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Developing the latest point of care ocular surface testing protocol: Making advanced decisions from advanced diagnostics

CME questions (Circle the correct answer)

1. **According to Dr. Holland, about how many Americans have dry eye disease?**
 - a. 5 million
 - b. 25 million
 - c. 55 million
 - d. 200 million

2. **Meibomian gland dysfunction (MGD) with evaporative dry eye is the most common cause of dry eye.**
 - a. True
 - b. False

3. **About how long will it take the MMP-9 test to give a positive or negative test result?**
 - a. 10 seconds
 - b. 10 minutes
 - c. 1 hour
 - d. 1 week

4. **Which of the following is an advantage of advanced point of care diagnostics over traditional diagnostic testing?**
 - a. High specificity
 - b. High objectivity
 - c. Reimbursement options
 - d. All of the above

5. **What can tear film osmolarity tell about dry eye?**
 - a. It can confirm diagnosis and severity of the dry eye disease.
 - b. It can tell what type of dry eye disease a patient has.
 - c. It can analyze the lipid layer of the tear film.
 - d. It can test for biomarkers.

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Developing the latest point of care ocular surface testing protocol: Making advanced decisions from advanced diagnostics



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Ocular surface diagnostics: Then and now

by Eric D. Donnenfeld, MD

In ophthalmology, we are beginning to understand the importance of and adopt point-of-care testing. Decision-making in every other specialty is predicated on objective testing. When we have the opportunity to present information that changes the way ophthalmologists practice, I think it's an eye-opening event. Point of service testing is a dynamic way to improve patient care.

The 2013 ASCRS Clinical Survey results provided feedback on dry eye and tear film diagnostics. Responses indicated that in cataract surgery cases, 21% of patients present with at least level 2 ocular surface disease, meaning that they need more than artificial tears. For laser vision correction, this number is about 24%. We need to be treating our pre-surgical patients more aggressively to improve outcomes.

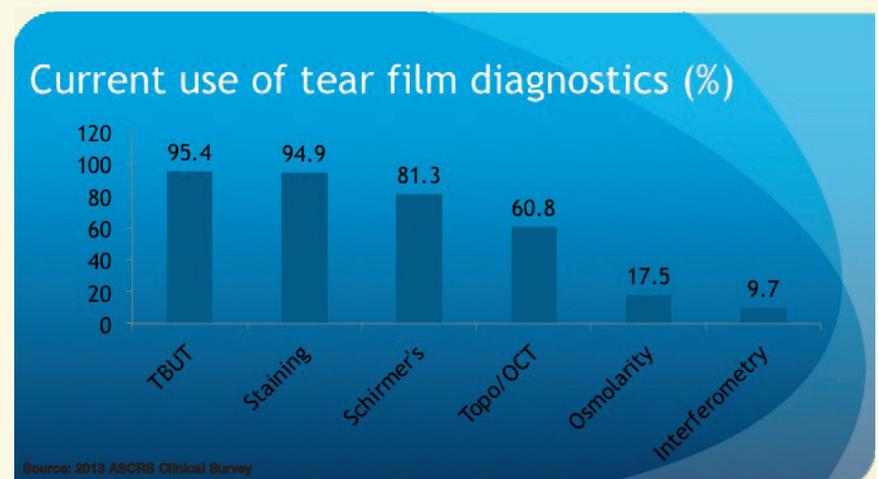
Dry eye is the single most common reason that patients come into our office. It's estimated that 50% of the patients that come into our office have some form of dry eye disease, so this makes it the most important diagnosis we make. Managing dry eye is a stepwise progressive process, and there are a lot of interesting therapies. Even better, there are many new therapies that are being developed.

Of those responding to the survey, 82% agreed or strongly agreed that dry eye patients take more time to manage in their practices. We're going to show you how to reduce the time, give your patients great care, and make them happier. Eighty-six percent agreed or strongly agreed that mild to moderate dry eye significantly affects postoperative satisfaction in cataract and refractive patients. By improving the ocular surface, we become better surgeons.

The progression of ocular surface diagnostics has changed little over time until recently. The Schirmer's test was invented in 1904. This progressed to options

like tear breakup time (TBUT) and supravital staining, which are more than 50 years old. Current options for the tear film have changed dramatically over the last several years and have expanded to include topography/OCT, osmolarity, MMP-9 and lactoferrin levels and interferometry. We need to be more cost effective in our practices and see patients more efficiently. I think that these new point of service diagnostic tests will be helpful.

Dr. Donnenfeld is clinical professor of ophthalmology at New York University. He can be contacted at ericdonnenfeld@gmail.com.



There are a number of diagnostic tests currently available to evaluate the tear film.

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Educational Objectives

Ophthalmologists who participate in this course will:

- Describe the levels of patients presenting with symptomatic and asymptomatic ocular surface disease before refractive and cataract surgery, and discuss the impact of this on visual quality and patient satisfaction outcomes;

- Review the steps involved in new ocular surface protocols that incorporate advanced tear film testing into the point of care, including alterations to patient flow and impact on quality of care, patient satisfaction and chair time; and
- Identify the new ocular surface diagnostic data that is being used to implement modern ocular surface disease treatment decisions.

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The impact of ocular surface disease on refractive cataract surgery

by Edward J. Holland, MD

mixed pattern with evaporative and aqueous tear deficiency. Of the patients with a classified dry eye disease subtype, 86% demonstrated signs of MGD. This is the leading cause of dry eye throughout the world, and can be influenced by age, hormonal disturbance, and topical medication. Additionally, insufficient lipids in MGD can create hyperosmolarity and tear film instability and can lead to evaporative dry eye and ocular surface inflammation.

About 40% of MGD patients come into the office complaining of classic dry eye symptoms. Note that 16% of patients with MGD come in as surgical patients, and it's important to diagnose these patients and treat them.

There are an estimated 55 million Americans with dry eye disease and an estimated 39 million with undiagnosed dry eye. This number is going up every year because of the aging population.

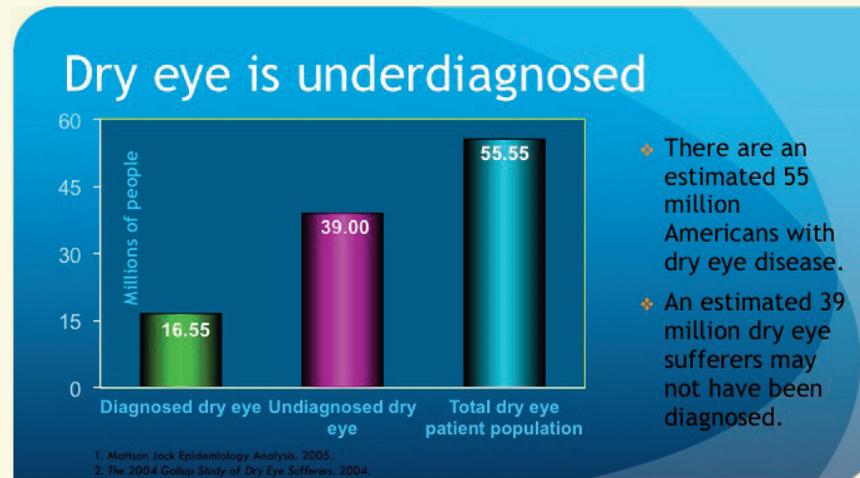
There have been a number of advancements in cataract and refractive surgery, but these can be neutralized by dry eye disease and poor ocular surface quality. The tear film is the first refractive interface, and the anterior surface of the precorneal tear film has the greatest optical power of any ocular surface.

Dry eye disease can have an impact on refractive cataract outcomes

Edward J. Holland, MD, has received a retainer, ad hoc fees, or other consulting income from: Abbott Medical Optics, Alcon Laboratories Inc., Bausch & Lomb, SARCode BioScience, Senju Pharmaceuticals, TearScience, and WaveTec Vision Systems. He is a member of the speakers bureau of Abbott, Alcon, and Bausch & Lomb. Dr. Holland has received research funding from Alcon and WaveTec.

The understanding of dry eye disease has evolved with time, but it is still underdiagnosed. Studies on prevalence of dry eye indicate that it could range anywhere from 7% to 48%, which also depends on how dry eye and ocular surface disease are defined. We do know that dry eye is increasing with age, and as patients live longer, we're going to have more patients with dry eye to treat.

A decade ago, clinicians considered the majority of dry eye to be aqueous tear deficiency, but the most common cause of dry eye is meibomian gland dysfunction (MGD) with evaporative dry eye. The second most common is the



A large number of Americans suffer from dry eye.

because it can affect the accuracy of measurements used for determining candidacy and for IOL selection and power. Potential consequences of its effects include excluding a patient from consideration for a multifocal IOL due to irregular astigmatism, selecting the wrong monofocal IOL, selecting the wrong IOL power, planning for toric IOLs or LRIs when not needed, positioning a toric IOL on the wrong axis, and performing unnecessary lens exchanges or enhancements.

Dry eye is very common in both the refractive and cataract patient population and has a significant impact on a patient's vision, comfort, and quality of life. It can have significant impact on surgical outcomes,

and it is important for ophthalmologists to diagnose and properly treat.

I believe we need to do a better job of screening and diagnosing. Advanced tear film diagnostics can assist the cataract surgeon by aiding in quicker and more accurate diagnosis of dry eye for improved accuracy in IOL power calculation and surgical planning, as well as maximizing postoperative acuity and satisfaction. As we move to this aging population, we're going to be overwhelmed with patients. I think we need to be more efficient in evaluating and treating dry eye.

Dr. Holland is professor of clinical ophthalmology at the University of Cincinnati. He can be contacted at eholland@holprovision.com.



Using diagnostics to drive treatment of dry

by Terry Kim, MD

A lot of diagnostic modalities enable you to evaluate dry eye disease on a more specific level. Some of the advanced diagnostic modalities include tear composition analysis, serum biomarker testing, tear film structure and other image analysis.

Tests include osmolarity, the MMP-9 inflammatory marker, serum testing for biomarkers of Sjogren's syndrome, and lipid layer analysis.

Tear film osmolarity has been embraced by a number of advocates with its potential for in-office tear analysis. A CLIA waiver is needed,

but it is a small, portable, and user-friendly device that is easily placed in the examination lane or testing suite. The device takes a very small sample of tear (i.e., 50 nL) from the lateral tear meniscus without the need for any topical anesthetic. After 10 seconds, the device produces an osmolarity number for each eye that confirms the diagnosis and severity of dry eye disease. While it does not specify the type of dry eye disease (i.e., aqueous-deficient, evaporative, combination), it can be helpful in gauging patient response to dry eye treatment.

The MMP-9 inflammatory marker is another in-office tear analysis, which tests for the presence of the matrix metalloproteinase MMP-9 by giving a positive or negative test result in 10 minutes. This test indicates whether there is an inflammatory component to the dry eye disease and hence can guide which patients should be treated with anti-inflammatory therapies.

Serum testing for biomarkers of Sjogren's syndrome can be helpful for these types of patients as well. Standard biomarkers have a specificity of 40% to 60% and are not detected in early stages of the disease.

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How to implement point of care diagnostics for dry eye into a practice

by Elizabeth Yeu, MD

Elizabeth Yeu, MD, has received a retainer, ad hoc fees, or other consulting income from: Allergan, Bausch & Lomb, and TearLab Corporation.

Refractive cataract surgeons can't afford to ignore ocular surface disease, and it doesn't need to be that hard to deal with.

First, ask patients about their problems. Testing only when patients complain of dryness is absolutely insufficient because between 40% and 60% of people with objective evidence of dry eye are asymptomatic. Cataract surgery patients often complain of fluctuating vision rather than dryness or foreign body sensation.

Traditional diagnostic testing has low objectivity, low specificity, and no reimbursement, with more time required per patient to do these tests. Meanwhile, with advanced point of care diagnostics, the time required to perform the tests is low, the specificity and objectivity are

	Traditional diagnostics	Advanced point of care diagnostics
Time required	High (5-7 minutes)	Low (10-20 seconds)
Specificity	Low ~ 30%	High ~ 90%
Objectivity	Low	High
Reimbursement	None	Yes

Advanced point of care diagnostics may improve objectivity and specificity while reducing the time required to perform the tests.

high, and often there is reimbursement.

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

Tear analysis should be done before exposing the eye to any positive stimuli, dyes, dilation, direct contact, or bright lights. We need to empower staff to perform testing based on physician ordered indications so the physician can diagnose quickly and begin ocular surface disease management right away.

I use osmolarity in my practice for every patient with a dry eye complaint or a history of dry eye,

foreign body sensation, burning, redness, epiphora, preoperative cataract or LASIK, and patients post infection.

The examination is key. The lid exam is now the longest part of my slit lamp examination. Exam features include an examination of lids and diagnostic expression of meibomian glands to determine quality of secretions, meibomian gland health, tear film height and quality, and a choice of in-office tests based on history and findings.

Based on results from the exam, the next step is to refine the treatment plan and provide an aggressive treatment to improve the ocular surface prior to a preoperative exam.

This includes customized treatment that takes into account long-term needs of the patient.

The ASCRS Cornea Clinical Committee is developing a more detailed point of care testing protocol with goals of improving the ability to identify the type and extent of the disease, making a more informed and evidence-supported diagnosis, focusing doctors' time with patients on management strategies, and better communicating with patients regarding dry eye disease.

Clinicians should increase suspicion of dry eye and MGD in the cataract population and lower the threshold for treating prior to surgery. Advanced point of care diagnostics provide quick, objective and highly specific results that are easy to use and to explain to patients. Protocols are evolving; however, clinicians don't have to wait for the perfect protocol to begin implementing advanced diagnostics. New tests are commercially available and can be integrated into your practice now.

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eye disease

However, some new biomarkers (i.e., salivary protein-1, carbonic anhydrase, and parotid secretory protein) have been identified and are expressed earlier in the disease with higher specificity and sensitivity. A new in-office blood testing kit can measure these traditional and new biomarkers. The serum specimens can then be sent to a lab to get results in a week to confirm or rule out the diagnosis of Sjogren's syndrome.

Finally, lipid layer analysis provides both a quantitative and qualitative analysis of the lipid layer of the tear film. The diagnostic device measures the thickness of the lipid layer of the tear film (ICU

in nanometers) with interferometry and provides real-time video of the tear film along with blink analysis in about 20 seconds per eye. The clinician should combine this with meibomian gland expression at the slit lamp to observe the ease of gland expression and quality of secretion. The results can help confirm the diagnosis of meibomian gland dysfunction and guide therapy with thermal pulsation devices.

Some tests that are already being used in the office can help with dry eye diagnosis, including corneal topography, wavefront aberrometry, and OCT. Corneal topography maps and their accompanying

Placido disc images can provide a noninvasive and objective measure of the ocular surface and TBUT. Wavefront aberrometry provides another approach to look at the tear film surface and TBUT as well as its impact on higher order aberrations and quality of vision. Although OCT is available in most offices, its ability to measure tear meniscus height has not yet been widely utilized in dry eye disease diagnosis.

With the availability and clinical utility of these new diagnostics for dry eye disease, I think our paradigm is moving away from using some of the more traditional (and outdated) tests, including

Schirmer's testing and fluorescein staining. These new advanced devices increase the specificity and positive predictive value (PPV) of the diagnostic assessments for dry eye and demonstrate how point of care testing can allow the clinician to make appropriate treatment decisions regarding dry eye therapy more easily, quickly, and reliably.

Dr. Kim is professor of ophthalmology at Duke University School of Medicine, and director of fellowship programs, cornea and refractive surgery services at Duke University Eye Center, Durham, N.C. He can be contacted at terry.kim@duke.edu.