1. Introduction

Recently, lab-on-a-chip technology capable of simultaneous multiple sample collection and analysis has been developed to address the barriers in vivo/culture test testing. The first in a series of fluid analyte utilizing this technology was the emergence of human tear to aid in the diagnosis of dry eye disease in patients suspected of having dry eye disease, in conjunction with other methods of clinical evaluation (TEARLAB™ Osmolarity System – TYS-1000). The TEARLAB™ measures osmolarity of a 50 nL tear sample collected directly from the inferior meniscus of the ocular surface within 15 seconds by placing it between the DEWS severity grades of 2 & 3. Typically, a normal tear would be calculated as 250 – 300 mOsm/L, representing the highest level of severity.

2. Purpose

PURPOSE: Dry eye disease is frequently diagnosed by conflicting signs and symptoms, with patients reporting multiple signs and symptoms (Bell 2007). The goal of the current study was to assess the diagnostic performance of TEARLAB™ osmolarity measurements within the context of the ocular surface and clinical signs.

3. Methods

Continuous Mapping

An example of graphical and configuration, most of whom were DEWS signs, provided a progression of signs across disease severity on a linear scale. Figure 4 shows a linear scale with the DEWS severity grades of 2 & 3. Typically, a normal tear would be calculated as 250 – 300 mOsm/L, representing the highest level of severity.

4. Results

To define normal and dry eye subjects based on clinical signs, extending the study protocol applied the several signs and symptoms of each subject to construct the index. The other clinical signs perform well for the more severe patients, but poorly for normal through moderate quartiles.

5. Conclusions

Osmolarity was found to have superior dynamic range and resolution compared to other signs such as Schirmer strips, TBUT, and OSDI. TEARLAB™ can be considered a surrogate biomarker for detecting disease severity.

6. References