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# **Cessation of Systane<sup>®</sup> Lubricating Eye Drops and Return of Dry Feeling Eyes**

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## Abstract

**Purpose:** To determine the length of time after discontinuing use of an effective lubricating eye drop before symptoms associated with dry feeling eyes return.

**Methods:** 20 successful users of Systane were enrolled at one site in the United States in an open label non-controlled clinical study of 5 weeks duration. Average pre-study Systane use was 1/day. Symptom frequency was obtained at each visit. The Shein questionnaire was used to obtain symptom frequency (0 = none; 4 = all of the time for Burning, Dryness, Grittiness, Redness, Crusty Lashes and Stuck Eyelids). Subjects were told to discontinue Systane use and return for reevaluation on a weekly basis.

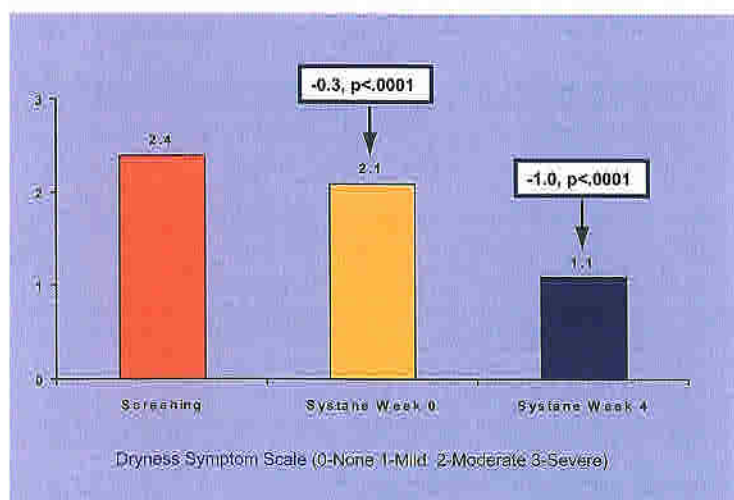
**Results:** Two subjects exited after one week without Systane use and five made it to 5 weeks (Average time off Systane use = 3.5 weeks). Symptom frequency showed significant increases from baseline for Burning ( $p=0.0004$ ), Dryness ( $p<0.0001$ ), Grittiness ( $p=0.0005$ ) and Redness ( $p=0.0141$ ) with a trend for Crusty Lashes ( $p=0.0583$ ). Stuck eyelids did not show a significant difference ( $p=0.2845$ ). A composite of all symptoms demonstrated a highly statistically significant ( $p<0.0001$ ) change from baseline.

**Conclusion:** Previous studies have demonstrated Systane's efficacy when compared to a marketed control by reducing the symptoms associated with dry feeling eyes. This study showed that upon discontinuation of Systane, subject's symptoms return on average within 3.5 weeks. This study was sponsored and conducted by Alcon Research Ltd, Fort Worth, TX USA.

## Introduction

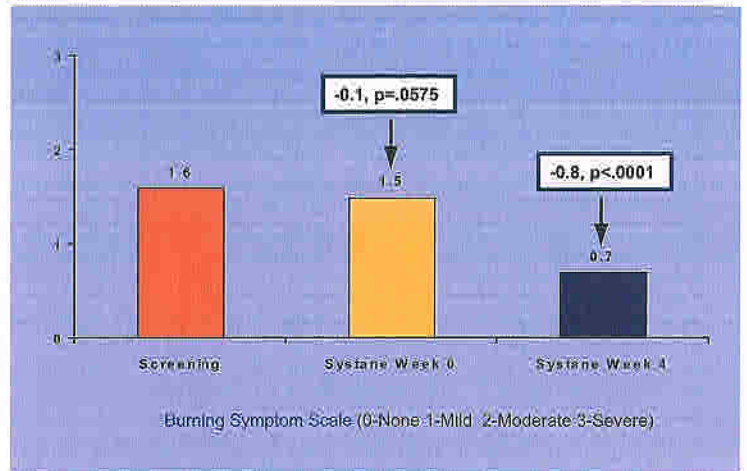
The efficacy of Systane® Lubricating Eye Drops has been demonstrated in at least two previous studies. The first study enrolled 168 subjects at 29 sites in a 28 day non-controlled clinical study conducted in the United States.<sup>1</sup> Systane effectively reduced ocular discomfort and dry feeling eyes. Selected results are shown in Figures 1-2 below.

**Figure 1:** A comparison of ocular discomfort severity (Dryness)



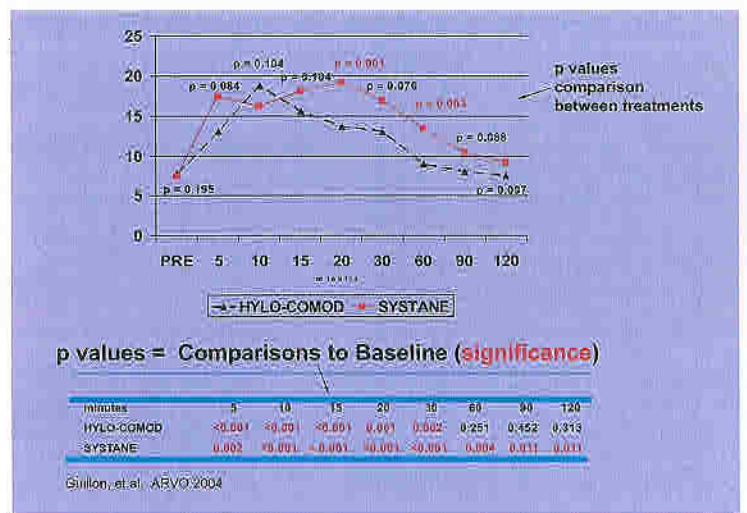
## Introduction - Cont'd

**Figure 2:** A comparison of ocular discomfort severity (Burning)



The second study compared tear film break-up time (TFBUT) between Systane and Hylocomod using the TearScope™.<sup>2</sup> 15 patients with unstable tear film were enrolled in this double masked cross-over study. Systane extended TFBUT for 120 minutes compared to only 30 minutes for Hylocomod (Figure 3).

**Figure 3:** A comparison of Tear Film Break-up Time results



The purpose of this study was to understand the length of time for the return of dry feeling eyes once use of Systane has been discontinued.

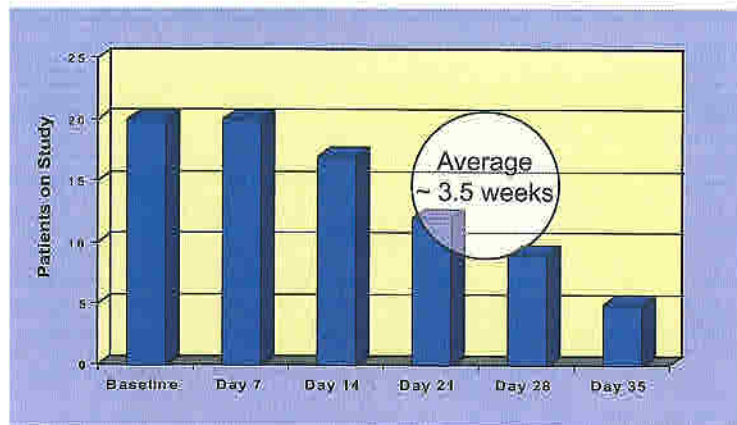
## Methods

20 successful users of Systane were enrolled at one site in the U.S. in an open label non-controlled clinical study of 5 weeks duration. Subjects were required to be using Systane at least one time per day. Average pre-study Systane use was 2.1/day. Frequency of symptoms over the previous 3 days (1 = none; 4 = all of the time for Burning, Dryness, Grittiness, Redness, Crusty Lashes, Stuck Eyelids) were obtained at each visit. Subjects were told to discontinue Systane use and return for reevaluation on weekly basis. Subjects were evaluated upon exit from the study by the investigator.

# Results

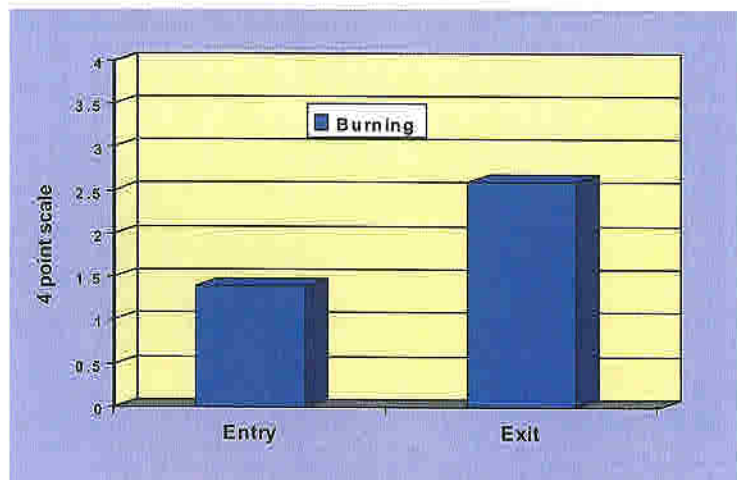
Two subjects exited after one week without Systane and five made it to 5 weeks (Figure 4) with an average time off Systane of approximately 3.5 weeks.

**Figure 4:** Time required before the feeling of dry eyes caused subjects to exit the study.

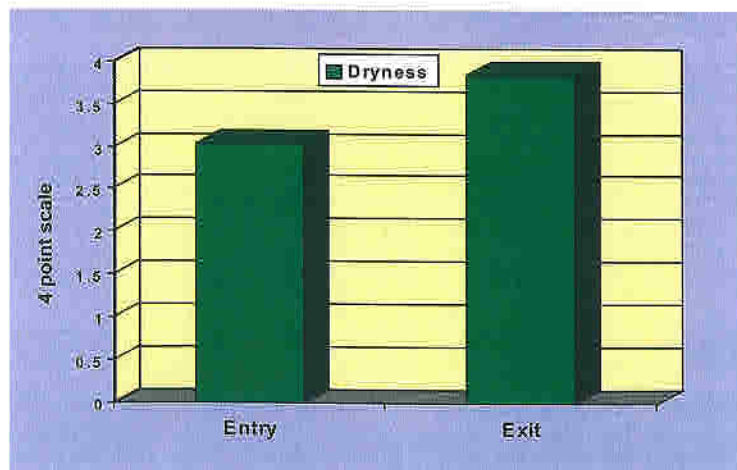


Symptom frequency showed significant increases from baseline for Burning ( $p=0.0004$ ), Dryness ( $p<0.0001$ ), Grittiness ( $p=0.0005$ ) and Redness ( $p=0.0141$ ) (Figures 5-8).

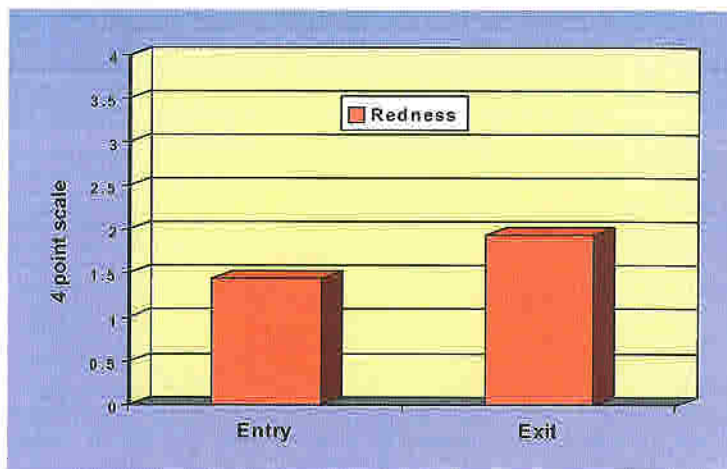
**Figure 5:** Subjective assessment of ocular discomfort (Burning) at Entry with Systane and Exit without Systane.



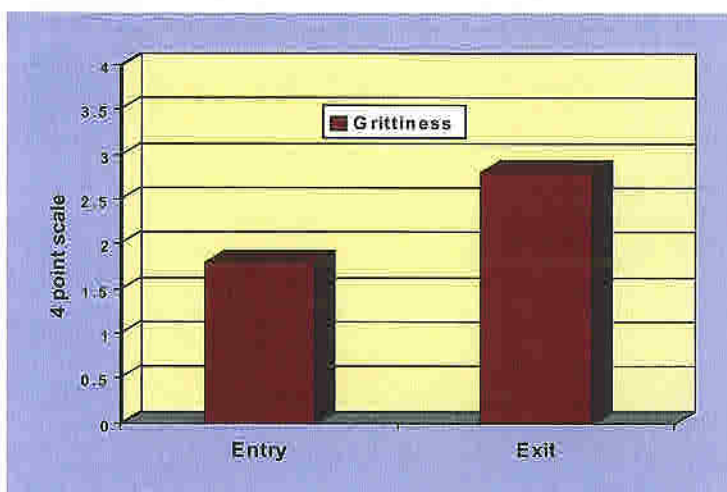
**Figure 6:** Subjective assessment of ocular discomfort (Dryness) at Entry with Systane and Exit without Systane.



**Figure 7:** Subjective assessment of ocular discomfort (Grittiness) at Entry with Systane and Exit without Systane.



**Figure 8:** Subjective assessment of ocular discomfort (Redness) at Entry with Systane and Exit without Systane.



## Conclusions

Previous studies have demonstrated Systane's efficacy when compared to a marketed control by reducing the symptoms associated with dry feeling eyes. This study showed that upon discontinuation of Systane, subject symptoms return on average within 3.5 weeks. With continued use of Systane, the symptoms of dry feeling eyes are significantly reduced.

## References

- 1 Hartstein I, Khwarg S, Przydryga J. An Evaluation of Systane Lubricant Eye Drops for Relief of Dry Eye Signs and Symptom in an Adult Population. *Current Medical Research and Opinions*. 2005;21(2):255-260
- 2 Guillon M, Chamberlain P, Marks MG, Stein J. Effect of Eye Drop Compositional Characteristics on Tear Film. 2004 ARVC Abst. #3878.