



The ROYAL COLLEGE of
OPHTHALMOLOGISTS

Clinical Guidelines

Serum Eye Drops for the Treatment of Severe Ocular Surface Disease

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Lay Summary

Ocular Surface Disease (OSD) is a global public-health problem. Severe dryness of the eye has significant impact on a person's physical, emotional and social well-being.

The front of the eye is complex and has an outer surface known as tear film. A range of components contribute to how tears are made, what they contain and how they are distributed to keep the surface of the cornea smooth to enable sight and comfort. Failure of one or more of these complex components due to disease or injury result in dryness of the eye. In its severest form, OSD may lead to blinding complications.

Current Practice for Patients with Ocular Surface Disease

A patient with dry eye disease is treated in a stepped approach. When commercially available artificial tears do not provide relief and the patient does not respond to conventional treatments, the ophthalmologist might suggest that a patient with severe ocular surface disease might benefit from Serum Eye Drops (SED) which are made from blood. Artificial tears made from blood have been shown to be effective because they contain many of the substances found in normal tears. They have been found to be superior to conventional treatment for improving ocular surface health and providing comfort.

Autologous SED (Auto-SED) are made from blood donated by the patient. Patients who are not suitable to provide an autologous donation can receive allogeneic serum drops (Allo-SED) which are made from blood donated by a male volunteer donor. SED are currently reserved for people who have severe disease who have not responded to standard intervention. They are also used for those who require supportive therapy for specialist ocular surgery or for management of ocular surface injury.

The Production of Serum Eye Drops

The NHS Blood and Transplant (NHSBT) has been providing SED since 2003. It is the only accredited production facility in the UK. NHSBT prepares SED from the patient's own blood (Auto-SED) and from individual (not pooled) male-volunteer blood donors (Allo-SED). To make the drops, the donated blood is processed to separate out the serum. Although there are variations in practice in other countries, in the UK, the serum is diluted with 50% saline and is transferred into sterile dropper bottles ready to be frozen. SED have a shelf life in the freezer of 12 months from the date of donation.

The Current Situation and Need for Guidance

Currently, SED is a highly specialised and high cost intervention for patients with Ocular Surface Disease. The Medicines and Healthcare products Regulatory Agency (MHRA), the government body that regulates medicines and medical devices, classifies SED treatment as an unlicensed medicine. This means all licensed medical options should be considered by the doctor responsible for the patient before they are able to prescribe SED. There is geographical inequity in access to treatment that is currently being considered for exclusion from the National Tariff as a High Cost Drug. This guidance aims to set out defined criteria for the use of SED, the monitoring of clinical and patient - reported outcomes and therefore improving patient care and safety whilst on treatment.

Good Practice Points and Recommendations Relevant to Patients

Using The Royal College of Ophthalmologists' Guidelines Development Manual, a systematic review of literature has been carried out in order to focus on the best evidence available so that key questions may be addressed. Recommendations affecting patients as key stakeholders may be summarised as follows.

- SED will benefit patients who have not responded or only partially responded to licensed interventions.
- When comparing the cost and clinical effectiveness of Auto-SED vs. Allo-SED in the treatment of people with OSD, it is recommended that if a patient is unable to donate one unit of blood or a patient requires urgent treatment, Allo-SED are recommended.
- Published studies internationally focus on concentrations of 20%, 50% and 100%. 50% is considered by NHSBT to be the best concentration for general use, although there are no internationally agreed standard procedures for the manufacture.
- There is no clear evidence regarding the duration of treatment or the effect of treatment with SED. It is recommended that treatment should either be for a defined period or there should be an appropriate point when it is stopped in order to assess the outcome. Patient- reported outcomes are an essential tool.

Monitoring

It is recommended that patients treated with Auto-SED and Allo-SED should be enrolled on a national programme of outcome reporting that include patient reported outcomes. Reports should include: frequency and duration of treatment and serious adverse events and reactions. Attempts to withdraw treatment and duration of remission should be recorded.