EQUIPMENT

Impressions of the i-Pen Osmolarity System

The measurement of tear osmolarity is increasingly used in the assessment of dry eye patients. **Jessica MacIsaac** describes a new osmolarity measurement device recently introduced into her practice

According to the 2007 TFOS DEWS report, tear osmolarity and tear instability are recognized as the core mechanisms of dry eye disease[1] and with the new report to be released this year these factors are likely to be highlighted again. Hyperosmolarity causes a loss of goblet cells, disturbance of mucin expression and initiates a release of inflammatory mediators into the tears resulting in damage to the ocular surface.[1] Physiological stress on the cornea caused by hyperosmolarity can lead to nerve damage[2] and so we cannot necessarily rely on patient symptoms to determine who has elevated tear osmolarity. Tear osmolarity is a biomarker for both aqueous deficient and evaporative dry eye, correlates well with disease severity, is superior in overall accuracy to any other dry eye diagnostic, and is a useful metric to monitor disease progression.[3]

WHY MEASURE OSMOLARITY?

Eye healthcare professionals welcome rapid, reliable and reproducible quantitative measures to both track disease progress in their patients and to help determine whether a patient is responding well to a recommended product or treatment. Ideally, tear osmolarity measures as a standard of care would be a prerequisite for any eye examination, pre-refractive surgery appointment or contact lens fit. Osmolarity readings give an objective indication of ocular surface health and help manage patients more efficiently. The initial measurement of osmolarity at a contact lens fitting appointment could, for example, help identify dry eye patients that are most likely to return with contact lens discomfort or even dropout from contact lens wear. Rather than spending multiple visits changing contact lens modality, material or solution, a measure of osmolarity could help guide an optometrist to manage the patient's ocular surface health first. Research has shown higher variability in keratometry readings and significant differences in intraocular lens power variability in subjects with hyperosmolar tears.[4] Preliminary tear osmolarity testing could help identify patients at higher risk of unexpected refractive outcome following cataract surgery.

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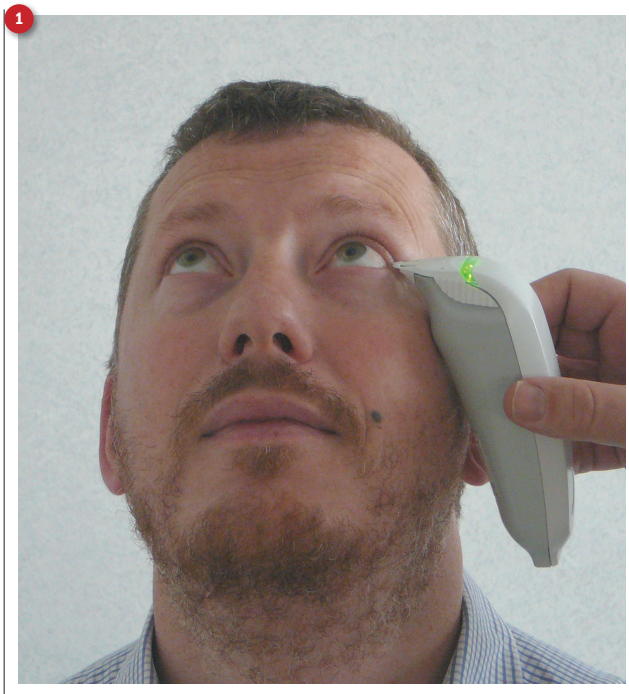

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CHALLENGES

Up to now the only commercially available measure of tear osmolarity in the UK was the TearLab. From a cost point of view, TearLab, though well established, is an instrument that uses a disposable tip for each measurement so has ongoing running costs. This introduces the challenge of fee adjustment and adjustment to the patient's perception of the instrument's value, especially if you are planning to use it as a screening tool for dry eye and the patient is asymptomatic.

For example, one recent study measuring the variability of the TearLab system indicates that tear osmolarity has to be measured at least three times in order to achieve reliable results.[5] Each

assessment requires a new tip and these incur a cost in addition to the initial outlay for the unit. The instrument also requires recalibration each day of use.

That said, there is now a significant body of literature validating its use and accuracy.

THE I-PEN

Recently a potentially more affordable option has been introduced that is easy to use and portable. This is the i-Med Pharma i-Pen (figure 1). The i-Pen is classified as a Class 1 medical device with a measuring function.[7] It is a less costly alternative method that displays a quantitative result without the need for a reader unit used to calculate and display the result. As the name suggests the i-Pen is no larger than a white board marker and can be carried in one's pocket unlike TearLab, which is not a truly portable unit as it requires the base station to operate. The i-Pen device is £795 (about 20% the cost of a TearLab system), and the consumables, referred to as single use sensors, are £5 each as opposed to £8 for TearLab test cards.

At BBR Optometry Ltd tear osmolarity readings, from the commercially available TearLab have been incorporated into the evaluation component of the dry eye workflow for the past five years. Just recently the i-Pen has been used to evaluate osmolarity. For the most accurate results, patients are advised to cease use of drops or ointment for at least 24 hours prior to their dry eye consultation. If they are on medication to control their intraocular pressure they are advised to instill at least four hours before their appointment. They are also asked to remove contact lenses for at least four hours prior to their consultation and avoid the use of cosmetics around the eye on the day of the appointment.

In comparison to the TearLab, the i-Pen auto-calibrates and requires no transfer of tear fluid samples to a separate measurement unit. This reduces the risk of evaporation. The device takes 250 measurements in four seconds with the final tear osmolarity reading shown on the liquid crystal display in units of mOsm/L.

It is very quick and is not at all unpleasant for the patient, with the tip of the single use sensor applied to the conjunctiva on the inside of the lower lid medially (figure 2). In contrast, the single use TearLab test card collects 50 nanolitres of tear fluid by passive capillary action, which can be uncomfortable for a patient with reduced tear volume.

The i-Pen determines tear osmolarity by measuring electrical impedance, similar to the Tearlab osmometer, but of the saline concentration of the extracellular fluid contained in conjunctival tissues as opposed to the tears themselves. The manual provides reference data on tear osmolarity that matches generally accepted ranges for human tear osmolarity levels,[8] including a mean value of 300 mOsm/L and range of 275-316 mOsm/L for normal patients, and a mean value of 327 mOsm/L for dry eye patients.[7] Clearly the two instruments are not giving results that are directly comparable but as long as the practice is using one consistent method this is unlikely to have practical significance. In vivo studies to compare the performance of tear osmolarity measuring devices in human subjects are needed, and clinical studies of i-Pen are underway in North America.

VIEW

The i-Pen clearly offers benefits from a practice perspective in terms of being able to enhance excellent high quality clinical care by enhancing dry eye assessment and offering capability to troubleshoot poor contact lens or refractive outcomes due to a failure to address ocular surface issues.

This is a measure that can be taken by trained clinical support staff and considering its affordability, could be a fixture in all practice consulting rooms. At BBR Optometry Ltd the i-Pen is used in dry eye consultations, and it has been noticed that when a quantitative result can be applied to a patient's problem, the patient is more likely to comply with the advice given and reap the tangible rewards.

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For further information see www.imedpharma.com/i-pen

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