Novel device provides rapid measure of tear osmolarity

After several seconds of contact with eyelid tissue, tool shows result on LCD in units of mOsms/L

November 01, 2016 By <u>Nancy Groves</u>

Reviewed by Henry Reis, MD, OD

Quebec—A new handheld, tear osmolarity device (i-Pen, I-MED Pharma) for diagnosis and monitoring of dry eye disease works by measuring electrical impedance in ocular tissues, which is converted by a proprietary algorithm to osmolarity.

Measurements are taken on the inside of the lower eyelid, with the device directly touching the tear-soaked conjunctival tissue.

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Results are obtained quickly and accurately, said Daniel Hofmann, vice president of I-Med Pharma, noting that the device takes 250 readings in 4 seconds and then shows the average on the LCD screen.

Testing is painless and quick and offers several advantages over other means of osmolarity testing as a tool for preliminary screening, as well as ongoing assessment, Hofmann said.

take-home

A new handheld, tear osmolarity device could enhance the convenience and reliability of dry eye screening and monitoring and be more affordable for many practices.



"The doctor will be able to identify the symptoms and then use this as a validation of the symptomology or of the patient's complaints," he said. "The doctor will be able to use this device and see right away whether the results fall within the normal or at-risk range or clearly dry eye.

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"And if it does fall into the dry eye or at-risk range, the patient is probably a candidate for further investigation or dry eye testing," he added. "If the result falls within the normal range, then the problems might be elsewhere."

About the device

Henry Reis, MD, OD, who is in practice in Burnaby, British Columbia, added the device to his clinic in May 2016. Dry eye management is a particular focus of Dr. Reis' clinic, making up about one-third of his patients, many of whom are referred from other part of British Columbia, other provinces, and the United States.

"The [device] doesn't rely on a lipid sample. It touches the conjunctival tissue itself so it can be much more reliable, especially in cases of severe dry eye, when a tear sample might be hard to acquire," Dr. Reis said. "When you work in a busy practice, this makes a huge difference because you avoid variables and ensure repeatability."

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According to Hofmann, the device does not require temperature calibration because of the relatively static nature of the temperature on the inside of the lower eyelid. The device self-calibrates when turned on.

Dr. Reis purchased the device with the goal of having an objective and convenient means of diagnosing and monitoring dry eye, which has so many variables that diagnosis and treatment can often be highly subjective.

"Osmolarity testing provides you with an objective, repeatable metric, which is invaluable for dry eye management," he explained.

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Osmolarity is perhaps more important in monitoring than it is in diagnosing dry eye. Patients can be held accountable when their osmolarity score has not improved at a follow-up visit after a proper treatment plan has been recommended, he added.

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"In those cases, it would be reasonable to consider the patient hasn't been compliant," Dr. Reis said. "But the moment the patient knows that the tear osmolarity will be reassessed in a follow-up visit, the treatment compliance increases significantly. To me, the most important indication for using the [device] is to make sure that the treatment is being followed properly by the patient."

Small footprint

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The device is about the size of an electronic thermometer or small remote control. A physician or technician can carry the device in a lab coat pocket and screen a patient anywhere in the clinic rather than in a room where a stationary testing device is located.

The idea for the device can be traced back to conversations between its developer and physicians in 2010, when a doctor commented that methods of diagnosing dry eye disease were at best semiquantitative, which made it harder to explain the disease status to patients. He envisioned an ocular equivalent of a device such as a blood glucose meter that could calculate a number correlated to disease severity.

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"We heard that message, and about a year later we identified an inventor who was able to work with us to start this project," Hofmann said.

Osmolarity was chosen as the metric for the device because it is a good indicator of the presence of dry eye, although it does not identify the cause. After several years of development and testing, the product was launched in Canada in May.

I-MED Pharma plans to seek FDA approval for the i-PEN in 2017. Currently, it is approved by Health Canada and is CE-Marked.

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The device was developed using current technology, taking advantage of the trend toward miniaturization. While this is convenient for healthcare professionals and patients, it also helps lower the cost of the device, Hofmann said.

"We feel that for the first time osmolarity testing will be affordable to every single practitioner around the world," he said.

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Dr. Reis is on the medical advisory board for I-MED Pharma.