Results Of A US Community-based Evaluation Of A Lubricating Eye Drop Containing HP-Guar

Johan Przydryga, MD and Ilan Hartstein, MD

ABSTRACT

Purpose: Evaluation of a lubricating eye drop containing HP-Guar in reducing ocular discomfort and dry feeling eyes.

Methods: 168 subjects were enrolled at 29 sites in an open label study conducted in the US. Subjects enrolling in the study reported that their eyes "felt dry enough to want to use eye drops" at least "some of the time." Saline was used during a 7 day run-in period, 4 times per day (baseline). Eligible subjects met the screening requirements and used the test lubricating eye drop (**Systane**® Lubricating Eye Drops) 4 times per day for 28 days. Ocular discomfort assessments included feeling of dryness, irritation, burning, stinging, grittiness, foreign body sensation and overall ocular discomfort. Dry feeling eyes were rated using a Likert questionnaire.

Results: Overall ocular discomfort was significantly less at 28 days compared to baseline (p<0.0001) and screening (p<0.0001). Treatments used prior to screening included CMC, glycerin/ polysorbate and hypromellose containing eye drops. Feelings of dryness, irritation, burning, stinging, grittiness and foreign body sensation were all significantly less at 28 days compared to baseline (p<0.0001). Assessments of dry feeling eyes at 28 days were also observed in favor of **Systane**® with less morning (p<0.0001) and end of day dryness (p<0.0001) and ability to forget my symptoms during use of the drops (p<0.0001) compared to baseline.

Conclusion: **Systane**® Lubricating Eye Drops effectively reduces ocular discomfort and dry feeling eyes. Measurable improvement of symptoms is seen within 28 days for the majority of subjects.

INTRODUCTION

Ocular discomfort and dry feeling eyes may be caused by a variety of environmental factors such as dust, smoke, ozone, air conditioning and concentrated use of computers, among others. Environmentally induced ocular discomfort results from either a tear deficiency or excessive tear evaporation; both render the tear film susceptible to the environmental factor(s). The ocular surface environment is made up of surface epithelial cells, the glycocalyx and the tear film. An insult to any of these components caused by the environment can lead to a temporary disruption of the tear film, with possible accompanying damage to the epithelial cells. Symptoms felt may include dryness, burning, grittiness, and foreign body sensation.

The predominant strategy for relieving ocular discomfort and dry feeling eyes has been to use ocular lubricants. Ocular lubricants wet the ocular surface and combine with the existing tear layer to provide relief. Typically, only short-term relief is provided by the ocular lubricants due to a short retention time on the ocular surface. However, longer relief may be provided with new technologies that provide longer retention time.

Alcon Laboratories recently introduced **Systane**® Lubricating Eye Drops. **Systane**® contains polyethylene glycol 400 and propylene glycol demulcents with the polymer hydroxypropyl guar (HP-Guar) as a gelling agent. When exposed to the pH of the ocular surface and tears, the HP-Guar in **Systane**® forms a "soft" gel with increased viscosity and bio-adhesive properties that are designed to promote the retention of the two demulcents, protecting the ocular surface environment.[1] The formulation of this tear supplement is preserved with POLYQUAD (0.001%) and contains the essential ions potassium, calcium, magnesium, zinc, and sodium.

With many ocular lubricants available, it is increasingly important that their clinical efficacy be assessed under normal use conditions. This study was designed to learn about the performance of **Systane**® Lubricating Eye Drops in one month of use by subjects experiencing symptoms of ocular dryness.

METHODS

Study Design: This was an open label, multi-center, prospective design of five weeks duration.

Subjects: One hundred sixty eight subjects were enrolled at 29 sites in the US in environmentally dry areas; 147 subjects were evaluable per protocol. Subject ages ranged from 28 to 90, with the median age 67. Subjects enrolling in the study reported that their eyes "felt dry enough to want to use eye drops" at least "some of the time."

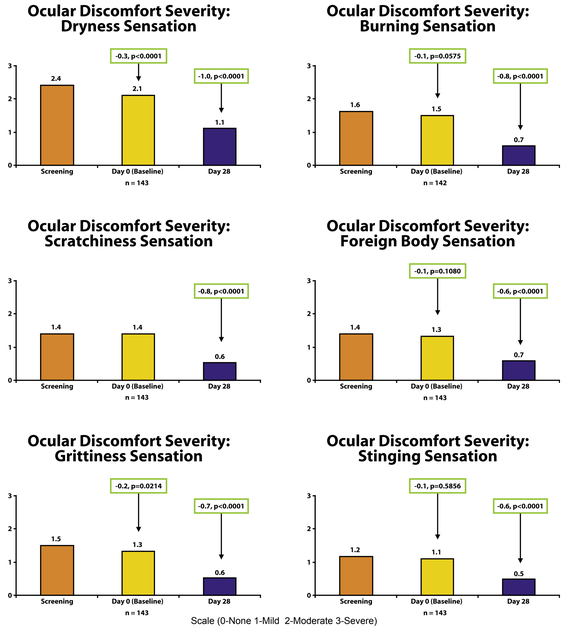
Study Design

Visit 1 Day -7	Screening Visit If eligible, dispense Rewetting Drops (QID)
Visit 2 Day 0	Eligibility Visit If meet enrollment criteria, dispense **Systane**® Lubricating Eye Drops (QID)
Visit 3 Day 28	Final Study Visit

Ocular Discomfort Scales: Severity of six ocular discomfort sensations was recorded on a four point scale (0=none, 1=mild, 2=moderate, 4=severe).

Comfort Subjective Questions: Subjects ranked their agreement to each Likert style statement from 1 (Strongly Disagree) to 5 (Strongly Agree). The change from baseline score is reported.

OVERALL RESULTS



Comfort Subjective Questions

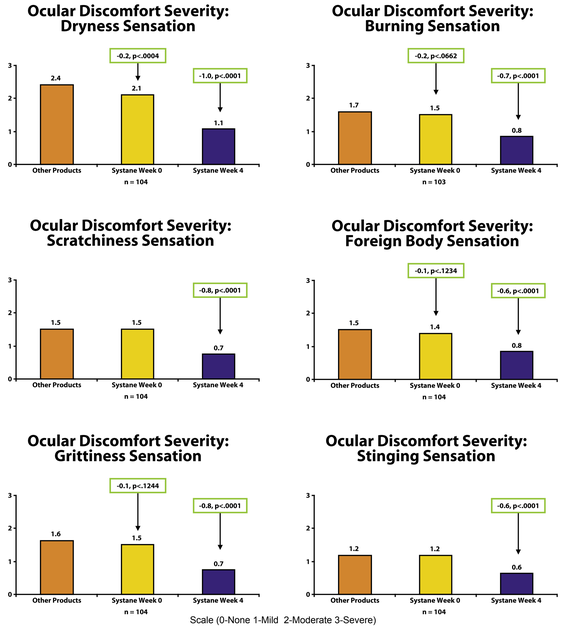
Change from baseline

Question	Change	% Change
My eyes feel dry in the morning.	-0.8*	-19%
My eyes feel dry at the end of the day.	-0.9*	-22%
My eyes feel comfortable upon instillation of drops.	+0.5*	+13%
My eyes feel refreshed when I use the drops.	+0.6*	+17%
My eyes feel refreshed longer than expected when I use the drops.	+0.8*	+28%
I frequently forgot my symptoms during the use of the drops.	+0.7*	+26%

*p<0.0001

SUB-GROUP RESULTS

Sub-Group = subjects that used other lubricating eye drops at screening



CONCLUSIONS

- A decrease in symptoms typically associated with ocular dryness was seen after use of **Systane**® QID for 28, including dryness, burning, scratchiness, foreign body sensation, grittiness, and stinging.
- Increased comfort was shown with **Systane**® use, as indicated by the subjects' responses to Likert style acceptability questions.
- These results may be attributed to the action of the demulcents (polyethylene glycol 400 and propylene glycol) and the polymer HP-Guar in **Systane**®.

REFERENCES

[1] Asgharian B, Nolen L, Meadows D, and Stone R, Novel Gel-forming Ophthalmic Polymer System for Artificial Tear Solution. Abstract #2472 *ARVO Meeting*, May 2003.