

# Trehalose SG for Dry Eye :

## Potential Clinical Applications

Dry eye syndrome, comprising Sjögren syndrome, is the most prevalent disease of the eye. Population-based studies have shown that the prevalence ranges from 10 to 20% and becomes higher among the elderly people.

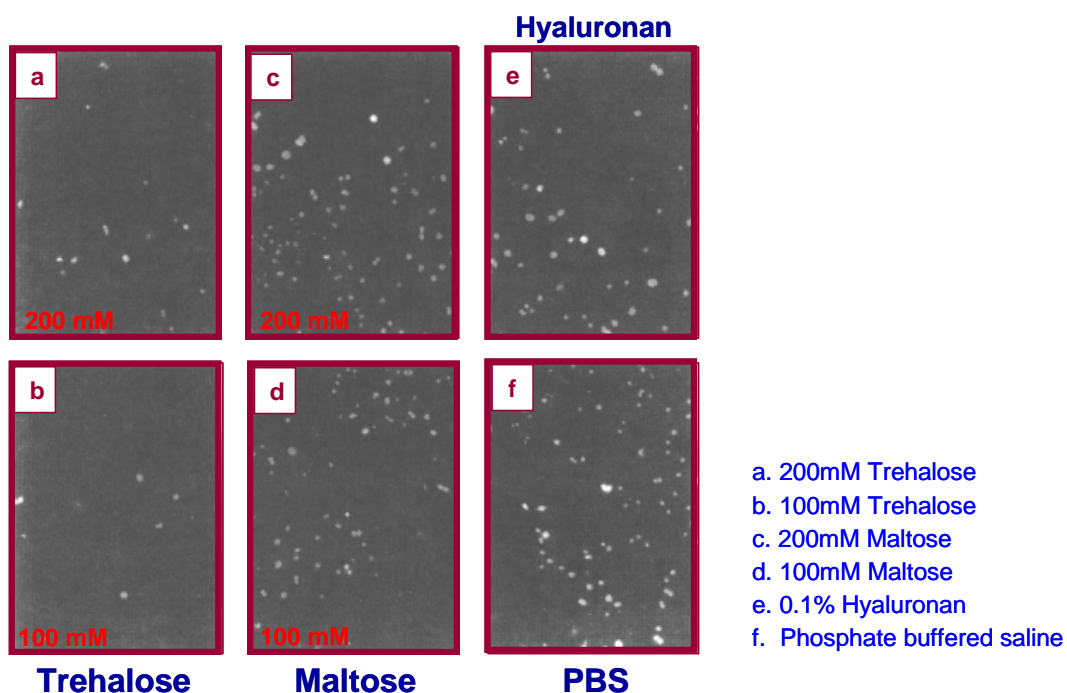
Trehalose SG is known as a carbohydrate resistant to dehydration, suggesting a medical application of Trehalose SG to the dryness-induced dysfunction of organs (e.g. eyes, nose, mouth). It is autoclavable and has a lower viscosity compared to hyaluronic acid, cellulose and dextran due to its low molecular weight. These characteristics make Trehalose SG ideally suited for use in eye drop formulations.

In Vitro and human clinical studies have been undertaken to assess the potential of Trehalose SG to address dry eye syndrome. [T. Matsuo, et al., *Ophthalmology*. \*1 & 2: **85**: 610-612, 2001, \*3: **109**: 2024-2029, 2002]

The in vitro studies have shown that Trehalose SG both reduces the number of dead human corneal epithelial cells and protects them from death by drying. The clinical studies showed that Trehalose SG was an effective and safe eye drop treatment of moderate to severe dry eye syndrome.

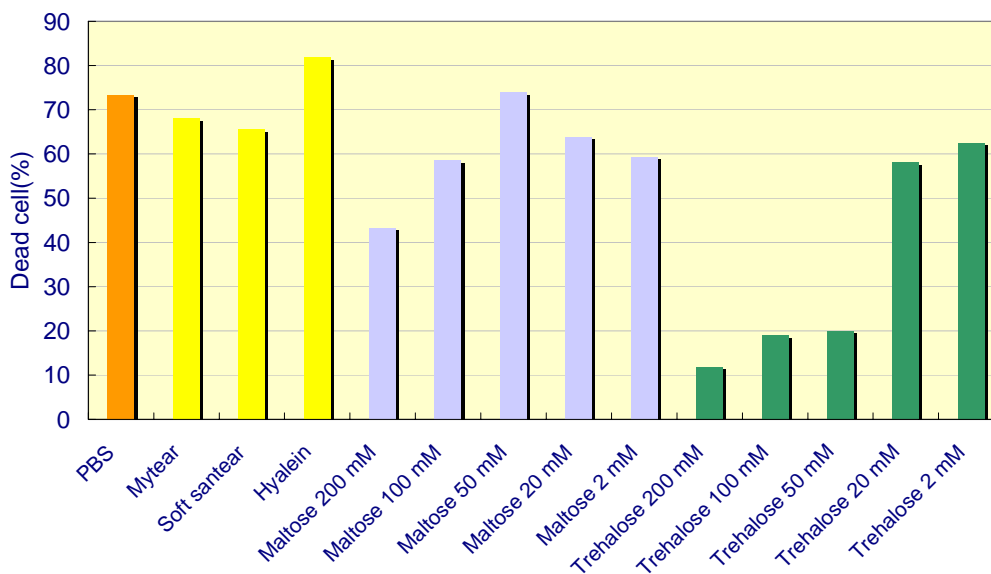
### In Vitro Study \*1

**The use of Trehalose SG reduces the number of dead human corneal epithelial cells after 30 minutes desiccation.**



## In Vitro Study \*2

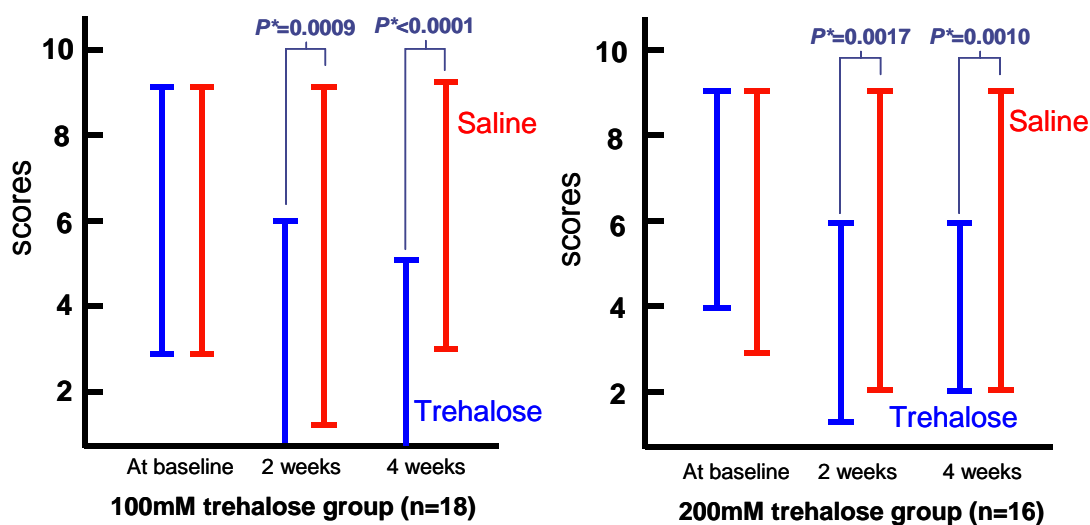
Trehalose SG protects corneal epithelial cells from death by drying.



## Human Clinical Study \*3

A randomized, double-masked, dose-ranging, fellow eye-controlled, clinical study in which the eyes of each patient were randomized to treatment or placebo (solvent) group. Thirty-four patients (1 male and 33 females) with moderate-to-severe dry eye syndrome including both Sjögren type (26 patients) and non-Sjögren type dry eye. The patients used either 100 or 200 mM Trehalose SG (18 and 16 patients, respectively) dissolved in saline six times daily in one eye and control saline in the other eye for 4 weeks.

### ◆ Rose bengal staining score



\*: by Mann-Whitney U Test

## **CONCLUSION**

Trehalose SG solution was an effective and safe eye drop for the treatment of moderate-to-severe dry eye syndrome in the group of patients in the clinical study conducted. The study showed that 100 mM was an appropriate concentration of Trehalose SG solution effective for tear film breakup time as well as fluorescein and roese bengal scores. No adverse effect was noted in the Trehalose SG group.