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Presentation Abstract

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Abstract Title: **Comparison of OcuSense and Clifton Nanolitre Osmometers**

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Abstract Body: **Purpose:** Tear hyperosmolarity is diagnostic of dry eye disease (DED), yet difficulty in measurement has limited its utility. Development of new instruments allowing clinical application may lead to the adoption of osmolarity as a primary diagnostic test in DED. The purpose of this study was to compare the new OcuSense osmometer (OcuSense Inc., San Diego, CA), based on electrical impedance and 'lab-on-a-chip' nanolitre technology, with the freezing point depression Clifton Osmometer (Clifton Technical Physics, Hartford, NY).

Methods: Thirty-six subjects were recruited, 15 DED (9F/6M; age 41.7 ± 16.9) and 21 controls (12F/9M; 35 ± 12.8). Inclusion criteria for DED were NITBUT < 10 secs and positive for symptoms. Tear samples were collected from the inferior-temporal conjunctival sac for testing with both osmometers.

Results: Osmolarity values for controls were 308 ± 6.2 mOsm/l (OcuSense) and 310 ± 7.2 mOsm/l (Clifton) and for DED 321 ± 16.5 and 323 ± 14.7 and were significantly different. Significant correlation was found between OcuSense and Clifton measurements ($r=0.904$; $p=0.006$). A scatter-plot with the regression line (dotted) is shown in the figure. Bland-Altman analysis showed general agreement between techniques; the majority of points fell within the 95% confidence limits. But the actual values differed by less than 1% with the OcuSense being lower. A cut-off value of >316 mOsm/l, derived from the distribution of osmolarity values was used to diagnose DED with an effectiveness for the OcuSense of 73% (sensitivity), 90% (specificity) and 85% (PPV) and for the Clifton 73%,

71% and 65%.

Conclusions: Tear film osmolarity measured with the OcuSense system correlates well with the Clifton Osmometer. The new instrument has the potential to provide clinicians with a readily available, clinically applicable measure, which could become the 'gold-standard' in DED.

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