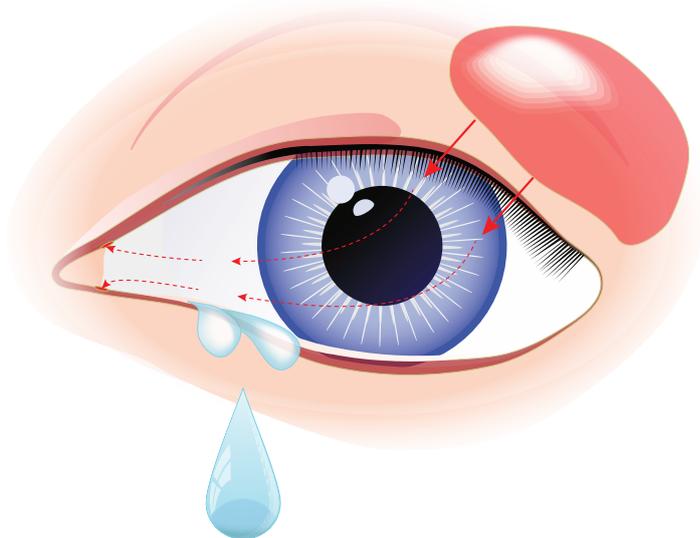


A sight for sore eyes

# Clinical guidelines for managing dry eye in Sjögren's patients



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AS PART of the Sjögren's Syndrome Foundation's initiative to develop clinical guidelines for practitioners, a panel of eye-care professionals and consultants was formed to determine consensus guidelines for managing dry eye associated with Sjögren's syndrome. Foulks et al published their recommendations in the April 2015 issue of *The Ocular Surface*. These clinical guidelines are based primarily on the 2007 report of the International Workshop on Dry Eye (DEWS), as well as evidence from key peer-reviewed publications. The level of evidence determined the strength of the recommendation.

## Sjögren's syndrome

Sjögren's is an autoimmune disease, primarily affecting the exocrine glands of mucous membranes, resulting in dry eye and dry mouth, often with additional musculoskeletal disturbance and damage to other body systems.

Dry eye is one of the most quality-of-life and activity limiting problems in Sjögren's syndrome. Symptoms include discomfort and fluctuation of vision. The researchers recommend the use of four specific questions to

evaluate the severity of symptoms:

- How often do your eyes feel dryness, discomfort or irritation?
- Would you say it is often or constantly?
- When you have eye dryness, discomfort or irritation, does this impact your activities, for example, do you stop or reduce your time doing them?
- Do you think you have dry eye?

A patient reporting 'yes' to any of these questions warrants further investigation.

## Diagnostic tests

The researchers note that in each patient, the clinician must determine whether the dry eye is due to aqueous production deficiency, excess evaporation, or combined mechanisms. Because the sequence of evaluation can influence the results of the subsequent tests, they recommend performing the tests from least invasive to more invasive.

Direct observation without any manipulation of the eyelids, tear film, or ocular surface should be performed first. Direct observation includes using the specular reflection to observe the tear meniscus (is it scanty?) and the tear lipid layer (is it coloured?) These observations alone help to show if an aqueous deficiency or meibomian dysfunction or both are present.

The phenol red thread test is then performed, prior to instilling dye and taking care not to induce reflex tearing. The Schirmer 1 test is tricky to interpret except in severe dry eye, as it can induce reflex tearing and instilling anaesthesia may change the tear volume. The phenol red thread test may be an alternative.

Instillation of topical fluorescein should be followed by measurement

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# Sjögren's patients

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of the tear film break-up time (TFBUT). Corneal staining should be recorded 1.5–3 minutes after fluorescein instillation. Conjunctival staining with fluorescein can be assessed using the yellow Wratten filter, or by instilling lissamine green and making observations after three minutes.

## MANAGEMENT APPROACHES

### Communication

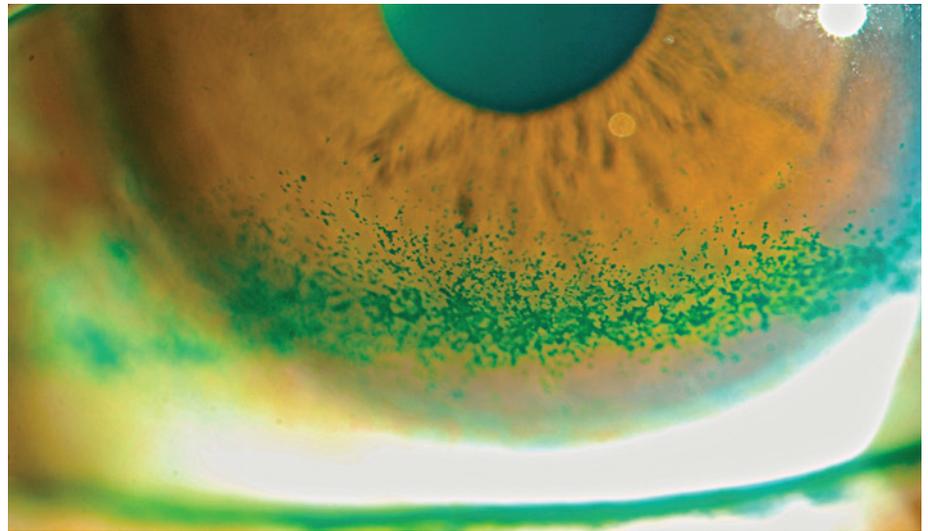
The researchers emphasise the importance of communication between the practitioner and patient regarding the nature of the disease, aggravating factors and goals of treatment. Given the multiple contributing causes of dry eye, the patient should consider dry eye therapy as part of their overall health management.

Mild, episodic dry eye can be managed with modification of the patient's environment and activities of daily living. These include: avoiding systemic medications that can reduce tear secretion, maintaining eyelid margin hygiene, avoiding very dry or windy environments and limiting certain tasks associated with reduced blink rate. When these preventive measures are inadequate, there is a logical sequence of therapies that can be used.

### Lubricants

Tear volume replacement with ocular lubricants is the first line of therapy for dry eye in Sjögren's disease. Among the wide variety of formulations using carboxymethylcellulose and hydroxymethylcellulose, the researchers concluded that none is clearly superior.

Given the toxicity of preservatives to the ocular surface, preservative-free unit dose vials are recommended when tear supplements are used more than four to six times a day. Ophthalmic ointments may be used before bedtime to provide relief of dry eye symptoms and enable sleep. Typically, thicker preparations have



▲ Figure 1. 45-year old female with Sjögren's syndrome. Inferior corneal lissamine green staining punctate and coalesced pattern. Image: Associate Professor Mark Roth

a longer residence time but are more likely to blur vision, although newer agents containing hyaluronic acid may disrupt this constraint.

### Therapeutics

Moderate-to-severe ocular surface disease often requires the use of anti-inflammatory therapies. Studies have shown topical corticosteroids are effective in decreasing clinical signs and symptoms. However, the possible complications associated with long-term use such as cataracts, intraocular pressure spikes and infection, limit their use to short-term or pulse therapy. The researchers recommend a two- to four-week course for cases inadequately controlled with other therapies.

Topical cyclosporine (Restasis or compounded) has been shown to increase tear production, and improve signs and symptoms in patients with chronic aqueous-deficient dry eye. No significant side-effects have been reported, and long-term safety of topical cyclosporine has been confirmed in the literature.

### Systemic therapy

Traditional treatments for posterior blepharitis and meibomian gland dysfunction include hot compresses and lid hygiene. In more recalcitrant cases, the researchers recommend the use of topical antibiotics or low dose oral tetracyclines to decrease bacterial colonisation of the lid margins. Omega 3 essential fatty acids supplements are also considered to have anti-inflammatory effects.

The evidence of their use in treating dry eye is growing, and at 1000–1500 mg per day for three months, it is considered a low-risk dietary supplement.<sup>1</sup> Foulks et al<sup>2</sup> recommend that patients taking more than 3000 mg per day omega 3 supplements should do so only under a physician's care.

### Contact lenses

Large-diameter rigid, gas-permeable lenses are recommended to control severe ocular surface damage, when other treatments are insufficient. Therapeutic scleral contact lenses

in Sjögren's patients serve to protect the ocular surface from the eyelids and environment, relieve discomfort and improve quality of vision. Retention of a fluid reservoir over the cornea and lack of corneal touch are key elements to the therapeutic effect of scleral lenses.

### Further options

Once the inflammatory component of dry eye is controlled, occlusion of the lacrimal puncta using plugs can be considered. This can be performed on a temporary or permanent basis. Those unresponsive to intensive lubricant and anti-inflammatory therapy may require use of topical autologous serum. This is typically dosed four times daily, and can be used in conjunction with other therapies. The most severe cases of dry eye may consider partial closure of the interpalpebral fissure, using botulinum toxin injections or surgical options, to reduce surface exposure.

Eye-care practitioners frequently encounter patients with dry eye symptoms. Although most patients complaining of dry eye do not have Sjögren's, it should be considered as a possible aetiology, particularly when it is associated with inflammation, difficulty in management, dry mouth, arthritis or other systemic evidence of inflammation or autoimmune disease. The researchers strongly encourage clinicians to refer patients with suspected Sjögren's disease to a rheumatologist for systemic disease diagnosis and management. ▲

1. Deinema LA, Vingrys AJ, Wong CY, et al. A randomized, double-masked, placebo-controlled clinical trial of two forms of omega-3 supplements for treating dry eye disease. *Ophthalmology* 2017; 124: 43-52.
2. Foulks GN, Forstot SL, Donshik PC, et al. Clinical guidelines for management of dry eye associated with Sjögren disease. *Ocul Surf* 2015; 13: 2: 118-132.

## FDA approves first treatment for GCA

THE US FOOD and Drug Administration (FDA) has approved subcutaneous tocilizumab for the treatment of giant cell arteritis (GCA) in adults. The drug is marketed as Actemra by health-care company Hoffmann-La Roche.

The decision follows the results of a double-blind, placebo-controlled study which involved 251 patients with GCA. Researchers looked for sustained remission from the disease from week 12 to week 52.

It was found that a greater proportion of patients receiving subcutaneous

tocilizumab along with standardised prednisone regimens achieved sustained remission compared to patients receiving placebo with standardised prednisone regimens.

The standard of care for patients with GCA is steroid therapy; however, prolonged courses of steroids often are required, leading to substantial steroid-associated complications.

The FDA granted the application for Actemra a 'Breakthrough Therapy' designation and a 'Priority Review'.

[www.fda.gov](http://www.fda.gov)

## Manage lid-disease before trabeculectomy

TO AVOID bleb-related infection (BRI), lid disease should be managed prior to trabeculectomy surgery, a study has found. Researchers conducted a clinical study of BRI following trabeculectomy surgery. The study involved documenting historical data review from patients' records, self-reported questionnaires specific to ocular surface symptoms and a repeated detailed clinical examination of the lid, ocular surface and tear film.

Twenty-eight cases and 31 controls were assessed. Researchers found that the overwhelming risk factor for development of BRI was chronic

blepharitis. No increased risk was identified with the antimetabolite used during trabeculectomy surgery or the type of conjunctival reflection adopted for surgery. Neither age nor dry eye was identified as a risk factor.

An increased risk of BRI was identified in eyes with chronic blepharitis. To minimise the risk of infection following trabeculectomy surgery, it may be advisable to manage lid disease in patients prior to performing trabeculectomy surgery, or offer an alternative treatment such as a shunt.

*Br J Ophthalmol* 2016; Oct 18 (Epub ahead of print)

## New study of infectious conjunctivitis

THE FIRST patient has been enrolled in a phase 3 clinical trial for SHP640, a combination broad-spectrum antiseptic and corticosteroid being evaluated for treating infectious keratitis in adults and children.

According to an announcement by the biopharmaceutical company Shire, international clinical trial sites are expected to open in the third quarter of 2017.

SYNCHRONIZE, the phase 3 trial, will include four multicentre, randomised, double-masked, placebo-controlled studies, with two for adenoviral

conjunctivitis and two for bacterial conjunctivitis.

Shire plans to enrol more than 2,700 patients to investigate the efficacy and safety of SHP640 in adenoviral and bacterial conjunctivitis.

SHP640 is a broad-spectrum antiseptic (povidone-iodine, 0.6%) and anti-inflammatory steroid (dexamethasone, 0.1%) combination. The treatment regimen being studied for SHP640 is one drop, four times per day, for seven days.

[www.shire.com](http://www.shire.com)