ABSTRACT

Purpose: To determine the ocular response associated with a silicone hydrogel lens and two marketed multipurpose solutions (MPS) based on comfort and corneal staining after 2 hrs of lens wear at multiple study sites. Methods: This was a multi-site, controlled, parallel, double masked, randomized, acute study of 2 hours duration. Approximately 10 subjects were enrolled at each study site and were assigned to one of two marketed multi-purpose solutions (Regimen 1: OPTI-FREE® RepleniSH® Multi-Purpose Disinfecting Solution, or Regimen 2: B&L ReNu MultiPlus® MPS) for 10 hours in a pre-cycled lens case. Within the regimen, an investigator assigned lenses that were soaked in Regimen 2 had significantly greater staining compared to baseline, 44.9% of Regimen 2 subjects (p=0.0002). Also, at the 2-hr visit when asked to compare lens comfort compared to baseline, 44.9% of Regimen 2 subjects reported comfort less compared to 25.0% of Regimen 1 subjects. Conclusions: The results of this study demonstrate significant differences in corneal comfort and staining between regimens in PureVision® lenses at multiple investigative sites. Physicians should be aware of the potential interactions with certain contact lens and MPS combinations.

INTRODUCTION

The advent of silicone hydrogel lenses has made the selection of an appropriate lens care system extremely important. Lens solution interactions caused by the uptake and subsequent release of biocides may result in excessive surface proliferation and punctate corneal staining for the wearer following disinfection.1 Also, corneal staining may arise from individuals with specific combinations of silicone hydrogel contact lenses and multipurpose lens care solutions. In such cases, diffuse punctate staining carring nearly the entire cornea or staining concentrated in a ring around the periphery has been observed.1 The severity of staining can be sufficient to necessitate cessation of lens wear.1 According to a recent retrospective analysis of contact lens patient records, subjects who experience low grade, punctuate, epithelial staining are more likely to experience a corneal infiltrative event and to report slightly lower subjective comfort.3 With the numerous lens materials and multipurpose solutions on the market, the lens fitter is faced with an increasingly difficult task in identifying and avoiding the lens/solution combinations which may cause unacceptable corneal staining.

A series of studies designed to assess corneal staining after two and four hours of lens wear has been conducted with several lens materials and multipurpose solutions.5 The two hour time points were selected based on the results reported by Garofalo et al., which suggests that corneal staining peaks between two and four hours post lens insertion.6,7 Results of these studies identified certain solution/lens combinations that may cause excessive staining as well as those lenses for which the intent of the current study was to further examine this staining using 23 clinical sites across the US.

METHODS

This was a multi-site, controlled, parallel, double masked, randomized, acute study of 2 hours duration. Approximately 10 subjects were enrolled at each study site and were assigned to one of two marketed multi-purpose solutions (Regimen 1: OPTI-FREE® RepleniSH® MPS; or Regimen 2: B&L ReNu MultiPlus®) MPS according to the predetermined randomization schedule.

Lens and Lens Case Preparation

Non-logo screw-top contact lens cases were pre-conditioned by Garofalo et al., which suggests that corneal staining peaks between two and four hours post lens insertion.6,7 Results of these studies identified certain solution/lens combinations that may cause excessive staining as well as those lenses for which the intent of the current study was to further examine this staining using 23 clinical sites across the US.

Lens wear with Regimen 2 resulted in significantly more corneal staining severity (p=0.0002) and area (p<0.0001) at 2 hours of wear when compared with Regimen 1. Observed staining distribution was consistent with previous reports of solution toxicity.7 Reported comfort significantly decreased from baseline for Regimen 2 (p=0.0002). Results from 23 clinical sites across the US are consistent with previous studies reporting corneal staining produced by the interaction of ReNu MultiPlus® MPS and PureVision® silicone hydrogel contact lenses.

RESULTS

At the baseline visit staining was minimal and similar for both regimens. At the 2 hour visit, subjects wearing lenses randomized to Regimen 2 reported more corneal staining type and area when compared with those exposed to Regimen 1 (p<0.0001). Comfort reported at the 2 hour visit significantly decreased from baseline for Regimen 2 (p=0.0002). The distribution of staining was consistent with the typical micropunctate staining attributed to solution toxicity.

REFERENCES


CONCLUSIONS

- Lens wear with Regimen 2 resulted in significantly more corneal staining severity (p=0.0002) and area (p<0.0001) at 2 hours of wear when compared with Regimen 1.
- Observed staining distribution was consistent with previous reports of solution toxicity.
- Reported comfort significantly decreased from baseline for Regimen 2 (p=0.0002).
- Results from 23 clinical sites across the US are consistent with previous studies reporting corneal staining produced by the interaction of ReNu MultiPlus® MPS and PureVision® silicone hydrogel contact lenses.

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