Corneal Staining Reductions Observed after Treatment with Systane® Lubricant Eye Drops

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ABSTRACT

Introduction: Because of the added emphasis on ocular surface damage included in the Dry Eye Workshop’s revised definition of dry eye, an evaluation of corneal staining reductions was conducted for propylene glycol/polyethylene glycol 400-based artificial tear drops (Systane® Lubricant Eye Drops; Alcon Laboratories, Fort Worth, TX, USA).

Methods: An analysis was conducted on the percent change from baseline in mean corneal staining scores as reported in two previously published, randomized, double-masked, 6-week clinical studies of Systane. A descriptive comparison was also made between the outcome of the composite analysis and data obtained for Optive™ Lubricant Eye Drops (Allergan, Inc., Irvine, CA, USA). Finally, results were reviewed for an open-label study that investigated corneal staining over a 5-week period after patients discontinued Systane therapy.

Results: The composite analysis included 107 Systane-treated patients. The results showed that Systane consistently reduced corneal staining at each visit; the percent change from baseline to day 42 (exit) was 47.1% ($P<0.0001$). After discontinuing Systane, immediate and significant increases in corneal staining were reported by 20 patients, with an overall increase from baseline to day 35 (exit) of 195.0% ($P<0.0001$).

Conclusion: Evaluations of sum corneal ocular staining scores provide clinically meaningful evidence of dry eye severity, and are an important indicator of dry eye disease progression. The results of the composite analysis of two peer-reviewed studies indicate that Systane significantly reduced corneal staining ($P<0.0001$), indicating a reduction in the severity of dry eye.
Finally, discontinuation of Systane results in a rapid increase in corneal staining that further confirms Systane’s ability to maintain ocular surface health.

**Keywords:** dry eye; inflammation; ocular staining; ocular surface; Systane

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**INTRODUCTION**

Dry eye (keratoconjunctivitis sicca) is an ocular condition that affects millions of Americans of varying ages, sexes, and overall physical health. In fact, a review of recent epidemiological studies indicates that the prevalence is approximately 10% in individuals who are over 40 years of age and increases to nearly 15% in patients who are over 65 years; the prevalence of the condition also increases in postmenopausal women and in patients with autoimmune diseases. More specifically, these estimates indicate that around 20-30 million US patients suffer from early-stage dry eye and that roughly another 9 million US patients suffer from moderate to severe dry eye.

Dry eye results from both an inadequate quantity of tear film and a disturbance of tear film stability. Unlike many conditions wherein the associated signs and symptoms generally manifest in fixed combination, patients who suffer from dry eye may or may not exhibit symptoms that include dryness, burning, photophobia, foreign body sensations, grittiness, and redness, and may or may not have signs that include rapid tear film breakup, increased osmolarity, and ocular surface staining. During the early stages of dry eye, it is not uncommon for symptoms to be present without any accompanying signs. As the condition progresses, however, the ocular surface damage becomes more significant even though the symptoms may lessen.

In 1995, the National Eye Institute (NEI)/Industry Dry Eye Workshop published a definition of dry eye that stated, “Dry eye is a disorder of the tear film due to tear deficiency or excessive evaporation, which causes damage to the interpalpebral ocular surface and is associated with symptoms of ocular discomfort.” In 2007, the International Dry Eye Workshop’s (DEWS) Subcommittee for Definition and Classification revised this definition to state, “Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.” This new definition not only recognizes the effect of dry eye on visual function, but also adds a new emphasis to the roles of hyperosmolarity of the tear film and inflammation of the ocular surface.

Current common management and therapy of dry eye includes the use of lubricants (so-called “artificial tears”), anti-inflammatory therapies, biological tear substitutes, and systemic use of antioxidants (omega-3 fatty acids). It should be noted, of course, that effective manage-