Which is better? Addipak versus ScleralFil™ for Dry Eye Scleral Lens Wearers

Chandra Mickles, OD, MS, FAAO, FSLS[1], Jennifer Harthan, OD, FAAO, FSLS[2], Melissa Barnett, OD, FAAO, FSLS, FBCLA[3]

[1]Nova Southeastern University College of Optometry, Fort Lauderdale, FL [2] Illinois College of Optometry, Chicago, IL [3] University of California, Davis Eye Center, Sacramento, CA

INTRODUCTION

The use of scleral gas permeable lenses (SL) has grown tremendously with indications to now include therapeutic rehabilitation for dry eye (DE) patients. While non-preserved artificial tears are ideal SL filling solutions, non-preserved saline is also used.[1]

It was shown that buffered ScleralFil™ (Bausch+Lomb; Rochester, NY) insertion solution has a pH within the range of ocular comfort while Addipak Unit Dose Vials (Teleflex; Wayne, PA) has one of the most acidic and widest ranges of pH of commonly used SL insertion solutions.[2,3] Despite these results, to our knowledge, the differences in ocular comfort and ocular surface staining between these frequently used SL filling solutions has not been investigated.

The ocular staining and comfort scores of DE subjects were compared between SL wear with Addipak Unit Dose solution and ScleralFil™ to help practitioners envisage which filling solutions are optimal.

METHODS

Twenty habitual SL wearers with dry eye completed a multi-center study at three geographically diverse locations.
Locations:

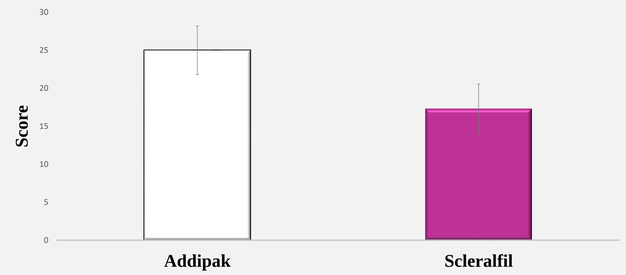
- **Nova Southeastern University College of Optometry**
- **Illinois College of Optometry**
- **University of California, Davis Eye Center**

Table 1. Eligibility Criteria

Inclusion	
Age	≥ 18
Dry eye	Score >12 on the Ocular Surface Disease Index, TBUT <10 seconds
Habitual SL wear	Scleral lens wear for at least 8 hours a day, at least 5 days a week for at least 3 months prior to enrollment
Scleral lenses	No older than 1 year Lens diameters between 15.0 mm to 19.0 mm inclusive
Exclusion	
	No corneal surgery within 3 months

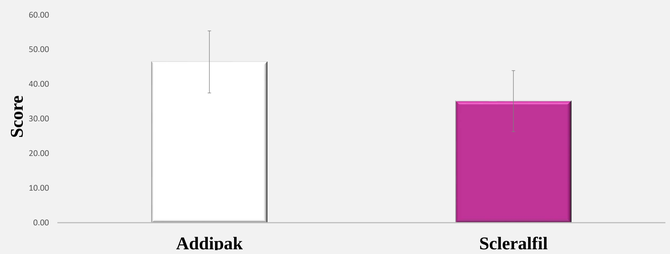
Outcome measures included: Sodium fluorescein and lissamine green ocular surface staining, lens comfort scores, and DE symptoms following 30 days of SL with Addipak Unit Dose Vials and 30 days of SL wear with ScleralFil. Lens comfort and DE symptoms were assessed with the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) and the Ocular Surface Disease Index (OSDI) respectively. Each subject had a one week wash out period of no SL wear between the two phases of habitual SL lens wear.

Figure 2. CLDEQ-8 Mean Score Comparison Between Addipak and ScleralFil



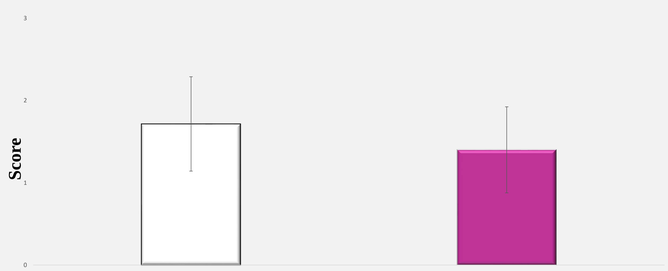
Wilcoxon Ranked Comparison between Addipak and Scleralfil. p<0.0001 One sided p value Scleralfil < Addipak. Lower scores are better

Figure 2. OSDI Mean Score Comparison Between Addipak and ScleralFil



Paired t-test comparison between Addipak and Scleralfil. p<0.02 One sided p value for Scleralfil < Addipak Lower scores are better

Figure 3. Corneal Fluorescein Staining Comparison Between Addipak and ScleralFil



Paired t-test comparison between Addipak and Scleralfil. P<0.05 One sided p value for Scleralfil < Addipak Lower scores are better

RESULTS

Paired-comparison t tests were performed for data exhibiting normal distribution using the Shapiro-Wilk test. Non-normal distributions were compared using the Wilcoxon Signed Rank test.

Lens comfort scores significantly improved and DE symptoms significantly improved with ScleralFil™ compared to Addipak Unit Dose Solution (Figures 1-2). Corneal sodium fluorescein staining reduced significantly with ScleralFil™ (Figure 3). Conjunctival lissamine green staining with ScleralFil™ was not statistically significant (p=0.09).

CONCLUSIONS

There was a significant improvement in scleral lens comfort, dry eye symptoms and corneal sodium fluorescein staining with ScleralFil™ compared to Addipak Unit Dose Solution in dry eye scleral lens wearers. Preservative free buffered scleral lens filling solutions such as ScleralFil™ may be an ideal alternative option for dry eye scleral lens wearers when artificial tears are cost prohibitive.

REFERENCES

1. Harthan J. et al. Scleral Lens Prescription and Management Practices: The SCOPE Study. Eye Contact Lens. 2017 Apr 6.
2. Yeung, D et al. Osmolarity and pH of Non-Preserved and Preserved Saline Solutions. Optom Vis Sci. 2017 E-abstract
3. Dahms T, Dekinder J. Is Buffered Better? Optom Vis Sci 2017. E-abstract

ACKNOWLEDGEMENTS

ScleralFil™ was donated by Bausch +Lomb

Co-Investigators: Andrea Janoff, O.D., FAAO, Perla Najman, O.D., and Zoe Schinas, O.D.
Research Assistant: Yanara E. Barreras, B.S.
Statistical support: Xiaohua Zhuang, Ph.D.