which has been shown to dramatically lower MMP-9 activity, is so effective.[7]

Dr. Kim: Are we advocating that clinicians should be using both tests in every patient who meets the criteria for having ocular surface disease?

Dr. White: In the beginning, I think many of us who are seeing a lot of patients with ocular surface disease will use both tests, especially at the initial visit. There are equally fascinating questions downstream, however. In follow-up visits of patients whose symptomatology has dramatically improved following initial treatment, how are we going to get an objective measurement of dryness? At what point are we going to use the MMP-9 test? Where are we going to retest the inflammation? What are we going to do if the patient's levels of MMP-9 are still elevated dramatically? I do not know the answer to these questions.

Dr. Starr: I think many of those answers are to be determined. My gestalt is that both tests are useful. Some patients will be mildly hyperosmolar with normal levels of MMP-9. For these types of patients, I would likely recommend conservative over-the-counter treatments like artificial tears, warm compresses, lid hygiene, etc. In the future, I expect to see study results that will shed light on the progression of early dry eye disease with no treatment. If left untreated, will it worsen? I think these new diagnostic tests we have been discussing will help us develop preventive measures of treating dry eye disease more aggressively at earlier stages, whereas the MMP-9 test result might be positive or the tear osmolarity test result might be negligibly elevated. I think we will be able to answer these questions of whether to treat with anti-inflammatory medication at an earlier stage.

Dr. McDonald: A study by Rau did not enroll a huge number of patients, so I agree with Dr. Starr that a large-scale study of the progression of early dry eye disease is warranted. Nevertheless, Rau showed that, if left untreated, one-third of dry eye patients reported symptoms that were one International Task Force (ITF) level worse in 12 months, whereas only 5.5% of cyclosporine-treated patients did.[8]

SJÖGREN PATIENTS

Dr. Kim: What about patients who test positive for Sjögren syndrome (Figure 6)?

Dr. Starr: Yes, has anyone started testing with the new Sjögren syndrome diagnostic panel?

Dr. Trattler: I have not, but the statistics are surprising. Female patients with dry eye disease seem to be the target, as Sjögren syndrome is more common in women.[9]

Dr. McDonald: We have been using the Sjögren test for a few months; approximately 70% to 75% of our tests have come back positive so far. We give the patients the results and refer those with positive results to a rheumatologist. The manufacturer keeps a list of the rheumatologists in each region who are interested in Sjögren syndrome. Early intervention can change the quality of their lives, and

the internist can screen periodically for lymphoma (5% to10% of Sjögren patients develop lymphoma[10]). Here is a practical tip: For speed, we draw a tube of blood rather than prick the patient's fingertip. It is faster and more comfortable for the patient.

Dr. White: My staff and I have started doing more Schirmer's tests, because we are anticipating that we are going to need the data from the positive, low Schirmer's reading for insurance coverage and to convince the rheumatologist to take a Sjögren syndrome referral, because that is a number that they understand. We are doing everything we can to make these referrals easier.

Dr. McDonald: This is a nationwide problem. That is why the manufacturer of the Sjögren test has a list of the rheumatologists who are interested in treating Sjögren patients.

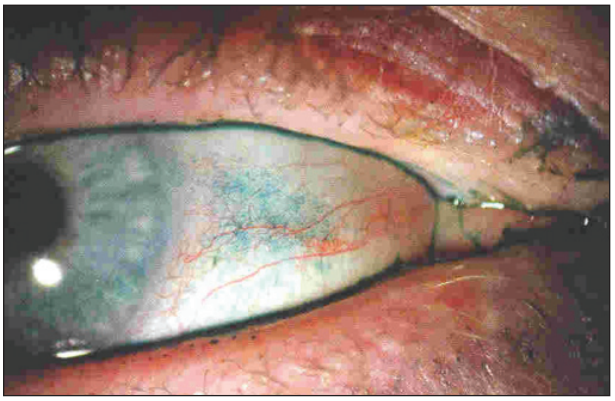
Dr. Kim: Are you advocating using a systemic or a topical anti-inflammatory medication for patients who test positive for Sjögren syndrome?

Dr. McDonald: I treat them as I would any other dry eye, in which I use topical steroids for induction of cyclosporine therapy and also for flare-ups, but I am more aggressive. For instance, I treat Sjögren patients with ITF level 2 dry eye as if they had level 3, as I know their dry eyes will be harder to manage.

Dr. White: Esen K. Akpek, MD, at the Wilmer Eye Institute, has shared data that if a patient has true Sjögren syndrome, it is an autoimmune disease, which inevitably and irrevocably destroys the lacrimal glands.[11] There is nothing that we can do to promote more or better-quality tear production from lacrimal glands that no longer exist.

The logical extension of that, which is a fascinating global question in our health care system, is even when we know we can prevent the progression of Sjögren syndrome with these biologics, should we do it? If we are treating a 55-year-old woman whose test results are dramatically positive for all of the immunologic tests for Sjögren syndrome, but she has only moderate dry eye, can we justify putting her on infliximab (a systemic medication for autoimmune diseases)? It is a fascinating question.

However, I advocate the use of biologics. One of my technicians has biopsy-proven Sjögren syndrome, and we are using her to educate local rheumatologists. We have two large academic systems at the Cleveland Clinic and the Case Western Reserve University Hospital, both of which are blessed with very good rheumatologists, all of whom are unbelievably busy and not terribly interested in seeing more patients.



(Courtesy of Terry Kim, MD, Durham, NC.)

Figure 6. Sjögren syndrome made visible with lissamine green stain.

Dr. Starr: On a practical level, where does testing for Sjögren syndrome fit into your protocol? How do you make the decision to test for it, because it does involve pricking the finger and drawing blood, which can be a little harrowing for an ophthalmologist.

Dr. White: We do not test for Sjögren syndrome as part of our same-day protocol. We have patients come back on a day when the doctors are not in the office and the technicians are doing visual fields.

Dr. Starr: You have patients come back?

Dr. White: Yes, because the test is not reimbursed, and we have dedicated testing time when there are fewer doctors in the office, and we have staff who are available to administer those tests. There is no way to fit that patient predictably into the regular clinical flow, because we do not know how long it is going to take to obtain the blood. We have been surprised by how difficult it is to get an adequate sample from some patients, because they do not produce enough blood.

Providing a service, such as the Sjögren test, for which we do not get paid generates incredible goodwill from patients. My partners and I think that having the opportunity to connect with local rheumatologists is going to create an additional source of patients, dry eye patients specifically.

Dr. McDonald: In one of the two offices where I see patients, I ask one of our technicians to draw a tube of blood, as he moonlights as a phlebotomist in a local hospital. At the other office, we have a basket with all the necessary tools for drawing blood for the Sjögren test. It takes me about 2 minutes to put on the tourniquet, hit a vein, and fill the tube myself.

Dr. Starr: What are your criteria for ordering the Sjögren panel test?

Dr. McDonald: I test any ITF stage 3 or dry eye patient who is in an unusual demographic of under 35, male or female; anyone with a history of an autoimmune disease to check for secondary Sjögren syndrome; and anyone with a poor response to treatment when good compliance has been established.

Dr. White: Our criteria are evolving, because it is a relatively new test for us. Certainly, we administer it to women between the ages of 35 and 55 who have particular signs and symptoms. If their Schirmer test result is under 8, if they have corneal staining, and if they have dramatically elevated tear osmolarity above 320, we suggest they return for the Sjögren test.

Dr. Kim: We are used to ordering serologic studies and sending them out for the standard antibody analysis that have specificities of 40% to 60%. We are now aware of a host of new serum markers for Sjögren syndrome—salivary gland protein-1 (SP-1), carbonic anhydrase-6 (CA-6), and parotid secretory protein (P-SP)—that have much higher sensitivity and specificity levels and are also elicited earlier in the disease process.[12] We are diagnosing these patients earlier and, hopefully, not only helping them with their ocular manifestations, but also other nonocular complications related to Sjögren syndrome. For their dry eye disease, I do not give those patients a choice; I prescribe them a topical anti-inflammatory agent indefinitely, which is currently topical cyclosporine A.

Dr. Trattler: When I diagnose a patient with Sjögren syndrome, regardless of whether there is documented dry eye, I automatically put the patient on topical cyclosporine to prevent the development of ocular surface disease. Dr. White is suggesting that we should be going one step further, which is getting these individuals systemic preventive therapy, and that recommendation has a lot of validity.

Dr. Starr: I will leave that to the rheumatologists.

Dr. White: I am doing the same. I am asking rheumatologists to evaluate these patients for treatment, because they may need a level of ongoing care that I am not qualified to provide.

Dr. Kim: I have heard positive feedback from rheumatologists about eye care providers referring them patients, especially when they learn that these patients are already coming to them with a confirmed diagnosis of Sjögren syndrome.

PREVALENCE OF DRY EYE DISEASE

Dr. Starr: Another question from the 2013 ASCRS Clinical Survey was, what percentage of your cataract and laser vision correction patients do you think have dry eye disease that is significant enough to treat with something other than artificial tears?

Dr. Trattler: I participated in a multicenter clinical study supported by Allergan that was designed to determine the incidence of patients scheduled for cataract surgery who have dry eyes. I was shocked at the high percentage of patients who tested positive for clinically significant dry eye disease—a little more than 80% of patients had a level II or higher dry eye. These patients were scheduled for cataract surgery and underwent dry eye testing prior to their scheduled surgery. Their symptoms did not suggest such a high level of dryness, as most of the patients did not complain of foreign body sensation or ocular irritation. The most common complaint was blurred vision. Of interest, this study also helps one understand why half of the questions on the Ocular Surface Disease Index (OSDI) questionnaire are actually visual questions asking the patient how well they see in certain conditions. The OSDI test has been shown to be quite sensitive at identifying dry eye. For that reason, it makes sense that patients are having visual issues and thinking these are all cataract specific, when in reality, it is the combination of cataracts and dry eye affecting the quality of their vision.

Dr. Kim: You mentioned blurred vision. I want the questionnaire I use for my practice to focus on patient symptoms. Based on my experience, I think the key symptom is fluctuating vision. I examine the biometry and keratometry readings of these individuals much more closely, because they are at a much higher risk for suboptimal surgical outcomes due to erroneous measurements caused by their abnormal ocular surface.

Dr. Starr: I agree that fluctuating vision is almost pathognomonic for dry eye disease.

Dr. McDonald: I completely agree; there is no other condition that causes moment-to-moment fluctuations in vision. In my practice, it is nearly always the first presenting symptom of a dry eye patient.

Dr. Trattler: Interestingly, some of these patients will respond so well to dry eye therapy that they no longer require cataract surgery. Their vision improves, and they are very satisfied with your care. While they may not have surgery with you in the short term, I have found that they refer their family and friends.

Dr. McDonald: In a recent dry eye prevalence study conducted at over 175 sites in the United States, TearLab assessed 9,326 subjects visiting these offices for any reason (cataract surgery, annual exam, glaucoma, etc.). Forty-nine percent of the "normals" (as defined by a tear osmolarity

score of 308 mOsm/L or less) had at least three out of nine symptoms of dry eye disease, and 47% of the "dry eye patients" (as defined by a tear osmolarity score of greater than 308 mOsm/L) had fewer than three of nine symptoms; that is, they were asymptomatic. So, we definitely want to treat our symptomatic dry eye patients to relieve them of their misery, but we should initiate therapy for the nearly 50% of patients with clinically significant dry eye who are asymptomatic.

Dr. White: My data are a little skewed, of course, because my practice is so heavily weighted toward treating ocular surface disease. I find that 75% to 80% of patients who we are undergoing a work-up for cataract surgery or laser vision correction have some level of dry eye that needs to be treated.

Dr. Starr: I agree. In my practice, the incidence of dry eye is somewhere in that ballpark. In the 2013 ASCRS Clinical Survey, respondents said only 21% of cataract patients and only 24% of laser vision correction patients were symptomatic enough to treat with something other than artificial tears.[1] I question whether the incidence is really that low everywhere, or are many practitioners just overlooking the ocular surface while dealing with seemingly bigger issues like cataracts and refractive surgery.

TREATMENT TIME BEFORE SURGERY

Dr. Starr: If a patient of yours presents for cataract surgery and you see some corneal staining, high osmolarity, and signs of MGD, what do you do? How long do you wait before you perform the surgery?

Dr. Trattler: In my practice, the first question patients ask is when can they have surgery. I find it is best for me to schedule them for surgery about 1 month in the future, and my goal is to try to optimize the ocular surface during this time period. I may bring them back for repeat testing with topography and the IOLMaster (Carl Zeiss Meditec) and then proceed to surgery as planned. If an individual returns 2 to 3 weeks later and testing shows that his or her ocular surface is still not optimized, I will delay the surgery. In most cases, however, I can optimize the ocular surface in just a few weeks.

Dr. McDonald: If I detect clinically significant ocular surface disease, I defer the A-scan and IOLMaster (Carl Zeiss Meditec) or Lensar keratometry (Haag-Streit) until I have treated the dry eye and/or meibomian gland disease for at least 1 month.

Dr. Kim: With such a high prevalence of meibomian gland dysfunction, we should all be assessing meibomian gland function by pressing on the lower lid margins with a cotton-tipped applicator and examining the quality and quantity of the gland expressions, and by checking tear film breakup time on every patient. Let's say we have a cataract surgery patient with MGD who is symptomatic with fluctuating vision. The patient may also have some dropout on his or her corneal topography. I tell the patient there are two ways we can approach treatment. He or she can spend potentially up to 4 to 6 months using warm compresses and lid hygiene, or we can accelerate treatment with thermal pulsation (LipiFlow; TearScience) and if needed, IPL therapy. This way, the patient understands the importance of a healthy ocular surface and that addressing it has a bearing on the timing of his or her surgery.

Dr. White: Is there a difference in your patients' acceptance of that strategy based on what level of IOL they are choosing?

Dr. Kim: Surprisingly, no. We certainly know that patients who choose a multifocal IOL have higher expectations than those who choose a monofocal IOL. However, now that we are also integrating femtosecond laser treatment into our discussion for our monofocal IOL patients with treatable corneal astigmatism, these patients are just as motivated and accepting of optimizing their ocular surface so that they can achieve the best possible visual and anatomic outcome.

Dr. Starr: That is even more of a compelling reason to optimize the ocular surface before taking those final limbal relaxing incision measurements and topographies. Do you use IPL and/or thermal pulsation?

Dr. White: We do not. I am in an interesting market. My entire group has been unsuccessful in having patients with MGD move forward with either IPL or heat pulsatile treatment, although I think both technologies are wonderful. Most of the treatments we have been doing with dry eye patients preoperatively have been traditional mechanical treatment, nutraceuticals, or some of the topical medications that we have mentioned.

My group participated in an unpublished study in which we performed tear osmolarity preoperatively and postoperatively on every cataract patient. It showed that there was a statistically significant increase in tear osmolarity postoperatively in every patient, regardless of whether they had been diagnosed with dry eye preoperatively. There are certain patients in whom we are prescribing an anti-inflammatory ocular surface therapy based on what type of surgery they are having, even if they do not have a strong diagnosis of dry eye preoperatively. The best example is women who wish to have multifocal IOLs implanted. We know that they are going to get dry eye disease that will decrease their quality of vision and increase the time

for neuroadaptation to the multifocal IOLs, so we automatically place them on treatment.

Dr. Kim: So, in addition to topical corticosteroids, you are adding topical cyclosporine A?

Dr. White: Yes, all these patients receive steroids postoperatively. We have continued to use steroids, usually for 3 weeks postoperatively, along with a nonsteroidal anti-inflammatory medication. In patients who are having multifocal IOLs implanted, especially women, we place them on topical cyclosporine for a mandatory 6 months.

Dr. Starr: Are you using IPL and thermal pulsation?

Dr. McDonald: We have been using thermal pulsation for 2 years, with great success. I very much admire the work of Rolando Toyos, MD, who invented IPL. Clearly, it works. When choosing which thermal system to purchase, we went with thermal pulsation because there are more published data in the peer-reviewed literature documenting its safety and efficacy, and skin pigmentation isn't an issue. As you know, patients with darker complexions are suboptimal candidates for IPL, because of the risk of pigment alterations.

Dr. Kim: Yes, our practice is offering both thermal pulsation as well as IPL. In my practice, if I see a cataract patient with a turbid meibomian gland secretion and a soapy tear film, I offer the patient thermal pulsation to expedite the treatment, as I often find that these patients are noncompliant and forgetful with warm compresses and lid hygiene therapy. If I'm not able to express anything from their glands, I scrape their lid margin with a blunt instrument (Kimura spatula) to de-epithelialize their plugged glands to improve their response to thermal pulsation therapy. If they still do not respond, I refer them to my colleague who performs IPL.

Dr. Starr: What about warm compresses?

Dr. Kim: Although we know the benefit of providing warm compresses, lid massage, and lid hygiene, I feel that patients are simply noncompliant with this regimen alone and oftentimes get frustrated and run out of patience when it is offered as the only treatment. However, in conjunction with thermal pulsation and/or IPL, I think the patients get more motivated to comply with this regimen since they have invested in more interventional therapy to restore their ocular health. I guess an analogy may be how people may be more motivated to work out on a regular basis when they've invested in a gym membership and/or trainer as opposed to working out on their own.

ENCOURAGING PATIENT COMPLIANCE

Dr. White: It is incredible how many patients stop taking their medication if you have them come back on an annual basis. The notion of ongoing treatment for something is ephemeral and difficult to adhere to from a patient standpoint. Dry eye is a dramatic problem, so we aggressively monitor patients' adherence by mandating that they return every 6 months after they are stabilized.

Dr. Starr: I think that is a good strategy. Other things that encourage patient compliance are setting expectations and telling the patients, especially with cyclosporine A, that they should not expect a tremendous improvement or the reversing of their condition in 1 week or even 1 month. Usually, I tell them they will have a clinically relevant effect between 3 and 6 months. I say all of this at the beginning of the very first visit when I write the prescription for cyclosporine A. I tell patients to commit to me, look me in the eyes, and promise me that they are going to use it for at least 6 months, and if they do not feel like that is something they can do, then I am not going to write the prescription, because there is no point in starting it. I have never had a patient say no.

Dr. White: What do you think about using the MMP-9 test for monitoring the length of time that you have patients on the steroid? If they still have a positive test result at a certain point on cyclosporine and a topical steroid, I could envision encouraging them to stay on the topical steroid longer as you are waiting for the cyclosporine to kick in.

Dr. Kim: That is a great point.

Dr. Starr: There are a lot of interesting after-market studies to determine how long it takes for biomarkers to trend down, reverse, or even go from positive to negative. So, it is an exciting time to be treating dry eye disease. ■

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CME QUESTIONS

1. Which of the following would be described as point-of-service testing for ocular surface disease?
a. TearLab Osmolarity Test
b. AdenoPlus
c. InflammaDry
d. all of the above

2. Dry eye symptoms that could initiate a diagnostic workup include
a. fluctuating vision
b. foreign body sensation
c. tearing
d. all of the above

3. Dry eye syndrome
a. is rarely a factor in cataract surgery outcomes
b. may be found in as many as 80% of patients prior to cataract surgery
c. does not require treatment prior to cataract surgery
d. none of the above

4. Which of the following does NOT represent a newer diagnostic modality for dry eye disease?
a. lipid layer analysis
b. tear osmolarity testing
c. lissamine green staining
d. matrix metalloproteinase-9 (MMP-9) testing

5. Which of the following does NOT represent a newer marker for Sjögren syndrome?
a. salivary gland protein-1 (SP-1)
b. Sjögren syndrome antibody (SS-A)
c. carbonic anhydrase-6 (CA-6)
d. parotid secretory protein (P-SP)

6. Which of the following represent treatment options for patients with MGD:
a. increased omega-3 fatty acid oral intake
b. thermal pulsation therapy
c. intense pulse light therapy
d. all of the above

7. Which of the following are true about the Inflammadry test:
a. it is used for the diagnosis of dry eye
b. it measures inflammatory mediators (MMP-9) that are associated with inflammation and dry eye
c. the test takes less than 5 minutes to perform
d. the test is reimbursable in patients who have signs and/or symptoms of dry eyes
e. all of the above

8. Failure to diagnosis dry eye in patients scheduled for cataract surgery can lead to the following:
a. inaccurate keratometry readings, which can result in the incorrect IOL power being selected
b. patients may report fluctuations in vision postoperatively
c. increased risk of vitreous loss during surgery
4. pupillary Miosis during cataract surgery
5. answers a and b

9. The following are TRUE of tear osmolarity testing, EXCEPT
a. it diagnoses the presence of dry eye disease
b. it can provide information on the severity of dry eye disease
c. it can distinguish between aqueous deficiency and evaporative forms of dry eye disease
d. it is an easy test for technicians to learn

10. According to the results of the 2013 ASCRS Clinical Survey,[1] all of the following tests for dry eye disease are commonly used by the majority of respondents, EXCEPT:
a. corneal staining
b. lipid interferometry
c. Schirmer test
d. tear breakup time

Did the program meet the following educational objectives?	Agree	Neutral	Disagree
Diagnose acute dry eye conditions and chronic ocular surface disease	_____	_____	_____
Identify patient groups at risk for ocular surface disease in the practice	_____	_____	_____
Recognize the chronic nature and inflammatory pro-cesses in ocular surface disease	_____	_____	_____
Understand new ocular surface disease diagnostic technologies	_____	_____	_____
Differentiate palliative versus therapeutic treatment of ocular surface disease	_____	_____	_____
Discuss the impact of ocular surface disease on surgical outcomes	_____	_____	_____

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