Matured milk was found not to have any inhibitory effect on these causal organisms, whereas colostrums had an inhibitory effect on *Staphylococcus aureus, E. coli,* and *Pseudomonas aeruginosa* organisms. This effect was short lived, however, and showed no effect on all other organisms.

Conclusion: Due to this short-term effect of colostrums on only some of the causal organisms, colostrums alone may not be effective in combating *ophthalmia neonatorum.* Neonates with *ophthalmia neonatorum* should be taken to the hospital and appropriate treatment should be administered to them.

POSTER 76

A Comparison of Systane® Lubricant Eye Drops Versus Refresh Tears® Lubricant Eye Drops When Used as Supportive Therapy with Restasis® Ophthalmic Emulsion

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Background: Evaluate the efficacy/compatibility of two marketed artificial tears in relieving dry eye signs/symptoms when used as supportive therapy to a cyclosporine-based ophthalmic emulsion.

Methods: Sixty evaluable patients, by intent-to-treat analysis, took part in this randomized, investigator masked, parallel study of 6-months duration. Enrollment criteria: corneal staining of > 3 (NEI grid), Schirmer without anesthesia of < 7 mm, and subjects had to answer that they needed artificial tears at least "some of the time." Subjects were randomized to one of three treatment (Tx) groups:

Treatment 1: Restasis® (0.05% cyclosporine) b.i.d. w/Systane® (PEG 400/propylene glycol w/HP-Guar as gelling agent)used a minimum of 1/day as supportive therapy.

Treatment 2: Restasis® b.i.d. w/Refresh Tears® (carboxymethylcellulose) used a minimum of 1/day as supportive therapy.

Treatment 3: Systane® used alone q.i.d. Signs/symptoms were measured at Days -7, 0, 7, 14, 28, 42, 120, and 180.

Results: Statistical difference seen in favor of Tx1 (Restasis® + Systane®) *vs.* Tx2 (Restasis® + Refresh®) for greater reduction in corneal staining ($p = 0.0048$) and a trend ($p = 0.0725$) for increased TFBUT at 6 months. Schirmer showed nonsignificant increases from baseline at 6 months: Tx1 = 1.41; Tx2 = 2.15; Tx3 = 1.42 mm. Significant differences seen in favor of Tx1 *vs.* Tx2 for less frequent ocular burning ($p = 0.0210$), stinging ($p = 0.0314$), grittiness ($p = 0.0128$), and dryness ($p = 0.0132$). Tx3 (Systane® alone) was better than Tx2 (Restasis® + Refresh®) for less frequent ocular burning ($p = 0.0288$), dryness (p = 0.0480), and scratchiness ($p = .0294$).

Conclusion: Artificial tears used as supportive therapy with Restasis® has significant indications for outcome measures. There were significant clinical advantages with Restasis® +Systane® *vs.* Restasis® + Refresh Tears®. There were no clinical or statistical differences seen between Restasis® + Systane® and Systane® used alone. Both supportive therapies were compatible with Restasis®.

(This study was sponsored by Alcon Research Limited, Fort Worth, Texas.)

POSTER 77

A Comparison of Performance Attributes Between a New Concept Artificial Tear and Systane® Lubricant Eye Drops

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Background: The purpose of this study is to evaluate characteristics of a new artificial tear (Concept Tear) vs. Systane® Lubricant Eye Drops under acute dosing.

Methods: Two studies were conducted that compared attributes of the Concept Tear vs. Systane. The Concept Tear is multi-dose with buffer ingredients that work in concert to provide preservative efficacy without a traditional preservative. The Concept Tear contains PEG-400 and propylene glycol as demulcents and HP-Guar as a gelling agent.

Study 1: Twenty patients with dry eye were enrolled in this single-center, randomized, double-masked, two-period crossover study. Eligible patients had to have a diagnosis of dry eye and answer that they needed artificial tears at least "some of the time" due to dry eye. Drops were administered OU per randomization. Drop instillation comfort (10-pt. scale), overall acceptability (10-pt. scale), and 3-minute blur profile (50-pt. scale) comparisons were made.

Study 2: Sixty patients were enrolled in this single-center, randomized, double-masked, two-period crossover study. Eligible patients had to have Tear Film Break-Up Time (TFBUT) < 5 seconds and demonstrate a deficient Ocular Protection Index (TFBUT/Inter-Blink Interval). Treatment with 40 µL of the assigned tear was administered OU. Treatment with 1 µL of sodium fluorescein was administered, and TFBUT measured at 5, 10, 15, 20, 30, 45, and 60 min. post-drop instillation.

Results: *Study 1*: No statistically significant differences between Concept Tear and Systane® were seen for drop comfort (Concept Tear mean = 1.0; Systane® mean = 1.0); drop acceptability (Concept Tear mean = 1.0; Systane® mean = 0.8); or 3-minute blur profile (@ t0 Concept Tear Mean = 20.2; Systane® Mean = 21.5; both diminishing to < 0.1 @ 3 minutes).