



Measurement Repeatability of Two Point-of-Care Tear Film Osmometers

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Azadeh Tavakoli, Maria Markoulli, Judith Flanagan, Eric Papas
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Introduction

- Dry eye disease (DED) is a common multifactorial disorder that can be characterized by a loss of ocular surface homeostasis, and tear film instability which combine to initiate an inflammatory response, further damaging the ocular surface.
- Tear osmolarity is suggested to be one of the physiological biomarkers of ocular surface health and has an etiological role in DED.
- It has been suggested that there is a correlation between ...

Methods

- Approved by the University of the New South Wales (UNSW) Ethics Committee and followed the tenets of the Declaration of Helsinki.
- 28 participants were enrolled comprising 21 females and 7 males with the mean age of 25 ± 8 and a range of 18 to 40 years.
- The TearLab and iPEN were each used on two occasions in a random order over a two-hour period (one measurement every half hour for a total of four measurements). Both eyes were measured each time, and the eye order was randomized.
- The Ocular Surface Disease Index (OSDI) and Dry Eye Questionnaire (DEQ-2) were administered to assess ocular symptoms.
- Tear osmolarity measurements were conducted as per the instructions of the TearLab and iPEN manufacturers.

Results

- The average osmolarity measures for the TearLab and iPEN were 302 ± 10 and 290 ± 13 mOsm/L, respectively.
- The CoR for the TearLab right eye and left eye were 26.2 and 21.3, respectively.
- The CoR for the iPEN right and left eye were 33.6 and 28.3, respectively.
- The comparison between devices indicated that the limits of agreement (LoA) were 18.8 mOsm/L with a bias of 4.3.
- The OSDI and DEQ-2 Medians were 15 (Q-04) and 9 (Q-21) with an average of 18 ± 15 and 8 ± 5, respectively.

Discussion and Conclusion

Discussion

- The high value of the coefficient of repeatability for both devices indicated poor agreement between replicate measurements.
- The variations among the first and second repeats on the same eye for both osmometers raises serious concerns about the validity of these instruments in the clinical setting.
- TearLab osmolarity readings were consistently higher than those of the iPEN as similarly observed in another study.
- This study found no meaningful relationship between ...

Acknowledgements and References

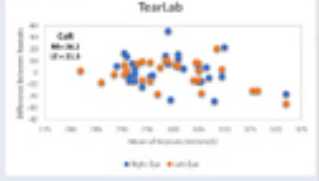
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The authors report no commercial relationships. The study was conducted as part of a postgraduate education grant supported by the Brien Holden Vision Institute.

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TeaLab Measurement



i-PEN



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INTRODUCTION

- Dry eye disease (DED) is a common multifactorial disorder that can be characterized by a loss of ocular surface homeostasis, and tear film instability which combine to initiate an inflammatory response, further damaging the ocular surface.
- Tear osmolarity is suggested to be one of the physiological biomarkers of ocular surface health and has an etiological role in DED.¹
- It has been suggested that there is 14a correlation between hyperosmolarity and severity of sign and symptoms of DED.^{2, 3}
- Accurate and repeatable measurement of osmolarity is an essential component of current approaches to the diagnosis and management of DED.
- The I-PEN (I-MED Pharma Inc) and TearLab Osmolarity System (TearLab Corp) are clinical methods for measuring tear osmolarity, but their accuracy and repeatability have been a matter of discussion.^{4, 5}

PURPOSE

To establish the:

- Repeatability of the TearLab Osmolarity System
- Repeatability of the I-PEN Osmometer
- Comparison of TearLab and I-PEN Repeatability

METHODS

- Approved by the University of the New South Wales (UNSW) Ethics Committee and followed the tenets of the Declaration of Helsinki.
- 28 participants were enrolled comprising 21 females and 7 males with the mean age of 25 ± 8 and a range of 18 to 40 years.
- The TearLab and I-PEN were each used on two occasions in a random order over a two-hour period (one measurement every half hour for a total of four measurements). Both eyes were measured each time, and the eye order was randomized.
- The Ocular Surface Disease Index (OSDI) and Dry Eye Questionnaire (DEQ-5) were administered to assess ocular symptoms.
- Tear osmolarity measurements were conducted as per the instructions of the TearLab and I-PEN manufacturers.^{6,7}

TearLab Measurement

0:00 / 0:52

I-PEN Measurement

0:00 / 0:47

Statistical Analysis

- The repeatability and instrument comparison analyses were carried out using the methods described by Bland and Altman.
- Coefficients of repeatability (CoR) were determined for each device, together with the bias and 95% limits of agreement between them.

RESULTS

- The average osmolarity measures for the TearLab and I-PEN were 300 ± 10 and 295 ± 13 mOsm/l, respectively.
- The CoR for the TearLab right eye and left eye were 26.2 and 21.3, respectively.
- The CoR for the I-PEN right and left eye were 33.6 and 28.3, respectively.
- The comparison between devices indicated that the limits of agreement (LoA) were 18.8 mOsm/l with a bias of 4.3.
- The OSDI and DEQ-5 Medians were 15 (0-64) and 8 (2-21) with an average of 19 ± 15 and 8 ± 5 , respectively.

Figure 1. Difference vs mean plots of repeatability for osmolarity measurements for the TearLab osmometer

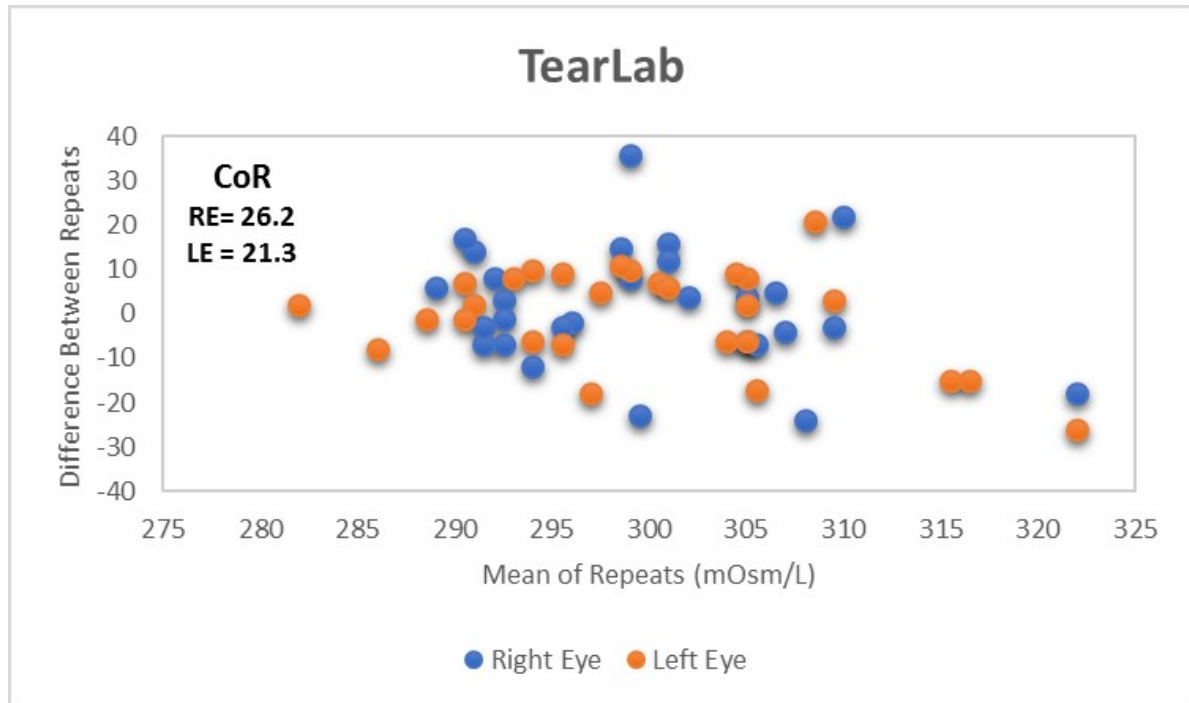


Figure 2. Difference vs mean plots of repeatability for osmolarity measurements for the I-PEN osmometer

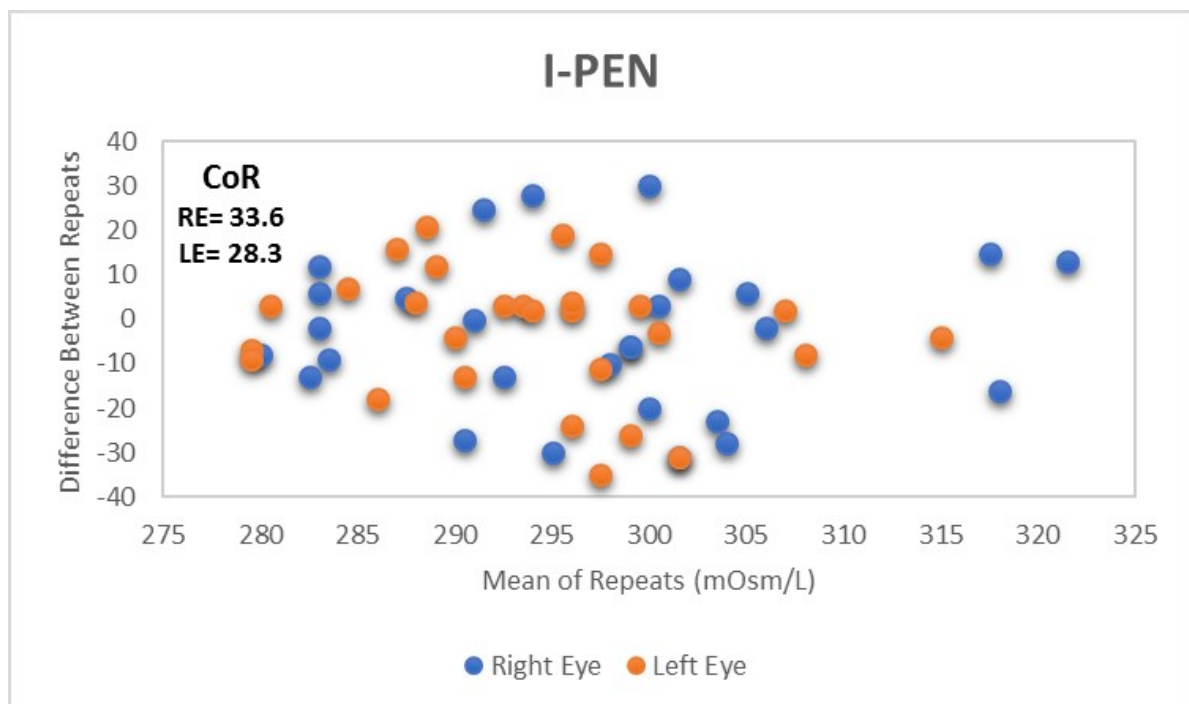
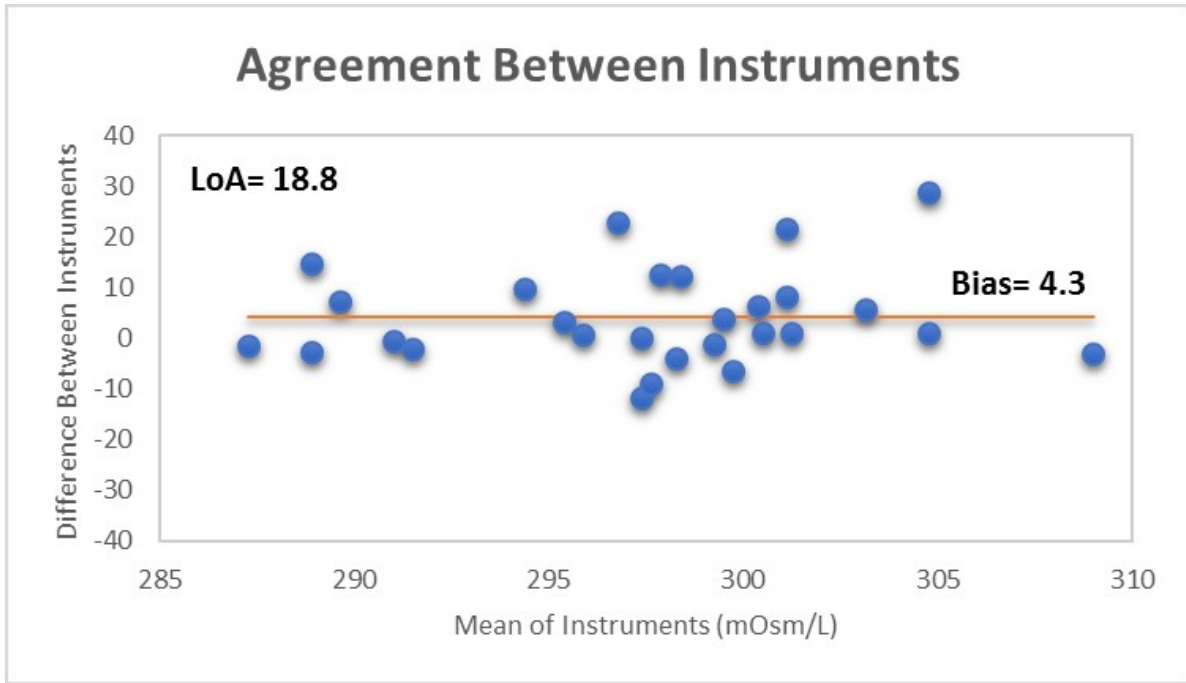


Figure 3. Difference vs mean plots of TearLab & I-PEN comparisons. The red line represents the average difference in the measurements between two devices (bias)



DISCUSSION AND CONCLUSION

Discussion

- The high value of the coefficient of repeatability for both devices indicated poor agreement between replicate measurements.
- The variations among the first and second repeats on the same eye for both osmometers raises serious concerns about the validity of these instruments in the clinical setting.
- TearLab osmolarity readings were consistently higher than those of the I-PEN as similarly observed in another study.⁸
- This study found no meaningful relationship between measurements by either the TearLab and I-PEN osmometers and ocular symptoms.

Conclusion

- TearLab showed slightly better repeatability than I-PEN, however the calculated CoRs were large enough to undermine confidence in the comparison between the instruments.
- This intrinsic variability casts doubt on the value of utilising a single osmolarity measurement, or an intra-ocular difference, from either instrument, as one of the diagnostic criteria for dry eye according to current recommendations (TFOS DEWS II).

ACKNOWLEDGEMENTS AND REFERENCES

Acknowledgements

The authors report no commercial relationships. The study was conducted as part of a postgraduate education grant supported by the Brien Holden Vision Institute.

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ABSTRACT

MEASUREMENT REPEATABILITY OF TWO POINT-OF-CARE TEAR FILM OSMOMETERS. Azadeh Tavakoli^{1,2}, Maria Markoulli¹, Judith Flanagan², Eric Papas¹. ¹School of Optometry and Vision Science, UNSW, ²Brien Holden Vision Institute, Sydney, Australia

Purpose: Tear osmolarity is suggested to be one of the physiological biomarkers of ocular surface health. In dry eye disease, hyperosmolarity can cause tear instability, which can instigate the cycle of inflammation and ocular surface damage. The I-PEN (I-MED Pharma Inc) and TearLab Osmolarity System (TearLab Corp) are clinical methods for measuring tear osmolarity, but their accuracy and repeatability have been a matter of discussion. The purpose of this study was to determine the repeatability of these instruments and compare their osmolarity measurements in a sample of individuals with no, mild or moderate dry eye.

Methods: This prospective, cross-sectional study evaluated the tear osmolarity of 28 participants. The TearLab and I-PEN were each used on two occasions in a random order over a two-hour period (one measurement every half an hour). Both eyes were measured, and the eye order was randomized. The Ocular Surface Disease Index (OSDI) and Dry Eye Questionnaire (DEQ-5) were administered to assess ocular symptoms. Coefficients of repeatability (CoR) were determined for each device, together with the bias and 95% limits of agreement between them.

Results: The average osmolarity measures for the TearLab and I-PEN were 300 ± 10 and 295 ± 13 mOsm/l. The CoRs for TearLab and I-PEN were 23.8 and 30.8 mOsm/l. The comparison between devices indicated that the limits of agreement were 18.8 mOsm/l with a bias of 4.3. The OSDI and DEQ-5 Medians were 15 (0- 64) and 8 (2- 21) with an average of 19 ± 15 and 8 ± 5 , respectively.

Conclusions: While the TearLab CoR was lower than I-PEN, the calculated CoRs were large enough to undermine confidence in the comparison between the instruments. This intrinsic variability casts doubt on the value of utilising a single osmolarity the measurement from either instrument or an intra-ocular difference, according to current recommendations (TFOS DEWS II), as one of the diagnostic criteria for dry eye.

Declaration of interest: The study was conducted as part of a postgraduate education grant supported by the Brien Holden Vision Institute, Sydney, Australia.

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