New era in dry eye management

By Jerry Nolfi, OD, MBA

How many times have you heard complaints from your patients about burning, stinging, or itchy eyes? Or complaints about eyes that are red and feel like there is something in them?

Before you as the clinician get the chance to seat such a patient behind a slit lamp or thrill him or her with Schirmer strips, chances are you are already thinking about a diagnosis of dry eye. To support this prediagnosis, all you need is objective clinical evidence.

Yet, herein is where the problem lies. Mildly symptomatic dry eye patients are common in all practices. But, objective clinical evidence is harder to find. Often, patients (and clinicians) suffer through Schirmer testing only to learn that the results are within normal limits. Or, clinicians insert fluorescein drops only to discover limited corneal staining. How many times have you heard complaints from your patients about burning, stinging, or itchy eyes? Or complaints about eyes that are red and feel like there is something in them?

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Dry eye often can be a chronic condition, and finding the right maintenance therapy for the long term is paramount, he said. Therefore, follow-up visits are important where the physician can alter the medications and the doses and choose therapy according to symptoms and the current level of severity of dry eye.

Certainly, there are those patients who feel comfortable when their medicine is tapered or changed...to maximize therapeutic outcomes,” Dr. Rao said. “Others are fine with a steady regimen and are satisfied with maintenance therapy. And as long as they can avoid having to use extra medications or extra artificial tears and remain symptom-free, a lot of these patients will opt to use cyclosporine as their maintenance therapy.”

The importance of tear osmolarity

From their work on the tear film, Tomlinson, et al. concluded:

The measurement of tear osmolarity arguably offers the best means of capturing, in a single parameter, the balance of input and output of the lacrimal system. It is clear from the comparison of the diagnostic efficiency was compelling that tear osmolarity as a marker for dry eye disease was likely the universal component and a key diagnostic biomarker for DED.

Therapeutics & Co-Management

Take-Home Message

Using the latest technology, in the form of the TearLab Osmolarity System, will help clinicians focus on the oft-presenting dry eye patient and the importance of tear osmolarity as a marker for dry eye disease.

Quest for a better way

In many patients, dry eye is the diagnosis of choice, but the limited and objective clinical evidence remains inconclusive.

The TearLab Osmolarity System (TearLab Corp.), which measures tear osmolarity to diagnose dry eye disease (DED), received significant attention after the 2007 Dry Eye Workshop (DEWS) report, when tear osmolarity was added to the definition of dry eye.2,3

The literature indicated that tear hyperosmolarity was the main source of ocular surface inflammation, damage, and symptoms, which initiated tear compensatory mechanisms.4 The evidence was compelling that tear osmolarity was the main source of ocular surface inflammation, damage, and symptoms, which initiated tear compensatory mechanisms. The evidence was compelling that tear osmolarity was the main source of ocular surface inflammation, damage, and symptoms, which initiated tear compensatory mechanisms. The evidence was compelling that tear osmolarity was likely the universal component and a key diagnostic biomarker for DED.

Ophthalmologists often need to monitor their patients with dry eye closely to keep them free of symptoms. Cyclosporine appears to be a good maintenance therapy for dry eye in terms of both efficacy and tolerability in the long term, thereby increasing the patients’ quality of life, Dr. Rao concluded.

FYI

Sanjay N. Rao, MD
Phone: 312/553-1818; 866/922-8825
E-mail: sanjayrao@pol.net
Dr. Rao is a speaker for and receives research support from Allergan. He also is a speaker for Bausch + Lomb and is on the scientific advisory board for EyeGate Pharmaceuticals.
Diagnostics
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The use of diagnostic tools to assess keratoconjunctivitis sicca (KCS), used singly or in combination, that osmolarity provides a powerful tool in the diagnosis of KCS and has the potential for being accepted as the gold standard for the disease.

Abnormal tear osmolarity is a failure of homeostatic osmolarity regulation. The higher the osmolarity, the more severe the dry eye. Historically, literature suggested a 316 mOsms/L cutoff for more moderate-to-severe disease.

Figure 3. A clinical integration plan was developed for TearLab.
(Chart provided by Jerry Nolfi, OD, MBA)

<table>
<thead>
<tr>
<th>Target Patient Population</th>
<th>Clinical Purpose</th>
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<tbody>
<tr>
<td>1. Symptomatic Patients</td>
<td>• Dry Eye disease (DED) – burning, stinging, itching, etc. • Differential diagnosis</td>
</tr>
<tr>
<td>2. Asymptomatic Patients</td>
<td>• Family history • Certain medications • Pregnant women • Identify mild DED</td>
</tr>
<tr>
<td>3. New Patients &gt; 50 years old</td>
<td>• Baseline value</td>
</tr>
<tr>
<td>4. Contact Lens (CL) Patients</td>
<td>• Baseline value • Determine CL effect on tear osmolarity</td>
</tr>
<tr>
<td>5. CL New Wearers Program</td>
<td>• Customized contact lens fitting • Determine patients at risk for DED • Determine CL effect on tear osmolarity</td>
</tr>
<tr>
<td>6. Refractive Surgery Work-up</td>
<td>• Determine patients at risk for DED</td>
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Therefore, osmolarity values above 308 mOsms/L are generally indicative of dry-eye disease. Clinicians should examine all points of subjective and objective data and not rely only on cut-off values because they are only guidelines.

It is important to note that this study demonstrated that TearLab outperformed both Schirmer’s testing and corneal staining with respect to the sensitivity and specificity in patients with the mild-to-moderate DED.

Understanding and interpreting osmolarity results in the clinical setting was critical to proper diagnosis of our patients. It is well understood that DED is usually of gradual onset and progression, especially in the early stages when full expression of markers may be intermittent or missing.

Below are some key observations for mildly symptomatic patients with tear osmolarity in the 308 to 316 mOsms/L range:
• Variability of osmolarity values between eyes is a hallmark indicator of early DED. In early disease, compensatory mechanisms—such as frequent blinking and increased secretion of aqueous—are intermittent and more frequent in one eye, thereby reducing osmolarity asymmetrically. Intercellular variability is a hallmark sign of early disease. The eye with the higher osmolarity result of the two is the key diagnostic indicator for DED.
• Large increases in tear osmolarity in patients in normal baseline can still produce symptoms. Patients with early disease may be identified by spikes at subsequent visits.
• Utilize other subjective and objective data to classify patients properly. Good clinicians always look at all the data before they make a diagnosis.
• I frequently utilize the Dry Eye Disease Severity Scale (see Figure 1) when counseling patients.

Combining the qualitative osmolarity scale (275 to 400 mOsms/L) with a quantitative range of severity makes it easier to visualize and communicate to patients. The diagram was placed in each exam room.

Reaping the benefits
New diagnostic technologies in the office produce moments of anxiety, excitement, and often frustration when things don’t go as planned. The TearLab unit amazed my technicians and increased their confidence with patient testing.

The TearLab system was designed as an efficient, technician-administered test. From sample taking to getting an answer literally takes seconds. The benefits are many, and include a quick learning curve (it took less than 2 hours to set up the unit and train the technicians). The unit also fits easily on an exam room or pre-test area counter.

Initially, I narrowed our patient criteria to middle-aged healthy adults in order to eliminate potentially difficult subjects while my technicians gained experience and confidence with patient testing. Initially, they were hesitant to place the pen tip into the lower tear meniscus of the temporal part of the eye for tear collection (see Figure 2).

However, those technicians with contact lens experience were more at ease with performing the test. By the tenth patient, all my technicians were obtaining consistent and repeatable results.

The compelling clinical feature of TearLab is data it generates. These data make differential diagnosis and patient counseling effective and efficient. This objective evidence results in a more complete patient assessment.

Health Canada approval in 2009 accelerated broad clinical acceptance of TearLab in our practice. A clinical integration plan was developed for TearLab (see Figure 3).

The plan identified patients in which performing a tear osmolarity assessment was clinically justifiable. The primary use of the technology was for DED diagnosis. Did it make sense to extend TearLab into contact lens fitting and pre-op surgery workups?

Our contact lens fitting process usually evaluates different contact lenses to determine superior performance. Using TearLab along with other factors, I selected the best lens for patients based on the least impact on osmolarity. Integrating TearLab into the contact lens fitting process made clinical sense.

Many refractive surgery patients experience extended periods of dry eye postoperatively, though they had no prior history of dry eye. Although DED usually dissipates between months 3 and 6 postoperatively, there are patients who develop chronic dry eye after refractive surgery and don’t seem to have improvement.

Although there are many possible causative factors for this result, integrating a tear osmolarity assessment into refractive surgery work-ups to identify asymptomatic, hyperosmolar tear patients proactively made clinical sense.
A 50-year-old patient may require greater in-depth medical testing than a 25-year-old patient. Recommending TearLab as part of comprehensive baseline testing for this demographic makes sense. Baseline osmolarity testing helps to identify patients with early DED so treatment can be initiated, reducing the risk for ocular surface inflammation.

Both eyes must be tested to obtain an accurate diagnosis because DED is bilateral, but typically asymmetrical. I decided to implement a simple, inexpensive introductory level fee for testing both eyes. By doing so, patient objections are limited due to cost, and acceptance rates are over 90% in the first 5 months of 2010.

The osmolarity data allow patients to understand their level of the disease and to gauge treatment effectiveness at follow-up visits. Patient compliance with treatment protocols has increased by making patients aware of a quantitative benchmark.

TearLab represents an opportunity to develop a dry eye specialty within an existing practice. Consider the number of patients who complain about dry eye symptoms on a daily basis. According to the DEWS report, the prevalence of dry eye is 5% to 30% among patients aged 50 years and older. How many patients does that represent in your practice?

Creating a disease-specific specialty in your practice is a strategic asset and an excellent practice builder and referral generator. Building a DED specialty including the latest technology involves some simple planning and execution, but can significantly increase patient satisfaction and add real returns to your bottom line.OP

References
1. FDA 510(k) clearance allows TearLab to market in the U.S. to clinical facilities categorized as high or moderate complex under the Clinical Laboratory Improvement Act of 1988 (CLIA ‘88). The company is now seeking a CLIA waiver.