

# Testing Tear Osmolarity

Simplify the diagnosis and management of dry eye.

BY JOSE M. BENITEZ-DEL-CASTILLO, MD, PhD

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 test 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.<sup>1</sup> Previously, this testing was only available in large reference laboratories and required a fairly large volume of tears. A new tear osmolarity testing system, 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 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 osmo-

“Testing tear osmolarity is an effective and objective assessment for dry eye disease.”

larity. 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.<sup>1,2</sup>

## 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 gotten 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 1. SCALE OF DRY EYE DISEASE CLASSIFICATIONS WITH CORRESPONDING OSMOLARITY MEASUREMENTS**

	Normal	Marginal	1	2	3	4
Osmolarity reading (msOm)	275 to 301	302 to 312	313 to 323	324 to 332	333 to 345	346+

*Note: Measurements of osmolarity are based on the classification system established in the Dry Eye Workshop Report.<sup>2</sup>*

## Anticipating the FDA 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? Well, some of the current assessment tools that we use are invasive and time consuming in the sense that a strip is placed inside the eye's lower fornix for 5 to 10 minutes. Then there is the Schirmer test with anesthesia, which can cause discomfort, irritation, superficial punctate keratitis, and reflex tearing if improperly administered. 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 one 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.<sup>1</sup>

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.<sup>2,3</sup> 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. ■

*Christopher E. Starr, MD, is an assistant professor of Ophthalmology, the director of the residency program, and co-director of the Cornea, Cataract & Refractive Surgery service and fellowship at Weill Cornell Medical College, New York-Presbyterian Hospital, New York City. He acknowledges no financial interest in the product or company mentioned herein. Dr. Starr may be reached at (646) 962-3370; cestarr@med.cornell.edu.*



1. The epidemiology of dry eye disease: report of the Epidemiology Subcommittee of the International Dry Eye WorkShop (2007). *Ocul Surf.* 2007;5(2):93-107.
2. Tomlinson A, Khanal S, Ramaesh K, et al. Tear film osmolarity: determination of a referent value for dry eye diagnosis. *Invest Ophthalmol Vis Sci.* 2006;47:4309-4315.
3. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop (2007). *Ocul Surf.* 2007;5(2):75-92.

We have found the TearLab to be quite user friendly; it does not require an ophthalmologist to apply it. Our patients have also found the test to be comfortable and have indicated their preference for it over the Schirmer test.

### IMPACT ON DIAGNOSIS AND MANAGEMENT

For diagnosis, the initial unpublished data from our multicenter study show that the TearLab system works and that there is a correlation between dry eye and the osmolarity value (Table 1). This should also mean that the system can differentiate between healthy corneas and dry eyes.

Managing dry eye is as equally important as diagnosing it and can also benefit from an objective test. Just as we should be able to see a corresponding decrease in osmolarity levels when we administer artificial tears that have properties of hyposmolarity, we intend to study

such cause and effect with the TearLab system. We expect the objective TearLab Osmolarity System to give us a better mechanism for tailoring treatments to the individual patient based on his osmolarity measurements—providing us with a much more effective way to manage dry eye. ■

*Jose M. Benitez-del-Castillo MD, PhD, is a professor of ophthalmology at the University Complutense, and director of the Ocular Surface Unit at Clinica Ruber, Madrid, Spain. He has received research funding from TearLab Corp. Dr. Benitez-del-Castillo may be reached at +34902875204; benitezcastillo@terra.es.*



1. Tomlinson A, Khanal S, Ramaesh K, et al. Tear film osmolarity: determination of a referent for dry eye diagnosis. *Invest Ophthalmol Vis Sci.* 2006;47:4309-4315.
2. Dry Eye Workshop (DEWS) Committee. 2007 Report of the Dry Eye Workshop (DEWS). *Ocul Surf.* 2007;5(2):65-204.