The purpose of this study was to evaluate the safety, efficacy and compatibility of two marketed artificial tear products when used as concomitant therapy with Restasis Ophthalmic Emulsion in patients with dry eye symptoms.

This was a six-month concurrently controlled, randomized, investigator-masked, multi-site clinical trial that was performed in compliance with the ethical principles of the Declaration of Helsinki and Good Clinical Practice. An IRB approved this study and all patients provided written informed consent. Masking was maintained by relabeling all bottles and only the study coordinators were allowed to open the product and compliance envelopes. One investigator (SH) (p=0.0128) and Dryness (p=0.0132). TX1 was better than TX2 for less Burning (p=0.0328), Dryness (p=0.0484) and Scratchiness (p=0.0254). Both supportive therapies were compatible with Restasis.

Conclusion. The choice of artificial tears as supportive therapy is important. There were significant clinical advantages with Restasis+Systane vs Restasis+Refresh Tears. While there were no clinical differences noted for Restasis+Systane vs Systane, Systane used alone dosed a minimum of four times a day.

REFERENCES


The main objective of this study was to demonstrate compatibility of System® Lubricant Eye Drops when used with Restasis® Ophthalmic Emulsion. The results of this study not only showed that Systane was as effective when used as a concomitant therapy when the combination of Restasis+Systane was statistically significantly better in reducing both the signs and symptoms of dry eye versus the combination of Restasis+Refresh Tears. Furthermore, Systane used alone was not statistically significantly different than Restasis+Systane.

Conclusions. System® is compatible for use with Restasis when the choice of concomitant medications used with Restasis has significant indications for signs and symptoms outcome measures. The combination of Restasis+Systane was superior to the Restasis+Refresh Tears treatment arm.