

# LONGITUDINAL VARIABILITY OF TEAR FILM OSMOLARITY IN NORMAL & DRY EYE PATIENTS

David C. Eldridge O.D.<sup>1</sup>, Benjamin D. Sullivan Ph.D.<sup>1</sup>  
Michael S. Berg<sup>1</sup>, Michael A. Lemp M.D.<sup>2</sup>, Daniel S. Durrie M.D.<sup>3</sup>

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Dry Eye II: Diagnosis, Mechanism & Nerves

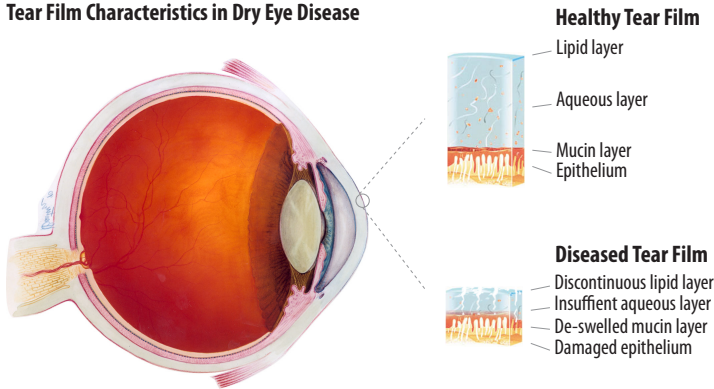
<sup>1</sup>TearLab Corporation, 11025 Roselle St., Suite 100, San Diego, CA 92121  
(858) 455-6006 · info@tearlab.com · www.TearLab.com

<sup>2</sup>Department of Ophthalmology, Georgetown & George Washington University, Washington DC

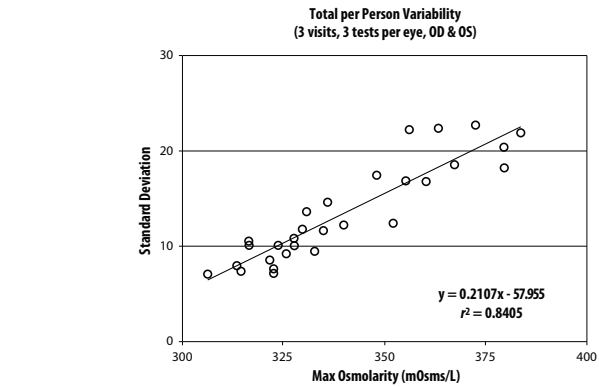
<sup>3</sup>Durrie Vision, Overland Park, Kansas



### Tear Film Characteristics in Dry Eye Disease



The tear film is a complex thin film that provides hydration, lubrication, and immunity for the ocular surface. Hydration comes from the micron-thick aqueous layer<sup>1</sup>, and is thought to be mainly supplied by the lacrimal gland. The meibomian glands, located in the lids, secrete a thin layer of interfacial polar lipids and a thicker contingent of nonpolar lipids that act in unison to inhibit evaporation of the aqueous layer. Supporting the aqueous and lipid layer is a gel-like mucin layer that helps to lubricate the ocular surface and protect the epithelial cells against shear stress.



In dry eye disease, the tear film becomes compromised and unstable, reducing both the quantity and quality of tears<sup>2</sup>. As the lipid layer degrades, the already small amount of tear film evaporates in just a few seconds<sup>3</sup>.

With each blink, the aqueous layer is reconstituted from a small, variable pool of tear in the lower meniscus<sup>4</sup>. A rough corneal surface destabilizes the tear film, contributing to rapid tear film breakup<sup>5</sup>. Without a stable tear film, the image formed on the retina becomes blurry and distorted within seconds after each blink, regardless of the health of the lens or retina<sup>6</sup>.

### 1. Purpose

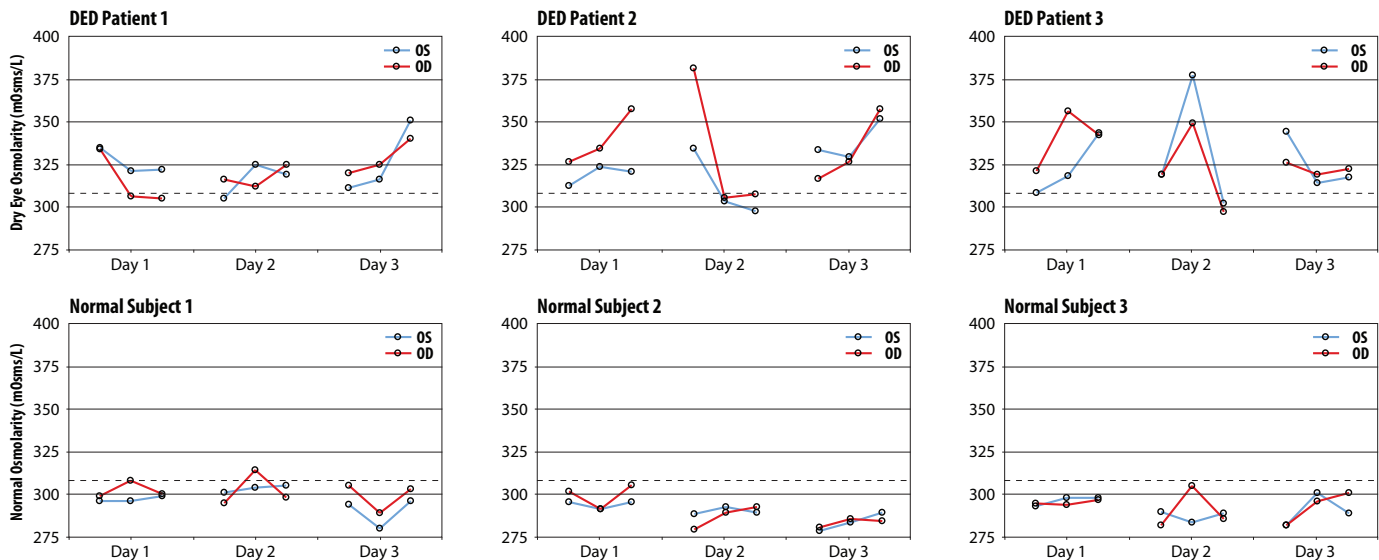
Tear film hyperosmolality and tear film instability are recognized as the two causative mechanisms of dry eye disease, yet the relationship between the signs are poorly understood. The purpose of this study was to evaluate the variability of OD vs OS tear film osmolality relative to tear film instability in the diagnosis of dry eye disease.

### 2. Methods

Bilateral tear osmolality was measured on three different days, with at least 2 weeks between each patient visit. 30 subjects were recruited for the study (n=16 normal, n=14 dry eye, determined by an average osmolality > 308 mOsm/L across all tests). At each visit, 50 nanoliters of tear fluid was simultaneously collected and analyzed (OD and OS) by the TearLab™ Osmolarity System, in triplicate.

### 3. Results

- The average ( $\bar{x}$ ) of normal subjects was 301.8±4.8 mOsm/L {range  $\bar{x}$ =290.2–307.7} while the average of the hyperosmolar subjects was 315.6±6.6 mOsm/L {range  $\bar{x}$ =308.1–329.4, indicating early stage mild disease}.
- Variability was significantly lower in normals than in dry eye (7.9 vs. 14.7 mOsm/L,  $p < 0.001$ ) and strongly correlated to the maximum of the bilateral measurements ( $r^2=0.84$ ), which is the recommendation for clinical assessment.
- When the highest of either the OD or OS osmolality result of an individual patient was considered, 86% of the early stage, mild dry eye subjects were correctly diagnosed with the first set of measurements. This number rose to 100% if eyes were measured in triplicate.
- If only one eye was used in the diagnosis, the mild dry eye subjects were correctly identified 69% (OD) and 62% (OS) of the time with the first set of measurements.
- These data indicate that tear film instability increased in dry eye disease.



1. King-Smith PE et al. Curr. Eye. Res. 2004, 29(4-5):357-368. 2. Sullivan DA et al. Ann. N.Y. Acad. Sci. 2002, 966:211-222. 3. Tsubota K et al. Invest Ophthalmol Vis Sci. 1992, 33:2942-2950. 4. Gaffney EA et al. Prog Retinal & Eye Res. 2010, 29:59-78. 5. Lemp MA et al. Arch Ophthalmol. 1973, 89(2):103-5. 6. Toda I et al. J Refract Surg. 2009, 25(1):69-73. Funding provided by Alcon Laboratories & TearLab Corp., Financial Disclosure: TearLab Employee, Owner, Patents: Sullivan, TearLab Employee, Owner; Lemp, Berg, Eldridge, TearLab Owner; Durrie.