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EVALUATION OF WEAR EXPERIENCE WITH WATER SURFACE DAILY DISPOSABLE LENSES IN SATISFIED REUSABLE SOFT CONTACT LENS WEARERS

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ABSTRACT

Purpose: Soft contact lens wearers are often prescribed the same lens material and modality for multiple years if patients express satisfaction and no significant problems with lens fit or ocular health are noted upon evaluation. Despite their satisfaction, other lenses may exist that could provide additional health or convenience benefits and a satisfied lens wear experience.

Methods: In this study, wearers of a specific monthly replacement lens brand (comfilcon A) were recruited for an open-label study. The habitual contact lens prescription was optimized for 2 weeks of wear, and participants confirmed that they were satisfied with their habitual lenses before being refit with daily disposable lenses (verofilcon A). Participants responded to visual analog scale (VAS) survey about their initial impressions of the lenses. After 2 weeks of lens wear, participants completed a final study visit and completed surveys about lens wear experiences with the daily disposable study lenses.

Results: Fifteen male and 15 female participants completed the study. Median (IQR) binocular LogMAR visual acuity was -0.20(0.12), equivalent to 20/12.5 Snellen acuity. Initial impression surveys revealed a median (interquartile range) of 92.5(22.3) for quality of vision; 95.0(19.3) for comfort; and 91.5(19.3) for satisfaction. At the final visit, median scores for EOD quality of vision was 86.5(24.0); EOD comfort was 84.5(30.3), and EOD dryness 25.5(47.0). Median overall VAS scores were 92.5(16.0) for vision; 88.0(18.3) for comfort, and 17.5(25.8) for dryness. Median satisfaction with the study lenses was scored 9(2.8) on a 1-10 scale.

Conclusions: In this study, satisfied wearers of comfilcon A reusable lens were refit with verofilcon A daily disposable lenses and showed high satisfaction scores with the new lenses, showing that refitting these patients can allow patients to have lenses with more frequent replacement and maintain satisfaction with daily lens wear.

Keywords: daily disposable lenses, comfilcon, verofilcon, comfort

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INTRODUCTION

Prescribing daily disposable contact lenses has greatly increased since their first installation in the late 1990s and most recently due to the introduction of silicone hydrogel daily disposables in 2008. Daily disposable lenses comprised approximately 45% of soft contact lenses prescribed worldwide in 2019, with silicone hydrogel daily disposables used more frequently than their hydrogel counterparts. Wearers of daily disposable lenses have been shown to have less corneal infiltrates when compared to reusable lense wearers. Silicone hydrogel daily disposable lenses are a preferred lens both for the health benefits, and the improved patient compliance when compared to reusable lens wearers.

Several silicone hydrogel daily disposable lenses are available on the market, and like reusable soft lenses, these lenses are made with different lens materials and lens parameters, making each lens choice unique,4 and requiring a contact lens fitting when changing to a different contact lens. Many recent advancements in daily disposable contact lens manufacturing have been made in an effort to optimize the wear experience of the contact lenses available for prescription. Due to the inherent hydrophobicity of silicone,⁵ developing a silicone hydrogel contact lens that maximizes on-eye wettability can be a challenge. Surface modifications over a silicone core can allow a contact lens to retain high oxygen transmissibility while providing wettability and lubricity at the lens surface.⁶ A study on lens parameters found that improved lubricity and the coefficient of friction on the lens surface is likely to play a role in improved comfort with lens wear.⁶ This is of great importance, since contact lens wear discontinuation is most frequently attributed to lens discomfort.7 Recently, a daily disposable contact lens with water surface technology has been introduced to the market, with the benefit of daily replacement and high oxygen permeability. Several studies have shown positive wear experiences with these lenses.⁸⁻¹⁰

While it is obvious that eye care practitioners should refit dissatisfied contact lens wearers with

lenses that fit well and have lens properties that can address their patients' symptoms, there may be less motivation to refit contact lens wearers who express satisfaction with their current lenses. A study by Orsborn and Dumbleton surveyed 200 eye care practitioners and found that 92% agreed with the statement, "Silicone hydrogel 1-day lenses provide the best benefits to my patients." Despite the recognized benefits of silicone hydrogel daily disposable lenses, this same survey found that reusable lens wearers were not always presented with the option of daily disposable lenses by eye care practitioners, generally due to concerns that changing lenses may upset patients and put patient retention at risk, particularly if the cost of the daily disposable lenses is higher.11 Refitting a contact lens takes time, and practitioners may be wary of suggesting that patients spend the time or money trying a new lens when they are already satisfied with their current reusable lenses.

Purpose

The purpose of this study was to refit satisfied wearers of a highly prescribed monthly replacement lens (comfilcon A) with a daily disposable silicone hydrogel lens with water surface technology (verofilcon A) and assess the quality of vision, comfort, and satisfaction scores after wearing the lenses.

METHODS

This open label, non-comparative clinical trial was approved by The Ohio State University Institutional Review Board, registered on clinical-trials.com (#NCT05096156), and was conducted under the tenants of the Declaration of Helsinki. A diagram of the study design is shown in Figure 1.

Participants recruited for the study were satisfied wearers of a specific monthly replacement soft contact lens (Biofinity, comfilcon A, CooperVision, Pleasanton, CA, USA) aged 18-40. After completing the informed consent process, entering visual acuity with current lenses was assessed, with eligibility requiring vision of 20/25 or better. Biomicroscopy

VISIT 1 • Informed Consent • Confirmation of satisfaction with habitual reusable study lenses. • Assessments of visual acuity, ocular health, and all

exclusion/inclusion criteriaRefitting of habitual lenses to optimize lens wear experience.

FIGURE 1. Study design.

VISIT 2

- Confirmation of satisfaction with habitual reusable lenses
- Assessments of visual acuity and ocular health
- Participants are fit with the daily disposable study lenses
- Surveys of initial impressions of vision, comfort and satisfaction are completed.

VISIT 3

- Assessment of visual acuity and lens fit
- Completion of surveys of overall and end of day vision, comfort and dryness with study lens wear
- Completion of wear experience surveys and CLDEQ-8
- · Assessment of ocular health.

was completed to ensure that no ocular inflammation was present. Participants were then refit with their habitual lenses to optimize vision, so that introducing a new lens later would not skew the impressions of vision if a prescription change was needed in the habitual lenses. The optimized habitual lenses were dispensed, and participants were instructed to continue with their habitual lens care products. Participants were instructed to wear the lenses every day. Participants returned after 1 week of lens wear. Visual acuity and fit were assessed, and it was confirmed that the participants were satisfied with their lenses. After an assessment of ocular health, participants were refit with the daily disposable study lenses (PRECISION1®, verofilcon A, Alcon, Ft. Worth, TX USA). LogMAR visual acuity and lens fit were assessed. Participants then completed a visual analog scale (VAS) survey with assessments of their initial satisfaction, initial comfort, and initial vision. All study surveys were completed electronically in REDCap (Research Electronic Data Capture). 12,13 Each VAS survey was completed by moving a slider along a line to correspond with their impression of each quality on a scale from 0 to 100. The initial quality of vision VAS was anchored with "POOR Quality" at 0 and "EXCELLENT Quality" at 100. The initial comfort VAS was anchored with "POOR Comfort" at 0 and

"EXCELLENT Comfort" at 100. The initial satisfaction VAS was anchored with "NOT Satisfied" at 0 and "EXTREMELY Satisfied" at 100. Lenses were dispensed to wear until the final visit, which was scheduled for 2 weeks (±3 days) later. At the final visit, participants completed VAS surveys of their overall vision, comfort, and dryness. Participants were also asked to score their vision, comfort, and dryness at the end of their daily wear. Overall and end-of-day quality of vision VAS surveys were anchored with 0 as "POOR Quality" and 100 as "EXCELLENT Quality". Overall comfort and endof-day comfort were each anchored with "POOR Comfort" at 0 and "EXCELLENT Comfort" at 100. Overall dryness and end-of-day dryness were anchored with "No Dryness" at 0 and "MAXIMUM Dryness" at 100. They also completed the Contact Lens Dry Eye Questionnaire (CLDEQ-8).14 The final survey captured convenience, ease of use, preference for modality, and satisfaction. The scale for convenience, ease of use, preference and satisfaction was 0 to 10, where a score of 0 is not convenient, easy, or satisfied; 5 was marked as neutral; and 10 was labelled as very convenient, easy, or satisfied. The visit also included assessments of visual acuity, ocular health, and lens fit.

Minitab version 21.3.1 was used for statistical assessments (Minita LLC, State College, PA).

Normality was assessed using the Anderson-Darling test. Because this was a non-comparative study, descriptive statistics were used to capture the participants' responses. Because the majority of data were not normal, median and interquartile range (IQR) values were calculated for overall results. Non-parametric statistical comparisons of the initial, overall and end-of-day VAS surveys was completed using the Mann-Whitney test.

RESULTS

Thirty habitual wearers of the spherical monthly replacement lenses were eligible for enrollment and began the study. There were no adverse events related to contact lens wear and all participants completed the study. The average age (mean \pm standard deviation) of participants was 30.5 ± 6.6 years (range: 18-40). The range habitual, spherical contact lens prescriptions worn was -1.00 to -11.00. There were 15 male participants and 15 female participants.

Twenty-eight of the participants of the study successfully completed the initial impression VAS survey after wearing the study lenses (a survey deployment error prevented data collection for two participants). Median values (IQR) for all of these initial impression surveys were above 90, with a score of 92.50(22.3) for quality of vision, a score of 95.0(19.3) for comfort, and a score of 91.5(19.3) for satisfaction.

After wearing the study lenses for 2 weeks, participants completed VAS surveys again at Visit 3. The median (IQR) acuity at the final study visit was -0.13(0.13) for the right eye and -0.15(0.14) for the left eye. The median binocular LogMAR visual acuity was -0.20(0.12), which is equivalent to 20/12.5 in Snellen visual acuity.

The results of all VAS surveys completed are shown in Table 1. Overall results (median [IQR]) were 92.5(16.0) for quality of vision and 88.0(18.3) for comfort. Dryness had a median score of 17.5(25.8). End-of-day median scores were 86.5(24.0) for quality of vision and 84.5(30.3) for comfort. The median end-of-day dryness score was 25.5(47.0). Participants also completed with CLDEQ-8 test at this visit, resulting in a median score of 6.5(7.0).

Results of the VAS surveys were compared to evaluate the known changes in vision and comfort that occur over a day of contact lens wear. Comparisons of initial impressions and overall scores showed no statistical differences for vision (P=0.9) or comfort (P=0.3). Median initial impression scores and end-of-day scores were also compared, with no statistical difference between initial vision and end-of-day vision (P=0.2), and a statistically significant difference between initial comfort and end-of-day comfort (P=0.03). Median overall and end-of-day scores were compared, with no statistical difference found for vision (P=0.1), comfort (P=0.2), or dryness (P=0.2).

TABLE 1 Median and interquartile range Visual Analog Scale results of initial impressions, overall wear experience, and end-of-day wear experience with study daily disposable contact lenses. A survey deployment error for the initial impression surveys occurred for two of the participants.

	Initial Quality of Vision	Initial Comfort	Initial Satisfaction	Overall Quality of Vision	Overall Comfort	Overall Dryness	End of Day Quality of Vision	End of Day Comfort	End of Day Dryness
Number of responses	28	28	28	30	30	30	30	30	30
Median	92.5	95.0	91.5	92.5	88.0	17.5	86.5	84.5	25.5
Interquartile Range	22.3	19.3	19.3	16.0	18.3	25.8	24.0	30.3	47.0

TABLE 2 End of study survey questions and results (Scale of 0-10) on experience using the daily disposable study contact lenses.

(n=30)	How convenient is daily disposable lens wear?	How easy to use are daily disposable lenses?	How satisfied are you with the study contact lenses?
Median	9.0	9.5	9.0
Interquartile Range	3.5	1.8	2.8

The final survey completed (Table 2) captured convenience, ease of use, and satisfaction with the study contact lenses. The scale for convenience, ease of use, preference and satisfaction was 0 to 10, where a score of 0 is not convenient, easy, or satisfied; 5 was marked as neutral; and 10 was labelled as very convenient, easy, or satisfied.

DISCUSSION

Comfort and vision are critical to contact lens wear success. The median scores found for comfort and vision were high throughout this study. It is well known that a decrease in ocular comfort occurs throughout wear time, for both contact lens wearers, and for non-contact lens wearers. 15,16 A study by Sapkota et al. in 2018 studied the decline in comfort over a day with various soft lenses, and concluded that lens material was the factor that most affected the difference in comfort between insertion and end-of-day.¹⁷ The current study showed a decline in comfort and vision when comparing overall scores to end of ay scores, as expected, but the high median satisfaction score at the end of the study may imply that this decline was not more than expected for these experienced lens wearers. This was further supported by examining the VAS dryness scores and CLDEQ-8 findings. Dryness concerns such as burning and stinging can be common complaints in contact lens wearers. These specific complaints may contribute to dissatisfaction in contact lens wear.¹⁸ While the VAS dryness scores were higher at the end of the day than they were overall, as expected, there was no statistical difference in the median scores, and the CLDEQ-8 score of 6.5(7.0) was considerably lower than threshold of 12, which

is the score associated with frequent symptoms of dryness.¹⁹ The results of the CLDEQ-8 and dryness scores together reflect normal daily declines in ocular symptoms for contact lens wearers, and supported excellent lens comfort with minimal dryness.

Comfort and satisfaction with vision have been shown to be related in contact lens wear.²⁰ The high scores for vision and comfort found in this study are reflected in the high median satisfaction score. The high score for "ease of use" with the daily disposable lenses is important and likely reflects the fact that these lenses do not require cleaning and care, but also have easy handling. The high convenience and ease of use scores likely contributed to the high satisfaction score along with the high comfort and minimal dryness that was demonstrated. While satisfaction can be largely subjective from one subject to another, and the weight of each of these factors is likely different among individuals, the criteria applied should be consistent from any participant from one lens to another. In this study, subjects were required to report satisfaction with their habitual monthly replacement silicone hydrogel lenses in order to be enrolled. Once switched to the study lenses, subjects demonstrated that they were very satisfied with the study lenses. The outcome of this study showed that wearers who were satisfied with habitual comfilcon A lens wear were also highly satisfied with verofilcon A daily disposable lenses. Larger studies with more types of lenses with various designs or surface treatments could be built to make direct comparisons. The current study should be useful when eye care practitioners weigh the necessary effort required to switch patients to a healthier lens modality. The prescription of a contact lens, much

like a medication, should consider factors important to ocular health and quality of life. Benefits of daily disposable soft contact lenses include fewer adverse events,1 fewer contact lens related infiltrative events,² less deposition of debris on the lens surfaces which can contribute to giant papillary conjunctivitis,²¹ and better compliance with lens wear.22 Removing the need for contact lens solutions and storage also lessens the risk of contamination of lenses and may decrease the risk of lenses becoming in contact with water, which can lead to microbial keratitis.²³ Convenience and efficiency of use are also benefits of disposable lens wear, particularly because wearers do not require time to clean lenses. Given that the current study was not comparative, the outcome of this study showed that wearers who were satisfied with habitual comfilcon A lens wear were also highly satisfied with verofilcon A daily disposable lenses. Larger studies with more types of lenses with various designs or surface treatments could be built to make direct comparisons. The current study should be useful when eye care practitioners weigh the necessary effort required to switch patients to a healthier lens modality.

It is important to note that patients who express satisfaction with their current lenses may be unaware of other contact lens options available or may be unwilling to discuss problems with lens wear out of fear that they will not be able to continue wearing contact lenses.¹⁸ In some situations, clinical manifestation of patient symptoms is absent. However, inquiring diligently about patient symptoms and educating patients about other options which may provide better health benefits may create the opportunity to improve further a patient's contact lens-wearing experience.¹⁸

CONCLUSION

In this study, habitual wearers of a widely prescribed silicone hydrogel monthly replacement lens rated their vision and comfort high throughout the study after being refit with a daily disposable lens with water surface technology. Participants reported high scores for ease of use, convenience, and overall satisfaction with the study lenses. Results suggest that satisfied wearers of comfilcon A monthly replacement contact lenses can be successfully refit into verofilcon A daily disposable lenses with water surface technology and achieve an excellent wear experience.

DATA SHARING STATEMENT

Data reported in this manuscript are available within the article. Study-level data including the study protocol are available. To request access to the data, the researcher must sign a data use agreement. All proposals should be directed to Jennifer Swingle Fogt (fogt.78@osu.edu) for up to 36 months following article publication.

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