

How to Incorporate Tear Osmolarity Testing Into Practice

Taking the guesswork out of diagnosing dry eye disease.

Recently, a panel of ophthalmologists from the Cornea, External Disease, and Refractive Society (CEDARS) convened to discuss the impact of dry eye disease on clinical practice. Because ocular surface dryness is so prevalent among cataract and refractive patients, and due to its impact on surgical outcomes, the accurate detection and measurement of dry eye disease is of critical importance and forms the foundation of a thorough preoperative workup. This lively discussion among respected colleagues highlights the issues and solutions to diagnosing and managing dry eye disease.

PARTICIPANTS



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Dr. Beckman: Dry eye disease in our cataract and refractive surgery patients poses potential risks and complications. When this disease is accurately diagnosed, the ocular surface can be treated prior to surgery, and optimal results can be obtained. Today, we are discussing how osmolality testing should be incorporated into this process. Dr. Jackson, what are you seeing in your office?

Dr. Jackson: When evaluating a dry eye patient for any type of ocular surgery, or simply for ocular surface disease, the most important thing is to accurately diagnose the disease and determine the key underlying problem. There are several diagnostic tests available to aid in diagnosis. As the DEWS international task force¹ showed, we can perform conjunctival staining, corneal staining, or an analysis of the tear breakup time, which are all excellent ways to classify dry eye. However, we have to look at dry eye in terms of producing hyperosmolar tears, which can lead to inflammation based on the international definition.

Dr. Beckman: Hyperosmolality is the endpoint to all mechanisms of dry eye, which I think should be our focus. Whether dry eye is categorized as evaporative, aqueous deficient, or lid margin disease, at the end of the day, the eye is hyperosmolar, which is a global indicator of dry eye disease and an at-risk ocular surface. For this reason, I think that having an objective test that we can use to monitor dry eye, like the TearLab Osmolality Test (TearLab Corporation), is critical for anyone in the field of eye care.

Although the other available tests work well, there is a component of subjectivity to them. The TearLab Osmolality Test shows the severity of the disease so that we can respond with the appropriate treatment.

Dr. Jackson: There has never been a way to measure the instability in dry eye disease until the TearLab Osmolality Test; all other tests have had a high variability in terms of determining a diagnosis. Tear osmolality has the highest accuracy (90%) in diagnosing dry eye disease.^{2,3}

CONTROLLING THE VARIABILITY OF TESTING

Dr. Beckman: We must keep in mind that patients may show conflicting data that complicate the diagnosis. They may show a normal tear breakup time and an abnormal Schirmer's test result, or normal Schirmer's and conjunctival staining or corneal staining. For this reason, osmolality testing as a global indicator of dry eye disease is critical; I know how to start treating a patient, and I can easily follow him or her over time. Patients will likely not have a consistent osmolality reading in the beginning due to the instability of the tear film, but they will gradually lower their

average and tighten their range of osmolality as reflected in a normal healthy tear film.

I, too, have found variability in the results of other tests I have used in the past, even when the patient's ocular dryness has shown improvement. With the osmolality test, however, the curve of patient's results tightens, which helps me find a more precise measurement over time (Figure 1A⁴).

Dr. Allen: I think those of us who are using osmolality testing see that it improves patients' compliance with their treatment regimen. We now have a number that is identifiable and acts as a barometer of their disease. Once these patients commit to treatment, they do not mind coming back into the clinic periodically to see if their osmolality number is lowering. It is not reasonable to perform Schirmer's testing every time the patient comes in, and as surgeons, we know that the signs and symptoms do not always correlate with the disease's severity. In having a true barometer of the disease's progression and being able to watch the osmolality readings come down, the patients seem to be more responsive and compliant with therapy.

Dr. Jackson: Osmolality is a global marker for these conditions and allows us to diagnose dry eye disease accurately. It also allows us to gauge a therapeutic response for the patient.

Dr. Luchs: I agree. As many of us know, osmolality will start to improve before patients' signs and symptoms improve. Having that motivational factor, where patients can see their osmolality numbers improving, can help them continue with the therapy, even though their eyes may not necessarily be feeling better yet.

Dr. Malhotra: We know it takes time to improve dry eye, and sometimes these patients do not feel better until their eyes are 100% better. If we can show them that their osmolality is dropping, that can be a powerful tool to induce them to continue with therapy.

USING TESTING TO INFORM CARE

Dr. Beckman: I really like osmolality testing because of how well it correlates both with the severity and progression of dry eye disease and the individual's response to treatment. A study published in *Cornea* last year⁵ looked at the various parameters of dry eye testing: osmolality, symptoms, corneal staining, tear breakup time, and Schirmer's. Osmolality lowered from a starting point of approximately 325 to around 300 mOsm/L, whereas none of the other tests generated a statistically significant response (Figure 1B-F⁵). As these patients improved over time, their tear breakup time may

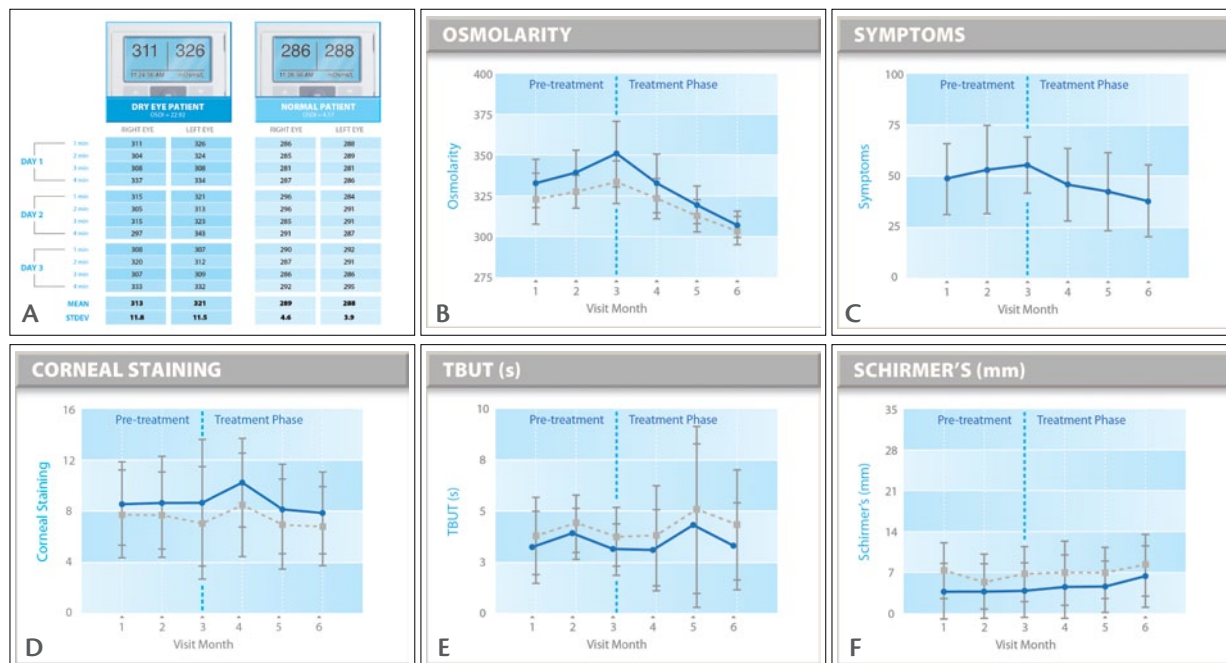


Figure 1. The TearLab Osmolarity Test keeps a record of a patient’s readings so they may be charted over time (A⁴). Of all the available tests for dry eye disease, osmolarity testing shows the greatest range of improvement after treatment is initiated (in this study, the treatment was with cyclosporine A) (B-F⁵).

have risen from 4 to 5 or 6, but the range at 5 months was almost from 2 to 10.

What do these numbers tell us? With osmolarity testing, we see the range tighten as the treatment begins to work. This is a measureable result that patients easily understand.

Dr. Tauber: I think having a number to measure ocular dryness can help inform our care. For example, consider the toxicity of some of our glaucoma agents. Let’s say we have an 85-year-old woman on a prostaglandin with IOPs in the mid-20s. Her poor vision is making her miserable. It may be possible for us to confer with her referring physician or glaucoma surgeon about giving her a break from the glaucoma agent while we treat her dry eye disease. Using a tear osmolarity test gives us the ability to measure her progress in addition to following her symptoms. So, using something like an OSDI or another modality is very helpful.

Also, as we have already discussed, these numbers are very helpful in patient education. Dry eye patients come in wanting to know their latest osmolarity scores.

Dr. Malhotra: Approximately 40% of the patients who have an abnormal osmolarity test result are asymptomatic.⁶ I always have my staff perform an osmolarity test, even if the patient has no chief complaint, because it is important to look for dry eye. Many patients present as asymptomatic but really aren’t, once you ask them about

certain symptoms. When you ask the patient the right questions, the floodgates open.

Dr. Luchs: That point illustrates why it is important for our technicians and us to key in on the history of these patients during the intake, because we want to test their tear film before it has been disturbed by anything else in order to get an accurate reading. So, we need to train our technicians to ask the right questions in order to gather that history ahead of time, even before we see the patient.

OSMOLARITY TESTING IN CLINICAL PRACTICE

Dr. Beckman: How do we incorporate this osmolarity test into our clinical practices? Dr. Luchs, what is your process?

Dr. Luchs: My clinic now has a couple of TearLab Osmolarity instruments, and we have our technicians screen the patients with the OSDI as they’re taking the history. As part of this history, we include questions about ocular allergies as well, because ocular surface disease is a continuum; there are usually several contributing factors, such as blepharitis, dry eyes, and allergy. If the patient answers positively to any of these questions, he or she immediately receives a TearLab Osmolarity Test from the technician. In this way, the test does not interfere with our flow, and the information is ready for me when the patient comes in the room. Thus, the test has been very helpful for us.

Dr. Jackson: My office has a TearLab Osmolarity system in each of the diagnostic rooms where the technicians are, so they do not have to wait to use it. Because ours is an anterior segment practice, we test every patient for dry eye disease, whether they are symptomatic or not, because studies have shown that optimizing the ocular surface improves the outcomes of cataract and refractive surgery.⁷ Whether patients present with symptoms of tearing and burning, or they simply are already on a glaucoma agent, the test helps us identify whether there is a disease process present. If I find the test result is abnormal, then my team and I can start the process of educating and treating the patient appropriately.

Dr. Trattler: We should specify that screening tests are not billable to insurance, whereas diagnostic tests are. We must define criteria for conducting a diagnostic test for patients we suspect may have dry eye disease.

Dr. Beckman: Correct. The protocol in my practice is for our technicians to use a questionnaire to ask patient about a series of symptoms. It could be the classic dry eye symptoms—burning, itching, tearing, grittiness, fluctuating vision, difficulty tolerating contact lenses, and trouble working on the computer for an extended period of time—or simply a history of previous refractive surgery, contact lens wear, or diabetes. The patient's answers to this questionnaire help the technician know when to proceed with the test. The questionnaire categorizes an individual's risk for dry eye disease.

Furthermore, I tell patients they need multiple tests to create a baseline to know how healthy their ocular surface is. If, for example, your patient measures 314 mOsm/L the first day, we start him or her on cyclosporine ophthalmic emulsion 0.05% (Restasis; Allergan, Inc.). At the 1- or 2-month follow-up visit, if he or she is up to 318 mOsm/L, I do not necessarily take that reading as an indication that the patient is getting worse, because maybe the eye is at the upper end of the curve now, where it could have been at the lower end of the curve before. Patients need multiple tests over a period of time in order to establish a reliable baseline.

CONCLUSIONS

Dr. Beckman: Has incorporating osmolarity testing changed the way any of you treat dry eye disease?

Dr. Parekh: The test has made diagnosing dry eye disease more fun. My colleagues and I at our center in New Jersey recently decided to become a point-of-care testing center, and so we underwent CLIA testing and adopted the TearLab Osmolarity Test, among other diagnostic tools. We are excited about this move, and we have not had any patients complain about having to pay a copay to return for testing. I think they believe in our ability to accurately diagnose whatever condition is bothering them.

Dr. Jackson: Having TearLab makes dry eye treatment more efficient. It helps us explain to patients why their eyes feel the way they do, and it motivates them to commit to dry eye therapy. This also enables clinicians to gauge therapy for the patient.

Dr. Luchs: This test helps make me a better doctor in an area where there is such overlap between our clinical findings and patients' clinical symptoms. Osmolarity helps take the diagnostic confusion out of this process.

Dr. Allen: No dry eye test is 100% accurate, but hyperosmolarity has shown to be the best predictor of disease severity that we have currently available.

Dr. Parekh: I think we were at a disadvantage by not having numbers to gauge our patients' progress with dry eye treatments. Now, there is no reason why patients cannot come back in a few months to follow up on the symptoms and to see if their osmolarity numbers are improving.

Dr. Allen: An attending of mine once told me, “**The problem you find before surgery is the patient's problem; the problem you find after surgery, that's the doctor's problem.**” This pearl has driven me to look more at repeat topographies if necessary, perform TearLab osmolarity screenings, take OCTs of the macula, and then analyze the health of the eye before intervening with another surgical procedure that could potentially worsen a dry eye condition. It is nice to have metrics that we can follow analytically to show the patient what he or she is at risk for and what other components of the disease process may be. To that end, the test has affected my screening process for refractive surgery patients. I am much more aggressive in looking for and asking questions about ocular surface signs and symptoms to see if we need to do a TearLab test before having a patient go under the laser.

Dr. Jackson: The point of diagnostic testing is to maximize outcomes. It is our responsibility as physicians to use the tests available now to make our surgical procedures safer and provide a higher-quality result. ■

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