Breakthrough in Diagnosing Dry Eye and Staging Disease Severity

A lot depends on treating patients with dry eye disease.

BY JAY S. PEPOSE, MD, PHD

Nearly one in five individuals in North America has dry eye disease (DED); it may be one of the most common yet frequently undiagnosed and untreated problems seen every day by ophthalmologists.[1] Less appreciated, perhaps, are the profound visual impact of DED and the progressive nature of the disease if left undiagnosed and untreated.

A hallmark of DED is the eye's decreased ability to regulate tear osmolarity in response to adverse environmental challenges. As a result, the patient becomes susceptible to having a new, more hyperosmolar set point, further variation in tear osmolarity, and greater tear film instability. An increase in both the temporal and interocular variation and the absolute value of tear osmolarity is not only a component of all forms of DED, it is central to its pathogenesis[2,3] (Figure 1).

DED has a profound impact on both high- and low-contrast visual acuity and contrast sensitivity,[4-7] because tears represent the most anterior refractive surface of the eye. It is essential to assess the osmolarity of tears in patients undergoing cataract and refractive surgery. The surgical trauma of these procedures along with the severing of nerves and associated inflammation presents a challenge to the ocular surface. Patients with DED lose the ability to respond to these challenges. Surgeons therefore must identify ahead of time patients who require treatment to optimize the tear film and ocular surface.

Whether a patient is considering cataract surgery with a conventional or premium IOL or LASIK, preexisting DED is a risk factor for a suboptimal visual outcome, fluctuating vision, and reduced contrast sensitivity. To avoid a poor result, accurate diagnosis, distinct staging of disease severity, and appropriate preemptive treatment are required. New technology can help.

WHY NOT RELY ON PATIENTS' SYMPTOMS?

Recent studies suggest that 30% of patients with DED are asymptomatic, particularly during early stages of the disease. Relying only on symptoms would thus leave many patients undiagnosed. Common complaints such as burning, itchy, gritty, irritated eyes, along with other vague symptoms, occur in patients with myriad other conditions. Some patients may be completely asymptomatic except in certain situations such as flying in an airplane, wearing contact lenses all day, or staring at a computer. Moreover, they may not spontaneously voice any complaints without having their ocular history solicited. Others may not complain because of an ocular surface that is desensitized and hypesthetic.

A DIAGNOSTIC DILEMMA DESPITE AVAILABLE TESTS

Until recently, a major problem in the diagnosis of DED was that ophthalmologists often have too many tests that provide conflicting results. For example, it is not uncommon to have patients with a rapid tear breakup time, no lissamine green staining, and a low Schirmer test value. The ophthalmologist then

Figure 1. TearLab's Osmolarity System is small and compact for easy use in the office. The system consists of a reader and two pens.

attempts to differentially weight discordant signs with vague, nonspecific symptoms that often poorly correlate. With TearLab Corporation's Osmolarity System, clinicians now have a unique marker that is much more central to the true underlying disease pathogenesis and that correlates much more closely to the overall disease severity.

RAPID, ACCURATE, IN-OFFICE DIAGNOSTIC

Compact and designed for use in the office, the TearLab Osmolarity instrument (Figure 2) consists of a reader and two pens. Without any drops or topical anesthetic that could dilute or destabilize the tear film, the "lab-on-a-chip" design inside each disposable test card quickly and atraumatically collects 50 nL of fluid from the anterior marginal tear meniscus near the lateral canthus (Figure 3). This method of tear collection minimizes both evaporation and reflex tearing, and the system analyzes the result in 3 seconds. With minimal training, technicians can easily perform the test.

Just as IOP fluctuates throughout the day in glaucoma patients, tear osmolarity may also cycle. As shown in Figure 1, the higher range of normal tear osmolarity is 308 mOsm/L. Patients with this osmolarity or higher in either eye should be considered to have DED because of the variations in the osmolarity cycle.

Both the absolute value of tear osmolarity and its interocular and temporal variation increase with more

Figure 2. Tears are collected from the inferior tear lake near the lateral canthus. Collection takes a fraction of a second.

severe disease. Tear osmolarity testing is an adjunct to aid in the diagnosis and management of a chronic disease. The ophthalmologist should also perform other dry eye tests, take a thorough history, and examine and express the meibomian glands. A patient's tear osmolarity provides an objective way of monitoring his or her response to treatment.

EASY TO IMPLEMENT

The tear osmolarity test is easy to implement in the office. Technicians should be reminded to perform the test before instilling drops and to instruct the patient

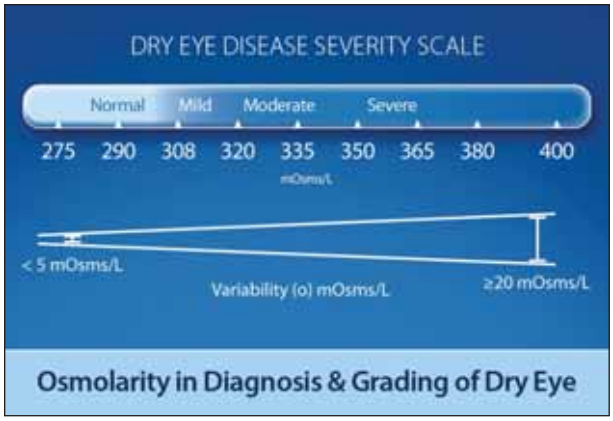

Figure 3. A dry eye osmolarity severity scale allows the clinician to plot severity and monitor therapeutic progress. To account for overlapping information in a variety of dry eye metrics, independent component analysis was used to derive an overall dry eye composite index that could be compared to tear osmolarity. Of interest, intereye variability in osmolarity increased with more severity.

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not to use artificial tears or other drops within 2 hours of testing. Patients adapt to TearLab testing because they are eager to have an objective readout of osmolarity that closely correlates with their disease severity and allows the clinician to assess the efficacy of treatment. The test has a Current Procedural Terminology (CPT) code from the Centers for Medicare & Medicaid Services (83861 "Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity") and is reimbursed by Medicare and insurance carriers. The TearLab Osmolarity System is regulated as a waived device under the Clinical Laboratory Improvement Act.

CONCLUSION

The addition of tear osmolarity testing to an ophthalmic practice facilitates ophthalmologists' diagnosis of DED and determination of disease severity. The test assists the clinician with treatment and monitoring. Furthermore, the examination is an important part of the preoperative assessment of cataract and refractive surgery patients, who expect crisp, stable, uncorrected, high- and low-contrast vision. Use of the system can also boost the referral of patients with DED to the practice. ■

Jay S. Pepose, MD, PhD, is the director of the Pepose Vision Institute and a professor of clinical ophthalmology and visual sciences at the Washington University School of Medicine in St. Louis. He is a consultant to TearLab Corporation. Dr. Pepose may be reached at (636) 728-0111; jpepose@peposevision.com.

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