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# Changing dry eye management

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# OTs Ryan O'Hare reports on how TearLab is using osmolarity as a marker for dry eye, and the potential for changing how the condition is managed in the community

Last month, at the annual meeting of the <u>European Society for Cataract and Refractive Surgeons</u> in London, TearLab held a symposium (September 15) on how its Osmality System is being used to effectively manage dry eye patients in optometric practice. The US-based company is confident that wider use of its diagnostic technology in the UK can be used to help better identify, classify and treat patients, saving the NHS time, resource and money.

While dry eye may not be the most urgent of clinical conditions, it is one of the more/most common seen in optometric practice, and can have a marked impact on the patient's life. Previous studies have put its prevalence at anywhere from 5–15% of the general population, affecting as many as one in 10 women, and this year an analysis by Companies & Markets has forecast the therapeutics market for dry eye will reach \$5.5bn (USD) by 2020.

Typically, administering fluorescein drops can help to indicate if any of the myriad symptoms could be due to the condition. Beyond these, or in a more intensive 'workshop' setting, other measurements such as a five-minute Schirmer test and tear film instability/tear break-up time (TBUT), can be used as key identifiers of the condition, as can the Ocular Surface Disease Index (OSDI) patient questionnaire.

#### **Changing definition**

In 2007, the International Dry Eye Workshop (DEWS) set up a grading system to classify the severity of the condition. Based on a range of measurements, including; tear break up, corneal staining, questionnaire score and checking for meibomian gland dysfunction; the DEWS score grades patients from 1 – mild and episodic, to 4 – severe and/or disabling and constant, suggesting a suitable treatment regimen. But the committee also changed the definition to incorporate elevated tear concentration, or hyperosmolarity, as a key factor accompanying inflammation of the ocular surface.

TearLab's Osmorality System is able to measure the severity of dry eye based on levels of osmolarity alone (mOsms/L). By taking a small tear sample from the patient and measuring using a disposable chip, it provides a value of the patient's tear film and categorises them accordingly. Its creators say it provides the 'first objective and quantitative' test for dry eye, with osmolarity correlating more closely with the DEWS score than any other single measure. The context in which the value is placed makes its potential for use as a biomarker very clear: 'the higher the osmolarity, the more severe the disease.'

## Clinical studies

A number of studies are ongoing to provide further evidence for the efficacy of osmolarity as a biomarker in practice. Interim results from a dry eye prevalence study of almost 600 patients in ophthalmology clinics in England reveal that more than 72% of patients had elevated osmolarity levels.

Francesca Harman, a consultant ophthalmologist from Hillingdon Hospital in West London and lead researcher on the study, said that it "shows the need for objective testing to be introduced on the NHS."

Presenting interim data from the study, which compares osmolarity against traditional dry eye measurements as an indicator, Dr Harman said that osmolarity "was the single most sensitive sign" in picking up dry eye. In 20% of patients, hyperosmolarity was the only sign of the condition in those who were otherwise asymptomatic.

Although the study is yet to finish, the data suggest that the value may provide clinicians with a better idea of what's going on, both in the absence of symptoms and more generally. While the research group aims to enrol a total of 1,000 patients, the preliminary findings show that the measure could help to spot those patients who may otherwise slip through the net using traditional tests. "Tear break up time is the least accurate, and we should be thinking about other methods to pick up dry eye," added Dr Harman.

## In practice

A pilot group is currently trying to demonstrate how this might work in the community setting, led by ophthalmologist Guy Smith, who trains optometrists in the area to carry out testing with the TearLab system.

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symptoms, are likely to be placed on hypromellose, which will often be insufficient for treating their symptoms.

"It costs the patient time having an ineffective treatment, it costs the NHS a small amount of money paying for that ineffective treatment, and also costs the GP time trying to sort these patients out," he told delegates.

"The DEWS report is really very good at recommending a treatment regimen once [patients] are graded," he explained, but added that the testing is the weak link in the chain. By carrying out a range of tests, including osmolarity, a composite score is generated which corresponds with the DEWS report, classifying the patient and indicating a suitable treatment regimen. Pointing to the importance of patients having a 'route back', he added the caveat that there was a need to ensure that "if things aren't going to plan in the community, then they can come back" to the hospital eye clinic.

"To make it work is going to take pulling all of the strands together," said David Goad, general manager of Robert Frith Opticians, who is working with Mr Smith to deliver the model. "Most dry eye patients are referred by GPs, we need GPs to refer to an accredited optometrist," he added.

The proposed model comprises a network of accredited optometrists, who would be trained by a community ophthalmologist – in this case, Mr Smith. All participating, accredited optometrists would have a TearLab system in practice, providing consistency of measurements. This, said Mr Goad, would provide "an objective, recordable and comparable" result, with the ophthalmology clinic able to use the data directly.

"We hope that we're going to be operating within the next couple of months," he offered, adding: "I'm really excited, because I think this could be a change to the way we measure dry eye in this country."

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