

## A useful therapy

# Drops significantly increase lipid layer thickness, study finds

Instillation of one drop increased thickness of lipid layer by 110% from baseline in trial

By Lynda Charters

Reviewed by Donald R. Korb, OD

Fort Lauderdale, FL—Instillation of one drop of Soothe eye drops (Alimera Sciences Inc.) significantly increased the thickness of the lipid layer, which is critical in dry eye disease, in patients with symptoms of dry eye. In these patients, the lipid layer thickness increased by 110% compared with the pretreatment

value, according to Donald R. Korb, OD.

In comparison, one drop of Systane (Alcon Laboratories), the second study drug, increased the thickness of the lipid layer by 18%, he said.

The results of the study confirm that the “lipid layer is an important component of the tear film that needs to be addressed in the treatment of dry eye states and dry eye symptoms,” said Dr. Korb, who is in private practice in Boston. He is also the director of research of Ocular Research of Boston, and reported the results of the study at the annual meeting of the Association for Research in Vision and Ophthalmology.

Soothe, he explained, is the first metastable, oil-in-water emulsion. It contains the active ingredient Restoryl (neutral oils) and a dual surfactant system. The neutral oils are the component that establishes the thickness of the lipid layer and the oils are joined to the aqueous system by the amphiphilic surfactant system. Systane is the first eye drop that contains hydroxypropyl

**‘[The] lipid layer . . . needs to be addressed in the treatment of dry eye states.’**

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guar, which does not seem to work in the same manner to increase the thickness of the lipid layer.

### Head-to-head comparison

Fifty subjects with dry eye participated in a double-blind trial of the two products. Individuals were eligible for the study if they had dry eye symptoms, which were verified by a questionnaire, a baseline lipid layer thickness that was less than 75 nm, and fluctuations in the lipid layer that were less than

### Take-Home Message

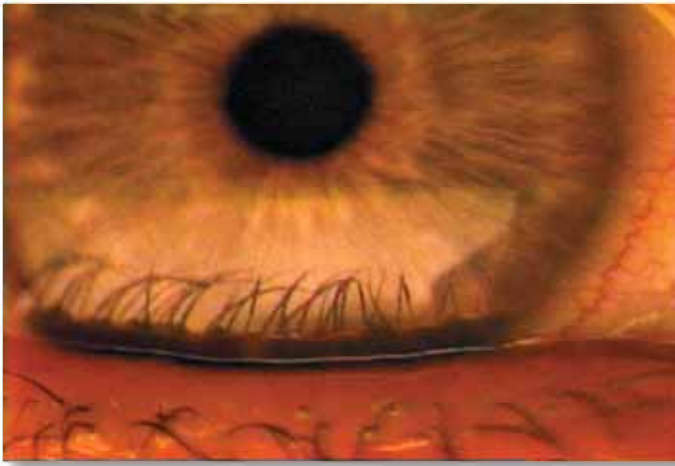
Instillation of one drop of Soothe eye drops (Alimera Sciences) significantly increased the thickness of the lipid layer by 110% of the pretreatment value, which is critical in dry eye disease, in patients with symptoms of dry eye. In comparison, one drop of Systane (Alcon Laboratories), the second study drug, increased the thickness of the lipid layer by 18%.



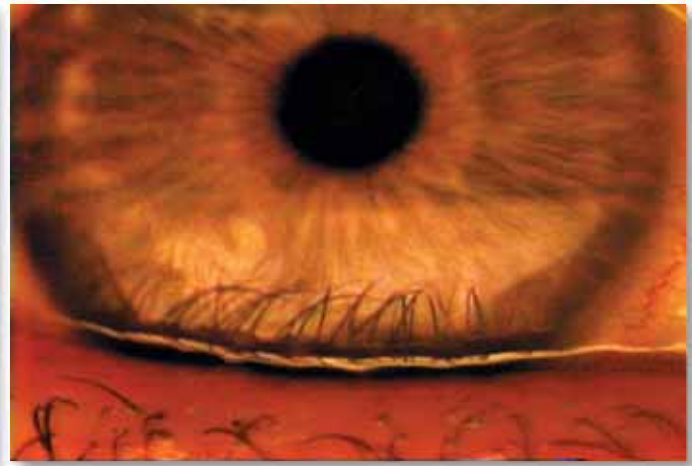
**Figure 1** The baseline lipid layer thickness (LLT) prior to Soothe is 45 nm. The colored waves in the interference pattern of the zone of specular reflection are classified as gray/white.



**Figure 2** Fifteen minutes after the instillation of Soothe, LLT (165 nm) is optimal. The colored waves in the interference pattern of the zone of specular reflection are classified as blue/brown. Note the horizontal wave patterns.



**Figure 3** The baseline LLT prior to Systane is 45 nm. The colored waves in the interference pattern of the zone of specular reflection are classified as gray/white.



**Figure 4** Fifteen minutes after the instillation of Systane, LLT remains unchanged (45 nm). The colored waves in the interference pattern of the zone of specular reflection are classified as gray/white. Note the splotchy pattern visible in the lipid layer. (Photos courtesy of Donald R. Korb, OD)

15 nm during a 15-minute period of observation.

The exclusion criteria included a baseline lipid layer thickness that exceeded 75 nm, a difference in lipid layer thickness of more than 15 nm between the two eyes, and an increase in the lipid layer thickness that exceeded 15 nm after forceful blinking.

Subjects also could not have used an eye lubricant or ointment during the 36 hours before the study started.

Each subject received one drop of Soothe in one eye and one drop of Systane in the other eye. After instillation, the thickness of the lipid layer was measured by interferometry 1, 5, and 15 minutes after instillation of the drops. Care was taken to maintain constant temperature (25°C) and humidity (35% to 50%) in the exam room.

The mean thicknesses of the lipid layer before eye drop instillation were  $59.7 \pm 1.8$  and  $61.5 \pm 1.8$  nm, respectively, in the eyes that received Soothe and Systane; the difference between the two values did not

reach significance.

After instillation of Soothe, the mean of the three measurements showed that the thickness of the lipid layer increased from 59.7 to  $125.1 \pm 4.9$  nm ( $p < 0.0001$ ). After instillation of Systane, the mean of the three measurements showed that the thickness increased from 61.5 to  $72.6 \pm 2.6$  nm ( $p < 0.0001$ ), Dr. Korb reported.

“The 110% mean increase in the lipid layer thickness achieved with Soothe was significantly greater than the 18% mean increase achieved with Systane ( $p < 0.0001$ , paired t-test,  $t_{39} = 11.94$ ),” he said.

Mimicking the mucin layer may be a key factor in how these products work, Dr. Korb said.

“The results of this study indicate that Soothe increased lipid layer thickness more than Systane. Evaporation of water from the eye decreases in higher ambient humidity, implying that the aqueous layer is thicker with higher ambient humidity,” Dr. Korb said. “Since lipid layer thickness has

been shown to be thicker with higher ambient humidity, it appears that an increase in lipid layer thickness, like that achieved with Soothe, probably corresponds to a related increase in the thickness of the underlying aqueous layer of the tears.

“Since Systane also increased the thickness of the lipid layer, albeit a small amount in contrast to Soothe, products designed to mimic the mucin layer may also increase the aqueous layer of the tears to some degree,” he said. OT

FYI

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Dr. Korb has a proprietary interest in this technology.

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