Comparison of Two FDA-Approved Buffered Scleral Contact Lens Filling Solutions

Michelle K. Man, OD, FAAO, FSLS; Shalynn Mills, BS; Sydney Teragawa, BS; Xiaohua Zhuang, PhD, FAAO
Illinois College of Optometry , Chicago, IL

3241 South Michigan Avenue, Chicago, Illinois 60616

INTRODUCTION

Scleral contact lenses (SL) have several indications including vision rehabilitation and ocular surface disease. Ocular comfort and lens wear time are important factors contributing to successful contact lens wear. SL are often filled with preservative-free sterile saline solution, either buffered or non-buffered. There are currently two FDA-approved buffered SL filling solutions on the market: ScleralFil™ (Bausch+Lomb) and Nutrifill™ (Contamac). ScleralFil™ contains boric acid, sodium borate, and sodium chloride. Nutrifill™ is the only filling solution that contains the essential ions potassium, sodium, calcium, and magnesium buffered with phosphate, which are naturally found in tears. In a study comparing ScleralFil™ to Addipak (Teleflex), it was suggested that buffered filling solutions may improve SL comfort and dry eye symptoms compared to non-buffered solutions. This study aims to compare SL comfort between the two available buffered filling solutions, specifically examining if the added electrolytes in Nutrifill™ increase SL comfort, quantified by lens wear time.

METHODS

Established SL wearers who were either students, residents, or faculty members at the Illinois College of Optometry (ICO) were recruited. Participants were randomized to use either Nutrifill™ (Filling solution A) or ScleralFil™ (Filling solution B) daily for one week. After one week, they were given the other filling solution to use daily for one week. The subjects were blind to the solutions given (Figure 1). At the end of each week, the participants filled out an Ocular Surface Disease Index (OSDI) questionnaire and a comfort survey noting average daily SL wear time. The study protocol was approved by the ICO Institutional Review Board.

RESULTS

Six participants completed the study; no one withdrew. Statistical analysis with a paired t-test (p=0.68) and Wilcoxon signed-rank test (p=0.46) showed no significant difference between OSDI scores when using Nutrifill™ versus ScleralFil™. Table 1 shows the OSDI scores for each participant. Comparison of average daily wear time between the two solutions was not statistically significant (p=0.35 with paired t-test, p=0.46 with Wilcoxon signed-rank test). Table 2 shows the average daily wear time for each participant.

TABLE 1

	Nutrifill™ OSDI Scores (Filling solution A)	ScleralFil™ OSDI Scores (Filling solution B)
Participant #1	4	20
Participant #2	0	2
Participant #3	4	6
Participant #4	0	10
Participant #5	13	2
Participant #6	18	10

OSDI SCORES KEY

Normal	0-12
Mild	12-22
Moderate	23-32
Severe	33-100

TABLE 2

	Nutrifill™ (Filling solution A) Average daily wear time (hours)	ScleralFil™ (Filling solution B) Average daily wear time (hours)
Participant #1	13	8
Participant #2	12.85	11.85
Participant #3	7.85	9
Participant #4	15.42	14.14
Participant #5	7.72	9.43
Participant #6	6	4.43

DISCUSSION

Due to decreased patient volume related to the COVID-19 pandemic at the time of the study, the protocol limited participants to ICO staff, faculty, students, and residents. To minimize exposure time, dry eye testing was not studied. This resulted in a small number of participants and limited the analysis of additional objective data. To further investigate this research question, the participant sample size should be expanded by opening the study to the public and dry eye testing such as corneal staining, tear break up time (TBUT) and osmolarity testing should be considered.

How filling solutions were masked may have also affected study outcomes. All identifiers on each vial of filling solution were masked (Figure 1), except for their shape. Nutrifill™ (Filling solution A) is rectangular and ScleralFil™ (Filling solution B) is cylindrical. Therefore, if study participants used either filling solution prior, they may have recognized the vial shape, potentially creating a bias in their comfort survey.

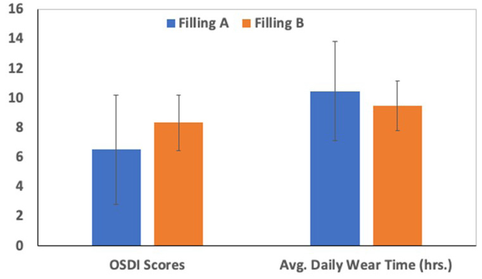
Figure 2 shows more participants with higher OSDI scores using ScleralFil™ and more participants with greater daily wear time when using Nutrifill™. However, statistical analysis with a paired t-test and Wilcoxon signed-rank test both showed no significant difference between OSDI scores or lens daily wear time.

FIGURE 1

Image of blinded solutions A and B given to subjects throughout the study.

FIGURE 2

Graph displays OSDI scores and average lens daily wear time using Nutrifill™ (Filling solution A) compared to ScleralFil™ (filling solution B) for one week each.



CONCLUSION

Buffered SL filling solutions have been shown to be beneficial in improving patient comfort and reducing dry eye symptoms versus non-buffered solutions. A direct comparison between the two FDA-approved buffered SL filling solutions has not been previously studied. This report suggests that both ScleralFil™ and Nutrifill™ are good options for SL patients. The added electrolytes in Nutrifill™ did not result in a statistically significant difference in SL comfort quantified by lens wear time, nor was there a statistically significant difference in OSDI scores. Further investigation with a larger sample size could be conducted to confirm the findings of the current study.

REFERENCES

Available upon request

ACKNOWLEDGEMENTS

Contamac donated Nutrifill™ filling solution vials

CONTACT INFORMATION

Michelle K. Man, OD, FAAO, FSLS
michman@ico.edu
www.ico.edu