

Contact Lens Update

CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

TFOS DEWS II: A Defining Moment

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Ten years have passed since the publication of the Tear Film and Ocular Surface Society (TFOS) Dry Eye Workshop (DEWS) report. Fulfilling the Society's aim of focussing the world's attention on this common, debilitating disease, by stimulating and guiding future research, there's been a veritable explosion in the volume of literature devoted to the ocular surface and dry eye disease. Researchers, clinicians and industry, alike have risen to the challenge of attempting to improve the lives of those affected by dry eye disease.

Triggered by this exponential rise in interest in the field, the second consensus-based Workshop, TFOS DEWS II, sought to consolidate the vast scientific evidence published since TFOS DEWS, to identify remaining gaps in our understanding and to offer suggestions on where and how to conduct future research to continue to drive the field forward. With industry support garnered through the tireless fundraising efforts of TFOS Executive Director, Amy Gallant Sullivan, the Workshop began in 2015. The process took 2.5 years and involved 150 members from 23 countries, who contributed to reaching consensus and creating the 400-page TFOS DEWS II report.

It was my privilege to serve as Vice Chair of the TFOS DEWS II steering committee, along with Dr. David A. Sullivan as Organizer, and Dr. J. Daniel Nelson as Chair. The TFOS DEWS II publication comprises 10 reports devoted to key areas related to dry eye. These were published in the *Ocular Surface* in July 2017, with an executive summary published in the subsequent issue, and they are accessible and free to download in their entirety through the TFOS website (www.tearfilm.org).

Very many findings in the report are relevant to the practising clinician. The Definition and Classification report describes updates that reflect our better understanding of the disease. According to TFOS DEWS II,

Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.

With a patient-centred focus, a newly designed flowchart encourages practitioners to classify a patient's dry eye status according to the presence or absence of symptoms and signs. Acknowledging that dry eye disease is a subset of ocular surface disease that exhibits both signs and symptoms provides practitioners with the potential to better understand the individual patient sitting before them, and enables more realistic expectations to be set with respect to treatment outcomes. The refined classification system takes account patients who present with signs but no symptoms, as well as those who present with symptoms but minimal clinical signs. Falling within a subset of the latter group are patients who experience neuropathic pain. Such neurosensory abnormalities require non-dry eye disease management, and are described in more detail in the *Pain and Sensation* report.

Appreciating the risk factors associated with dry eye disease is critical in educating patients and optimising management, and this is summarised eloquently within the *Epidemiology, the Sex, Gender, and Hormones*,

and the *Iatrogenic Dry Eye* reports. The most consistent dry eye disease risk factors identified include age, sex, ethnicity, certain systemic diseases, and meibomian gland dysfunction as well as modifiable risks relating to hormone imbalance, medication use, surgery, and the environment, most especially humidity and computer use.

The *Pathophysiology* and *Tear Film* reports describe the changes that occur in the ocular surface tissues and tear film components in dry eye disease, respectively. Tear hyperosmolarity arising from evaporative tear loss is the main driving factor in dry eye disease, and this initiates a cascade of events that result in a symptomatic, self-perpetuating cycle of instability, hyperosmolarity, inflammation and cellular damage that has become recognised as the 'vicious circle of dry eye disease.' Aqueous deficient dry eye and evaporative dry eye continue to be recognised as the main subtypes of dry eye disease, with evaporative dry eye being predominant, although significant overlap between subtypes is acknowledged to exist in many cases.

As identified in the *Diagnostic Methodology* report, global consistency in diagnostic criteria for dry eye disease would improve the accuracy of prevalence data and allow for more meaningful comparisons of clinical trial outcomes across the world. Diagnostic recommendations have therefore been provided to encourage just that. After excluding non-dry eye conditions and comorbidities with the aid of a series of triaging questions, the report recommends adoption of a specific series of tests of symptoms and signs for diagnosing a dry eye.

Accordingly, dry eye is diagnosed when a patient shows:

- a positive score on a validated symptom questionnaire (either ≥ 6 on the *Dry Eye Questionnaire* (DEQ)-5 or ≥ 13 on the *Ocular Surface Disease Index* (OSDI))

and a loss of tear film and ocular surface homeostasis as demonstrated by a positive result on one or more of the following tests:

- a non-invasive tear break up time of < 10 seconds (fluorescein to be used only if a non-invasive test is unavailable)
- hyperosmolarity of ≥ 308 mOsm/L in either the right or left eye, or an interocular difference of > 8 mOsm/L
- ocular surface fluorescein or lissamine green staining of > 5 spots on the cornea, or > 9 spots on the conjunctiva, or ≥ 2 mm length and $\geq 25\%$ lid margin width staining of the lid wiper

After confirming a diagnosis, further testing is used to establish the contributions of the aqueous deficient dry eye and evaporative dry eye subtypes, to help guide management. Aqueous deficient dry eye can be identified through tests of tear volume such as tear meniscus height measurement and evaporative dry eye through tests of meibomian gland function such as gland expressibility and lipid layer quality.

Staged treatment options are described in the *Management and Therapy* report in Steps 1 through 4. Treatment generally progresses to the next step if resolution cannot be achieved at the lower level, but the dry eye subtype and severity should be used to inform the practitioner of the most appropriate starting point. The aim of dry eye disease management is to restore tear film homeostasis. Some treatment options are indicated for short-term application to help break the vicious cycle of dry eye disease in order to achieve homeostasis, while the majority of treatments offer longer-term support in restoring and maintaining homeostasis.

TFOS DEWS II has highlighted to the world that these are exciting times for clinicians and their dry eye patients. The report offers an update on the current status of our knowledge of dry eye disease, and refined guidelines on how to diagnose and manage the disease. It has set the scene for future research, where we can anticipate that well-designed randomised controlled trials, as prescribed in the *Clinical Trial Design* report, will provide the scientific evidence necessary to take the field to the next level in our quest to reduce the suffering caused by dry eye disease. I, for one, feel incredibly honoured to be involved in this fast developing field, and am eager to see what the next 10 years holds. Bring it on!!