Systane® Ultra Lubricant Eye Drops for Treatment of Contact Lens–Related Dryness

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Objectives: To assess the clinical performance of Systane® Ultra lubricant eye drops in daily disposable soft contact lens wearers who experience contact lens–related dryness.

Methods: In this randomized, investigator-masked study, daily disposable lens wearers with symptoms of dryness were randomized to use Systane Ultra lubricant eye drops or to no treatment. The lubricant regimen was applied twice a day, 10 minutes before lens insertion and after lens removal, for the 2-week study period. Subjective comfort, wear time, and visual acuity were assessed at baseline and after 2 weeks.

Results: A total of 89 daily disposable lens wearers were randomly assigned to the Systane Ultra group (n=44) or the control group (n=45). Two weeks of Systane Ultra lubricant eye drop use resulted in a significant increase in comfortable lens wear time when compared with baseline assessment (P=0.001) and a trend toward significant improvement compared with the control group (P=0.078). End-of-the-day comfort was significantly improved in the Systane Ultra group compared with the control group (P=0.007). A significant reduction in the overall dryness (P<0.001) and end-of-day dryness (P=0.047) was observed in subjects using the Systane Ultra lubricant eye drops compared with the control group.

Conclusion: The study demonstrates that Systane Ultra lubricant eye drops applied before and after contact lens wear is an effective artificial tear for alleviating symptoms of contact lens–related dry eye.

Key Words: Artificial tear solutions—Contact lens—Contact lens-related dryness—Ocular dryness—Ocular lubricants—Rewetting drops.

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INTRODUCTION

Contact lens wear is frequently associated with symptoms of ocular irritation, including symptoms of dryness, discomfort, soreness, and tiredness.[1–3] Evidence suggests that the frequency of contact lens–related dry eye ranges between 25% and 50% among current contact lens wearers.[2,4,5] Although for some, the dryness is not bothersome enough to remove their lenses, as many as 20% of contact lens wearers experience dry eye symptoms that are severe enough for them to reduce their wearing time.[2,3] In addition, it has been reported that dryness and discomfort are the primary reasons for patients to cease contact lens wear.[1,6,7]

The origin of contact lens–related dry eye remains elusive. However, the presence of a contact lens on eye affects the nature of tear film dispersal.[8] Evidence suggests that lipid deficiency causing excessive evaporation of the tear film is associated with contact lens–related dryness.[9] A reduction in the prelens tear film lipid layer and an increase in tear film evaporation are attributed to contact lens wear, resulting in the precipitation of dryness symptoms.[9,10] Furthermore, the disruption of the tear film by contact lens wear may lead to compromised functional visual acuities,[11,12] reduced wear time,[2,3] and an increased risk of ocular surface desiccation, bacterial binding, and infection.[13,14]

Traditionally, rewetting drops are the most common first-line option for treating the symptoms of contact lens–related dryness. However, technologic advances and innovations have led to the development of artificial tear solutions, also known as lubricant eye drops, which mimic the tear film functionally and protect the ocular surface from dryness. Recently, several artificial tear solutions have been introduced to reduce dry eye symptoms. They differ mainly in the composition of electrolytes, metabolites, viscosity, osmolarity, and the presence or absence of compatible solutes and preservatives.[15] Systane Ultra lubricant eye drops (Alcon Laboratories, Inc., Fort Worth, TX) is a new-generation ocular lubricant that has been developed with a unique intelligent delivery system for the treatment of dry eye symptoms.[16,17] It is an aqueous solution composed of polyethylene glycol 400 (0.4%) and propylene glycol (0.3%) as demulcents and incorporates the benefits of hydroxypropyl guar as a gelling agent.

The constituents of Systane Ultra lubricant eye drops have been used successfully in ophthalmic preparations and contact lens care products and have demonstrated compatibility with the ocular surface.[18–20] On instillation in the eye, Systane Ultra lubricant eye drops spreads readily and distributes evenly across the ocular surface. Subsequently, the macromolecular in situ gelling agent, hydroxypropyl guar, in the Systane Ultra formulation interacts with borate ions and mucin in the tear film and facilitates the development of a viscoelastic gel matrix with bioadhesive and pseudoplastic properties. The gel matrix promotes retention of the active demulcents for tear film stability, lubrication, and protection of the ocular surface. Moreover, the Systane Ultra formulation contains a water-soluble nonionic compound, sorbitol, as a key ingredient that interacts with borate to control viscosity in the bottle for optimal delivery to the eye. The unique viscoelastic properties of

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Systane Ultra lubricant eye drops were designed to offer symptom relief for people experiencing ocular dryness and may also provide relief for contact lens wearers who experience contact lens–related dryness.

Previous studies have shown that Systane Ultra lubricant eye drops remain on the eye longer than other drops,[22] with one study showing no adverse events when used before, at least once during wear, and after contact lens wear.[16] These findings may indicate that lubricant eye drops deliver extended protection and provide long-lasting relief from dryness symptoms. The purpose of this study was to assess the clinical performance of Systane Ultra lubricant eye drops in daily disposable soft contact lens wearers who experience dryness symptoms.

METHODS

Study Population

Southern College of Optometry and Sterling institutional review board approval was obtained for the study. Informed consent was obtained from all study participants and the study was performed in compliance with good clinical practice guidelines and the ethical principles of the Declaration of Helsinki. This prospective multicenter, randomized, investigator-masked clinical study included subjects aged 18 years and older. All subjects must have had best-corrected distance visual acuity with contact lenses of 20/30 or better in each eye. Subjects were eligible only if they reported ocular dryness (symptomatic for end-of-day dryness) as a result of wearing daily disposable soft contact lenses.

Eligible subjects responded to the screening questions as stated in Table 1.[22,23] To question 1, subjects had to either strongly disagree or disagree and to questions 2 and/or 3, subjects had to either agree or strongly agree. Subjects with cardiovascular disease, hypertension, diabetes, or cystic fibrosis were excluded. Subjects must not have participated in any other ophthalmic drug or device clinical trial within 30 days of enrollment. Subjects were excluded for if they had any systemic or ocular disease or disorder (except refractive disorders or dry eye disease), complicating factor, or structural abnormality that would negatively affect the conduct or outcome of the study. Subjects were also excluded for recent use of medications that could confound study results. Investigators were masked to study treatment.

Eligible subjects with routine daily disposable lens wear were randomly assigned to receive either Systane Ultra or no treatment (control group). Subjects randomly assigned to Systane Ultra received a kit that included habitual daily disposable contact lenses and a bottle of Systane Ultra to use twice a day for the 2-week study period. Subjects were instructed to wear their habitual contact lenses for the 2-week study period. Subjects were instructed to shake the regimen bottle thoroughly and instill 1 to 2 drops of Systane Ultra into each eye 10 minutes before lens insertion and after lens removal. At the end of the study period, all subjects were evaluated for ocular comfort using a standard Likert-type questionnaire with a scale of 1 to 5.

Outcome Assessment

The assessments evaluated the efficacy and safety of Systane Ultra lubricant formulation in daily disposable soft contact lens wearers. Efficacy was established by assessing changes in comfort/acceptability in the Systane Ultra group versus the control group. In addition, change from baseline for all comfort variables was evaluated. Safety was assessed through measures of visual acuity, biomicroscopy examination, and adverse events.

Statistical Analysis

Statistical analysis was performed using SAS software (SAS Institute, Inc., Cary, NC). Outcomes between groups and change from baseline were analyzed by analysis of variance (ANOVA). Estimates of group differences were based on 95% confidence intervals on least squares means from the repeated measures ANOVA.

RESULTS

A total of 89 subjects with routine daily disposable lens wear and mean age of 31±9.6 years were included in this prospective, randomized, investigator-masked study. Ethnicity of the subjects included Caucasian (n=75), African American (n=5), Asian (n=4), and others (n=5). Eligible subjects were randomly assigned to Systane Ultra group (n=44) or control group (n=45). The mean age of the subjects in the Systane Ultra group was 31.3±10.6 years and that in the control group was 30.7±8.6 years. Both groups had a greater proportion of female subjects, and this difference was more pronounced in the control group (Systane Ultra group: 43% male, 57% female; control group: 24% male, 76% female). Study completion rates in the Systane Ultra and control groups were 95.5% (n=42) and 91.1% (n=41), respectively. Demographic

TABLE 1. *Eligibility Questions*

	Subject's Response				
Screening Questions	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
My contacts are comfortable all day long	☐1	☐2	☐3	☐4	☐5
During the day, I take my contacts out earlier than I like because my eyes feel dry	☐1	☐2	☐3	☐4	☐5
Late in the day, my eyes become dry, but I continue to wear my contacts	☐1	☐2	☐3	☐4	☐5

Eligibility screening questions were adapted from previously published studies.[23,24] Adapted with the permission of Alcon Research Ltd.

TABLE 2. *Patient Demographics*

Variable	Systane Ultra	Control	Total
Patients	44	45	89
Mean age, yr	31.3±10.6	30.7±8.6	31±9.6
Male, n (%)	19 (43)	11 (24)	30 (34)
Female, n (%)	25 (57)	34 (76)	59 (66)
Ethnicity (n)			
Caucasian	37	38	75
Black	2	3	5
Asian	4	0	4
Other	1	4	5
Completed study (n)	42	41	83

characteristics and baseline comfort and acceptability were similar in the 2 groups (Table 2).

Subjects in both groups were allowed to continue the use of rewetting drops throughout the study. Various brands of rewetting drops were used by the subjects at baseline (Table 3). Some subjects in both groups used rewetting drops (including artificial tears) at baseline (Systane Ultra: n=16, 36.4%; control: n=18, 40.0%). Few of these subjects decreased (Systane Ultra: n=7, 16.7%; control: n=3, 7.1%) or increased (Systane Ultra: n=2, 4.8%; control: n=4, 9.5%) their use of rewetting drops during the study. Although slightly more rewetting drop users in the Systane Ultra group decreased use compared with the control group, the difference was not statistically significant (P=0.134).

The findings presented in Figure 1 show change in comfortable lens wear time from baseline among the subjects in the Systane Ultra group and the control group. Although the regimen difference in comfortable lens wear time was not statistically significant, a trend toward improvement was observed after 2 weeks of the Systane Ultra lubricant eye drop use, compared with the control group (P=0.078). Two weeks of Systane Ultra lubricant eye drop use resulted in a significant increase in the comfortable lens wear time when compared with baseline (P=0.001). Subjects in the Systane Ultra group reported 1.44 additional hours of comfortable lens wear time. However, no significant change from baseline was seen in the comfortable lens wear time of subjects in the control group (0.34 hours; P=0.444).

Improvement in lens insertion comfort was similar between the Systane Ultra and the control groups (P=0.584; Fig. 2), with a trend toward better insertion comfort for the subjects randomly assigned to Systane Ultra group, when compared with their baseline (P=0.068).

The results presented in Figure 3 demonstrate the change from baseline in achieving comfort at the end of the day among the subjects in the Systane Ultra group and the control group. After 2 weeks of Systane Ultra lubricant eye drop use, subjects reported significantly better end-of-the-day comfort compared with those in the control group (P=0.007). Two weeks of Systane Ultra lubricant eye drop use resulted in a significant increase in end-of-the-day comfort when compared with baseline (P<0.001). However, no significant change from baseline was seen in the control group (P=0.693).

The findings presented in Figure 4 reveal the change from baseline in ocular dryness among the subjects in the Systane Ultra group and those in the control group. After 2 weeks of Systane Ultra lubricant eye drop use, subjects reported significantly less all-day dryness compared with those in the control group (P<0.001). Assessment at 2 weeks indicated that Systane Ultra lubricant eye drop use significantly reduced ocular dryness compared with baseline (P<0.001). However, the ocular dryness remained unchanged in subjects in the control group (P=0.835).

The results presented in Figure 5 indicate the change from baseline in end-of-day dryness. After 2 weeks, subjects in the Systane Ultra group experienced a significant decrease in end-of-day dryness compared with those in the control group (P=0.047) and compared with their baseline (P<0.001). End-of-day dryness was also reduced, albeit to a lesser extent, in subjects in the control group (P=0.020).

Safety Outcomes and Adverse Events

No notable changes were reported in visual acuities from baseline in either group. Slit-lamp biomicroscope examination revealed no abnormalities in the lids/eyelashes, anterior chamber, iris, or lens of all study eyes. There were no serious adverse events reported during this clinical study. However, two subjects, one each in the control group and in the Systane Ultra group, discontinued from the study as a result of mild infection, both of which were determined not to be related to study treatment. The

TABLE 3. *Brand of Rewetting Drops Used by the Study Participants at Baseline and Use of Rewetting Drops*

	Systane Ultra (n=44), n (%)	Control (n=45), n (%)	Total (N=89)
Brand of rewetting drops (baseline)			
Blink contacts lubricant eye drops	4 (9.1)	5 (11.1)	9 (10.1)
Blink preservative-free tears	0 (0.0)	1 (2.2)	1 (1.1)
Complete blink-n-clean lens drops	1 (2.3)	0 (0.0)	1 (1.1)
Equate sterile lubricating drops	1 (2.3)	0 (0.0)	1 (1.1)
Generic artificial tears	1 (2.3)	0 (0.0)	1 (1.1)
OPTI-FREE Express rewetting drops	1 (2.3)	0 (0.0)	1 (1.1)
OPTI-FREE RepleniSH rewetting drops	1 (2.3)	2 (4.4)	3 (3.4)
Optive eye drops	2 (4.5)	3 (6.7)	5 (5.6)
Refresh contacts drops	1 (2.3)	3 (6.7)	4 (4.5)
ReNu MultiPlus lubricating drops	2 (4.5)	1 (2.2)	3 (3.4)
ReNu rewetting drops	0 (0.0)	1 (2.2)	1 (1.1)
Soothe XP eye drops	1 (2.3)	2 (4.4)	3 (3.4)
Target lubricating and rewetting drops	1 (2.3)	0 (0.0)	1 (1.1)
None	28 (63.6)	27 (60.0)	55 (61.8)
Rewetting drop use (baseline and during study)			
Baseline	16 (36.4)	18 (40.0)	34 (38.2)
Decreased usage	7 (16.7)	3 (7.1)	10 (11.9)
Increased usage	2 (4.8)	4 (9.5)	6 (7.1)
No change in use	33 (78.6)	35 (83.3)	68 (81.0)
P value comparing treatment groups			0.134[a]

[a] P value based on a Cochran-Mantel-Haenszel test for row means score difference.

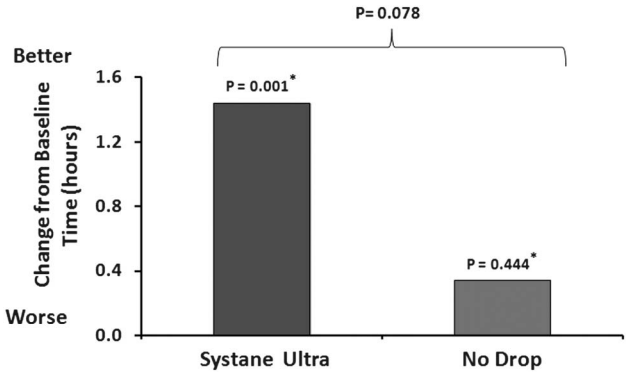

FIG. 1. Comfortable lens wear time change from baseline of the subjects in the Systane Ultra and control groups. Two weeks of Systane Ultra lubricant eye drop use resulted in a trend toward improvement in the comfortable lens wear time compared with the control (P=0.078). *A change in comfortable lens wear time from baseline. A significant increase in the comfortable lens wear time was seen after 2 weeks of Systane Ultra lubricant eye drop use compared with baseline (P=0.001).

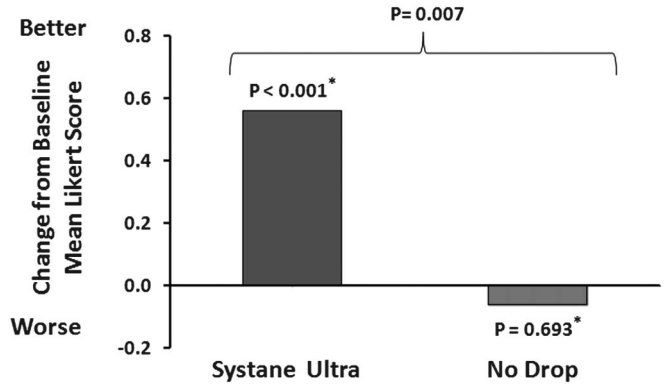

FIG. 3. End-of-the-day comfort change from baseline in the Systane Ultra and control groups. Two weeks of Systane Ultra lubricant eye drop use resulted in a significant improvement in end-of-the-day comfort compared with the control (P=0.007). *A change in end-of-the-day comfort from baseline. A significant increase in end-of-the-day comfort was seen after 2 weeks of Systane Ultra lubricant eye drop use compared with the baseline ($P<0.001$).

subject in the control group experienced herpes simplex virus keratitis; this infection was considered mild and resolved without treatment. The subject in the Systane Ultra treatment group experienced bacterial conjunctivitis, which was considered mild and resolved with antibiotic treatment.

DISCUSSION

The Systane Ultra lubricant eye drop is part of the Systane family of artificial tears, and it is designed to rebuild the tear film for long-lasting lubrication and extended protection of the ocular surface. It offers an additional benefit of an intelligent delivery system to further reduce the assimilation time of the product on the eye. Unlike its previous version Systane, the Systane Ultra formulation includes sorbitol, which serves to optimize the viscosity of the drop.[16,24]

Systane Ultra, when packaged in its bottle, has a pH of 7.9, and the sorbitol/borate/hydroxypropyl-guar complexes are in a state of dynamic equilibrium. On instillation, Systane Ultra lubricant formulation exhibits nonnewtonian characteristics with optimal elastic modulus and viscoelastic properties, which allow for the retention of active ingredients and a low coefficient of friction during the eyeblink process.[25] Moreover, Systane Ultra interacts with natural divalent ions in the tear film (e.g., calcium, zinc, and magnesium) and fortifies the borate/hydroxypropyl-guar cross-links, which in turn prolongs the retention of the demulcents on the ocular surface.[17,26] Furthermore, this cross-linked complex in the tear film provides sustained lubrication to the eye and protects the ocular surface from further damage while the surface epithelial cells undergo repair and renewal.[25]

Superior outcomes have been documented for Systane Ultra for tear film interaction, blur profile, viscoelasticity, and tensile strength, suggesting it to be a beneficial lubricant eye drop product for patients with dry eye symptoms.[16,22,27] The results from this 2-week study demonstrated that Systane Ultra lubricant eye drops are safe with proven efficacy in subjects with contact lens–related dry eye symptoms. Specifically, the results showed that the Systane Ultra lubricant eye drops significantly improve comfortable lens wear time and reduce ocular dryness in daily disposable contact lens wearers symptomatic

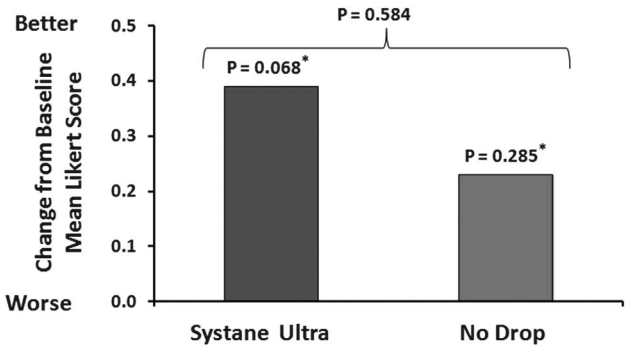

FIG. 2. Lens insertion comfort change from baseline in the Systane Ultra and control groups. Lens insertion comfort improvement was similar between the Systane Ultra and control groups (P=0.584). *A change in insertion comfort from baseline. A trend toward a better insertion comfort was seen after 2 weeks of Systane Ultra lubricant eye drop use compared with the baseline (P=0.068).

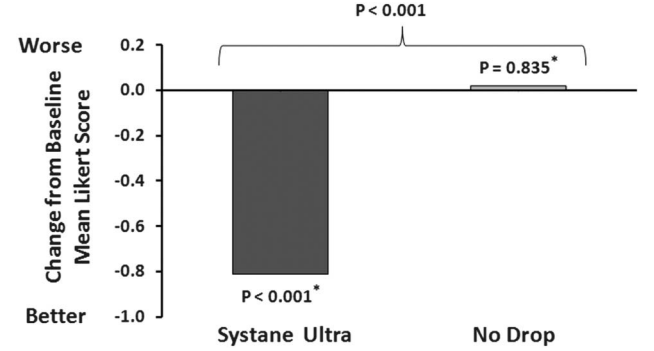

FIG. 4. Ocular dryness change from baseline in the Systane Ultra and control groups. Two weeks of Systane Ultra lubricant eye drop use resulted in a significant decrease in ocular all-day dryness compared with the control ($P<0.001$). *A change in ocular dryness from baseline. A significant decrease in ocular dryness was seen after 2 weeks of Systane Ultra lubricant eye drop use compared with the baseline ($P<0.001$).

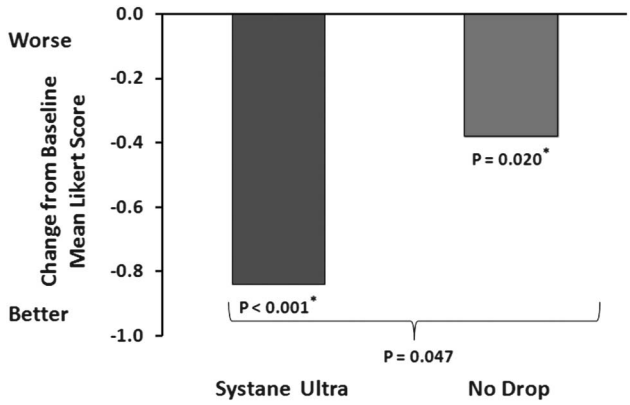

FIG. 5. Change in end-of-day dryness from baseline in the Systane Ultra and control groups. Two weeks of Systane Ultra lubricant eye drop use resulted in a significant decrease in end-of-day dryness compared with the control (P=0.047). *A change in end-of-day dryness from baseline. Compared with the baseline, both the Systane Ultra and control groups had significantly decreased end-of-day dryness (P<0.001 and P=0.020, respectively).

for dryness. Given that approximately 50% of contact lens wearers experience contact lens–related dry eye symptoms[28] and contact lens wear is known to increase the frequency of dryness symptoms,[5] the use of Systane Ultra lubricant eye drops could be useful for subjects with contact lens–related dry eye symptoms.

This was an investigator-masked, randomized study evaluating the clinical benefit of Systane Ultra lubricant eye drops versus no treatment (control) in subjects with contact lens–related dryness symptoms. Although the study did not include a placebo control, by randomizing a group to no treatment, we mimic the alternate standard of care and also addressed the potential bias of an uncontrolled study and associated placebo effect. A previous study included a control placebo drop, and improvement was shown for a similar artificial treatment in a similar population.[29] The results consistently revealed minimal changes from baseline in the control group, whereas those randomized to Systane Ultra lubricant eye drops reported significant effects of the added therapy. The findings of the study provide important insight related to the clinical performance of Systane Ultra lubricant eye drops in subjects with contact lens–related dryness symptoms.

Overall, the findings of the study provide contact lens wearers with an increased confidence in the use of Systane Ultra lubricant eye drops before and after lens wear for the treatment of contact lens–related dryness symptoms. In addition, the Systane Ultra regimen was safe and well tolerated by daily disposable soft contact lens wearers with dryness symptoms.

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