Therapeutic Continuous Wear Silicone Hydrogel Contact Lenses in the Management of Moderate to Severe Dry Eye

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Purpose

The objective of this study was to examine the safety and efficacy of extended-wear contact lenses in the management of moderate to severe dry eye signs and symptoms refractory to conventional treatment modalities.

Introduction

Normal sight depends on complex hormonal, neurosecretory and immunologic mechanisms that regulate the tear film and ocular surface.[1] Perturbations in this system by various means can disturb the ocular surface and cause significant dry eye often unresponsive to conventional treatments. The mainstay of current medical treatment of dry eye disease includes tear replacement with artificial lubricants, punctual occlusion, and newer agents targeted at the immunologic component of dry eye disease (topical cyclosporin A [Restasis®]).[2] These treatments often have limited utility in those with moderate to severe dry eye disease leaving patients to suffer chronic debilitating eye disease.

Recent developments in contact lens design have led to highly oxygen permeable silicone hydrogel lenses that may provide a new therapeutic adjunct in the treatment of dry eye disease.[3] The Night and Day™ soft contact lens was approved for 30-day continuous wear by the Food and Drug Administration.[4] The same agency has approved it as a therapeutic bandage lens. Various contact lenses have been used in the treatment of dry eye disease with limited success.[5] No studies have evaluated the use of newly designed extended-wear contact lenses in the treatment of moderate to severe dry eye disease. It is possible that these extended-wear contact lenses could stabilize the tear film, allow for corneal healing, and possibly restore normal cell turnover; all of which are critical in the treatment of dry eye disease.

Methods

This study was approved by the Loyola University Institutional Review Board. Patients were recruited from a cornea subspecialty practice. Inclusion criteria included patients over age 18; dry eye signs and symptoms secondary to exposure, inflammatory, autoimmune, or cicatricial disease; and dry eye disease refractory for at least three months to conventional medical treatment (artificial tears and ointments, punctual occlusion, and topical anti-inflammatory agents). Exclusion criteria included: patients unwilling or unable to give consent, unable to return for follow-up visits, or unable to insert or remove contact lenses; visual acuity worse than 20/400; previous contact lens intolerance; current gas-permeable lens wear; active or recurrent uveitis; active retinal disease; active inflammatory, infectious, or idiopathic keratitis; history of infectious keratitis; or epithelial defects at the time of enrollment.

At the initial visit, after signing the consent form, patients were first administered the Ocular Surface Disease Index Questionnaire (OSDI). Only those who scored in the moderate to severe categories were enrolled. Manifest refraction to determine best corrected visual acuity was performed. Visual acuity was measured with ETDRS charts. Schirmer I testing followed by vital dye staining to sodium fluorescein and Lissamine green was performed. Tear break up time was also measured.

Both eyes of each subject were fit with the Focus® Night and Day™ silicone hydrogel soft contact lens. All lenses were -0.25 D. The 8.6 base curve was used if the average keratometry reading was flatter than 44.00 D and the 8.4 base curve if the average keratometry reading was steeper than 44.00 D. The lenses were evaluated for proper centration and movement, changing base curves as indicated to achieve an acceptable fit. Insertion and removal training was conducted until satisfactorily performed. Optifree™ solution was provided. Lenses were worn for one week then removed, cleaned and re-inserted by the patient. Refresh Plus® lubricating drops were instilled every 1-2 hours while wearing the lenses. Subjects were instructed to remove the lenses and call the investigators if any discomfort or irritation was experienced. A one week follow-up was scheduled to evaluate the contact lens fit and corneal integrity. A one month follow-up was scheduled to collect data including the OSDI questionnaire, visual acuity, Schirmer testing, vital dye staining and tear break up time.

Results

A total of eight patients were enrolled in the study. All eight patients had dry eye disease as a consequence of graft vs. host disease. One of the subjects dropped out of the study after one week due to contact lens intolerance. This patient did not have an adverse event. This data is not included in the analysis.

OSDI scores improved significantly from baseline to one month (76.8 ± 5.1 v. 31.2 ± 6.7 (mean $\pm$ SEM, t-test), $p < 0.006$). LogMar visual acuity also improved significantly in both eyes from baseline to one month (see Table 1). There was improvement noted in visual acuity at the one week visit which did not reach statistical significance. No significant differences were observed in either eye with vital dye staining using sodium fluorescein dye or Lissamine green.

	Initial	1 Week	1 Month
OD	0.23 ± 0.05*	0.13 ± 0.05	0.04 ± 0.03*
OS	0.22 ± 0.05**	0.10 ± 0.04	0.04 ± 0.02**

Table 1: LogMar Visual Acuity

ANOVA, LSD (mean + SEM), *$p < 0.04$; ** $p < 0.01$

Basal Schirmer testing and tear break up time also showed no statistical difference from baseline to one month in either eye. No adverse events were reported or observed in any of the subjects throughout the course of the study. All subjects elected to continue wearing the bandage contact lenses at the conclusion of the study.

Conclusion

This study demonstrates the safety and efficacy of using Night and Day™ silicone hydrogel lenses in the treatment of moderate to severe dry eye in patients with graft vs. host disease. All the patients tolerated the contact lenses well even on a continuous wear basis. A dramatic subjective improvement in dry eye symptoms was noted after thirty days as measured by the OSDI questionnaire. A surprising finding was the improvement in visual acuity that continued over the course of the study. This occurred despite a lack of significant improvement in sodium fluorescein staining of the epithelial surface which when disrupted contributes to degradation of vision in ocular surface disease. Other objective measures of dry eye did not improve with contact lens use. Despite the fact that these were compromised corneas, continuous wear did not lead to any adverse events in this small sample.

This study suggests that the use of this FDA approved bandage contact lens even in the presence of a poor ocular surface can be safe and effective. This treatment modality provided significant relief from the debilitating symptoms of dry eye in addition to functional improvement. Further study is warranted using a larger sample size over a longer study period to verify the safety of this treatment modality.

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