in our corneal and external disease practice, my colleagues and I see many patients with dry eye disease. Although a patient’s signs and symptoms often make the diagnosis straightforward, in many cases, we rely on a series of tests. Most ophthalmologists are familiar with analyses upon which we have relied for many years, such as tear film breakup time, Schirmer testing, and conjunctival and corneal staining. The downside of these tests is that their results are mainly subjective and not easily quantifiable. In addition, they are not particularly effective at monitoring the efficacy of therapeutic treatments.

Corneal disease experts have known for many years that testing tear osmolarity—the measurement of the salinity level in tears—is an effective and objective assessment for dry eye disease.1 Previously, this testing was only available in large reference laboratories and required a fairly large volume of tears. A new tear osmolarity testing system, called the TearLab Osmolarity System (TearLab Corp., San Diego, CA), is eliminating these challenges. The TearLab Osmolarity System uses a minute volume of tears (50 nL) to measure the salinity level and provides the ophthalmologist with a quantifiable, real number that indicates the presence and/or absence and severity of the dry eye.

**HOW IT WORKS**

The TearLab’s technology uses a novel approach that concentrates laboratory functions on a single chip that requires less than 50 nL of tear fluid in order to measure tear osmolarity. The system uses a handheld pen on which the ophthalmologist or technician places the noninvasive laboratory chip test card. After he collects the tear sample (usually in less than 30 seconds), the device produces the measurement of osmolarity in less than 1 minute.

Studies have shown that, not only is osmolarity testing objective and quantitative, it is a highly specific biomarker. In dry eye disease, the accuracy of tear film osmolarity is considered superior to any other single measurement for dry eye analysis, including Schirmer testing and corneal staining.1,2

**CLINICAL EXPERIENCE**

My colleagues and I recently started a multicenter clinical study that will compare the results we obtain with TearLab to those we have received with the traditional means of dry eye diagnosis. Our initial impression is that the TearLab system works very well in patients with dry eye. All tested subjects show an increase in osmolarity, and these findings have correlated with those from traditional testing methods.

<table>
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<tr>
<th>Normal</th>
<th>Marginal</th>
<th>1</th>
<th>2</th>
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</thead>
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<tr>
<td>Osmolarity reading (msOm)</td>
<td>275 to 301</td>
<td>302 to 312</td>
<td>313 to 323</td>
<td>324 to 332</td>
<td>333 to 345</td>
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Note: measurements of osmolarity are based on the classification system established in the Dry Eye Workshop Report.2

“Testing tear osmolarity is an effective and objective assessment for dry eye disease.”
Anticipating the FDA’s Approval of TearLab

BY CHRISTOPHER STARR, MD

Later this year, my colleagues and I hope to incorporate a new test into our assessment of dry eye—the TearLab Osmolarity System (TearLab Corp., San Diego, CA). This system uses nanofluidics to take a tiny sample of tears and measure the osmolarity, or salinity level. Where will Tearlab fit in? Will some of the current assessment tools that we use are invasive and time consuming. The popular Schirmer test with anesthesia requires a strip of paper to be placed in the lower fornix for 5 to 10 minutes, and, when improperly performed, can cause discomfort, irritation, superficial punctate keratitis, and reflex tearing. More importantly, all of the in-office tests routinely used today have a high level of subjectivity to them. Five different ophthalmologists can assess the tear film and the ocular surface of the same patient, and each of them will likely have a different conclusion. The TearLab system will be the first in-office test for dry eye diagnosis that is quantifiable, objective, and reproducible.

We know from studies that osmolarity is a good indicator of the health and quality of tears and that hyperosmolarity (> 318 mOsm) has a high degree of sensitivity and specificity for dry eye disease. Will it correlate specifically to symptoms every single time? Probably not. The Delphi panel demonstrated that there can be a great deal of variability between a patient’s signs and symptoms and the results of our various tests. Therefore, the panel’s treatment algorithm for dysfunctional tear syndrome is based primarily on the severity of a patient’s signs and symptoms and not test results. TearLab provides ophthalmologists with an easy-to-use, minimally invasive in-office test that quickly produces results so that we may objectively quantify tear osmolarity. This will not only provide us with a simple and accurate diagnostic tool but will allow us to monitor the effectiveness of our treatments over time. I believe that the system could replace some of the other subjective tests that we routinely use.

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