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ORIGINAL RESEARCH

Comfort After Refitting Symptomatic Habitual Reusable Toric Lens Wearers with a New Daily Disposable Contact Lens for Astigmatism

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Purpose: To subjectively evaluate comfort with a daily disposable (delefilcon A for astigmatism) contact lens compared to other common weekly/monthly soft toric contact lenses in symptomatic wearers.

Methods: This open-label, single arm study enrolled current reusable soft toric lens wearers with minimum score of 12 on the contact lens dry eye (CLDEQ-8) questionnaire. Subjects were also administered the CLDEQ-8 after 1 replacement schedule of their optimized habitual toric lenses (2 to 4 weeks), and after 2 weeks of wear with delefilcon A toric daily disposable lenses (Dailies Total1 for Astigmatism; Alcon Vision LLC, Fort Worth, Texas).

Results: A total of 85 subjects completed the study. Mean total CLDEQ-8 score was 16.8 ± 8.1 for subjects refit with their optimized habitual toric lenses and 12.4 ± 7.5 for subjects refit with delefilcon A toric lenses, a difference of 4.3 ± 10.4 ($p < 0.001$). With delefilcon A toric lenses, 78.9% of subjects reported little to no intensity of eye discomfort, compared to 51.7% for the habitual toric lenses ($p = 0.005$). In addition, 77.7% of subjects reported little to no intensity of dryness for delefilcon A toric lenses, compared to 50.6% for the habitual toric lenses ($p = 0.001$).

Conclusion: The subjective comfort in symptomatic habitual reusable toric contact lens wearers was improved by refitting with delefilcon A toric lenses.

Plain Language Summary: Discomfort while wearing contact lenses is often a reason why patients decide to stop wearing their lenses. There are many different contact lens materials to choose from, and each may affect discomfort differently. The replacement schedule of a contact lens may also be a factor for discomfort, with lenses replaced daily (daily disposables) offering advantages over those replaced weekly or monthly (frequent replacement). The purpose of this study was to subjectively evaluate comfort with a new daily disposable toric contact lens. The results of this study suggest that subjective comfort in symptomatic habitual reusable toric contact lens wearers was improved by refitting with a new daily disposable toric lens.

Keywords: comfort, toric, contact lens, delefilcon A, Dailies Total1 for Astigmatism

Introduction

Contact lenses are a popular and effective modality for the correction of refractive error. However, contact lens dropout continues to be high. A recent review of the literature reported a pooled dropout rate of 22%.[1] An often-cited reason by patients for contact lens dropout is contact lens discomfort,[2] though poor vision may be another factor for dropout.[3]

The replacement schedule of a contact lens may be a factor for discomfort, with lenses replaced daily (daily disposables) offering advantages over those replaced weekly or monthly (frequent replacement). One benefit with daily disposable lenses, is that accumulation of surface deposits from the tear film may be lower than with frequent replacement lenses, which may improve comfort.[4,5] In addition, daily disposable lenses are not exposed to care solutions and storage cases, and thus have less potential to adsorb components from each that may reduce comfort.[6,7] For patients

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experiencing contact lens discomfort with their frequent replacement lenses, refitting with daily disposable lenses may offer relief and help prevent contact lens discontinuation.[8,9]

Different contact lens brands can have distinct material properties and interactions with the ocular environment that may also affect contact lens comfort.[4,6,9–11] Delefilcon A is a daily disposable silicone hydrogel lens material (Dailies Total1®; Alcon Vision LLC, Fort Worth, Texas). It is a water gradient lens, with a core water content of 33%, which transitions to nearly 100% water at the lens surface.[12] Comfort with the delefilcon A material is well established.[13–16] However, this material has only recently become available for toric lens wearers, and there is minimal data regarding the comfort with the toric version of this lens. Toric lens wearers have been reported to discontinue lens wear at higher rates than spherical lens wearers,[17] which could be caused by uncorrected astigmatism or increased discomfort.[18]

The contact lens dry eye (CLDEQ-8) questionnaire is a tool that can be used to subjectively evaluate comfort with contact lens wear.[19] The questionnaire asks subjects to rate the frequency and intensity of eye discomfort, eye dryness, and changeable, blurry, or foggy vision. Chalmers et al[19] reported a cut-off score of 12 on the CLDEQ-8, at or above which patients would be considered symptomatic of contact lens dry eye. In addition, Chalmers et al[20] reported that an improvement of 3 or more on the CLDEQ-8 could be considered clinically meaningful.

The purpose of this study was to subjectively evaluate comfort with Dailies Total1® for Astigmatism contact lenses (DT1fA) compared to other common weekly/monthly contact lenses in symptomatic wearers.

Methods

An independent Institutional Review Board (IRB) reviewed and approved this prospective study (Salus IRB, approval number KW-22-001). An independent IRB was used as the study was conducted at a private practice. The study was conducted in compliance with Good Clinical Practice (GCP), the tenets of the Declaration of Helsinki, and International Harmonization (ICH) guidelines, and was registered on clinicaltrials.gov (NCT05498649). All subjects gave written informed consent before participation in this study.

The inclusion criteria were non-presbyopic adults (18–38 years of age), current reusable soft toric lens wearers with at least 3 months of wearing experience who currently wear lenses at least 5 days per week and ≥ 10 hours per day, and a minimum score of 12 on the CLDEQ-8 questionnaire. Subjects also had to be wearing silicone hydrogel contact lenses (toric). There was no minimum or maximum cylinder requirement, however, subjects had to have corrected distance visual acuity (CDVA) of 20/25 or better. Subjects were excluded if they had any ocular anterior segment infection, inflammation, abnormality, or active disease including diagnosed dry eye that would contraindicate contact lens wear, were using any systemic or ocular medications for which contact lens wear could be contraindicated, were fitted with only 1 toric lens or monovision, had a history of ocular surgery including refractive surgery, or had an irregular cornea.

Subjects attended 3 total visits, including the baseline visit where informed consent was given. To eliminate uncorrected astigmatism as a cause of subjective discomfort, eligible subjects were dispensed new habitual toric lenses with an optimized prescription (determined in each eye individually). The next follow up visit occurred after 2 or 4 weeks of wear with the dispensed habitual toric lenses, which corresponded with the recommended biweekly or monthly replacement schedule of the habitual lens. At this visit, subjects were dispensed optimized prescriptions of the delefilcon A toric lenses (Dailies Total1® for Astigmatism; Alcon Vision LLC, Fort Worth, Texas). The delefilcon A lenses were worn on a daily disposable replacement schedule. The last visit occurred after 2 weeks of wear with delefilcon A toric lenses. Study measurements included manifest refraction, monocular contact lens corrected distance visual acuity (CLCDVA), and administration of the CLDEQ-8 questionnaire (©The Trustees of Indiana University) and the supplementary questionnaire. The supplementary questionnaire asked subjects about the number of hours of comfortable wear experienced per day.

The primary endpoint of this study was the total CLDEQ-8 score after 2 or 4 weeks of wear with optimized habitual toric lenses compared to 2 weeks of delefilcon A toric lens wear. Other endpoints included responses to individual questions on the CLDEQ-8, refraction, CLCDVA, and hours of comfortable wear. Subjects were also monitored for adverse events at all visits.

Statistical analyses were conducted using the statistical software R (version 4.1.2; The R Foundation for Statistical Computing, Vienna, Austria). Normality was assessed using the Shapiro–Wilk test. A paired *t*-test was used to compare

parametric data, the Wilcoxon signed-rank test was used to compare non-parametric data, the McNemar test was used to compare categorical data. For all comparisons, a p-value less than 0.05 was considered significant. We estimated that the study would require a sample size of 34 subjects to achieve a power of 80% and a level of significance of 5%, for detecting a difference of less than or equal to 3.0 points between groups on the CLDEQ-8, and assuming the standard deviation of the differences to be 6.0 points. For additional power and to have a representative sample of comparator habitual lenses, a sample size of 85 subjects was targeted.

Results

A total of 86 subjects were enrolled in this study. One subject was lost to follow up and was excluded from analysis. Therefore, the final sample size for our study was 170 eyes of 85 subjects. There were no reported adverse events. Baseline and demographic information are summarized in Table 1. A summary of the contact lenses worn by subjects in this study is shown in Table 2.

The primary objective of this study was to compare the total scores on the CLDEQ-8 between the habitual toric lenses and delefilcon A toric lenses. Figure 1 shows a boxplot of the total scores between these 2 groups and at baseline. Baseline mean score was 18.5 ± 4.9. The mean score was 16.8 ± 8.1 for subjects refit with new and optimized habitual toric lenses and 12.4 ± 7.5 for subjects refit with delefilcon A toric lenses. The mean of the difference was 4.3 ± 10.4 between groups and was statistically significant ($p < 0.001$). Post-hoc power analysis indicated an achieved power of 96%. Table 3 summarizes the number of subjects that had a CLDEQ-8 total score less than 12 (or ≥ 12) with habitual lenses and refits with delefilcon A lenses. The number of subjects that were symptomatic when refit with delefilcon A lenses, but not symptomatic when refit with habitual lenses was 7 (8%) compared to 33 (39%) subjects that were

Table 1 Demographic and Baseline (Habitual Lens) Data

Baseline Factor	Outcomes*
Eyes (participants)	170 (85)
Sex	
Female	58 (68.2)
Male	27 (31.8)
Age (Years)	28.5 ± 5.9 (18 to 38)
Cylinder (D)	−1.39 ± 0.58 (−3.00 to −0.50)
MRSE (D)	−3.48 ± 2.31 (−10.12 to 0.88)
CLDEQ-8 Total Score	18.45 ± 4.88 (12.0 to 34.0)

***Presented as Mean ± SD (Range) or n (%). Abbreviations**: CLDEQ-8, contact lens dry eye questionnaire; D, diopters; MRSE, manifest refraction spherical equivalent; SD, standard deviation.

Table 2 Contact Lenses Evaluated in This Study

USAN	Trade Name	Manufacturer	Percentage of Total (Habitual Lenses)
Senofilcon A	Acuvue Oasys for Astigmatism	Johnson & Johnson	32.9
Senofilcon C	Acuvue Vita for Astigmatism	Johnson & Johnson	4.7
Lotrafilcon B	Air Optix for Astigmatism	Alcon	11.8
Fanfilcon A	Avaira Vitality Toric	CooperVision	9.4
Samfilcon A	Bausch and Lomb Ultra for Astigmatism	Bausch and Lomb	10.6
Comfilcon A	Biofinity Toric	CooperVision	30.6
Delefilcon A	Dailies Total1 for Astigmatism	Alcon	–

Abbreviation: USAN, United States adopted name.

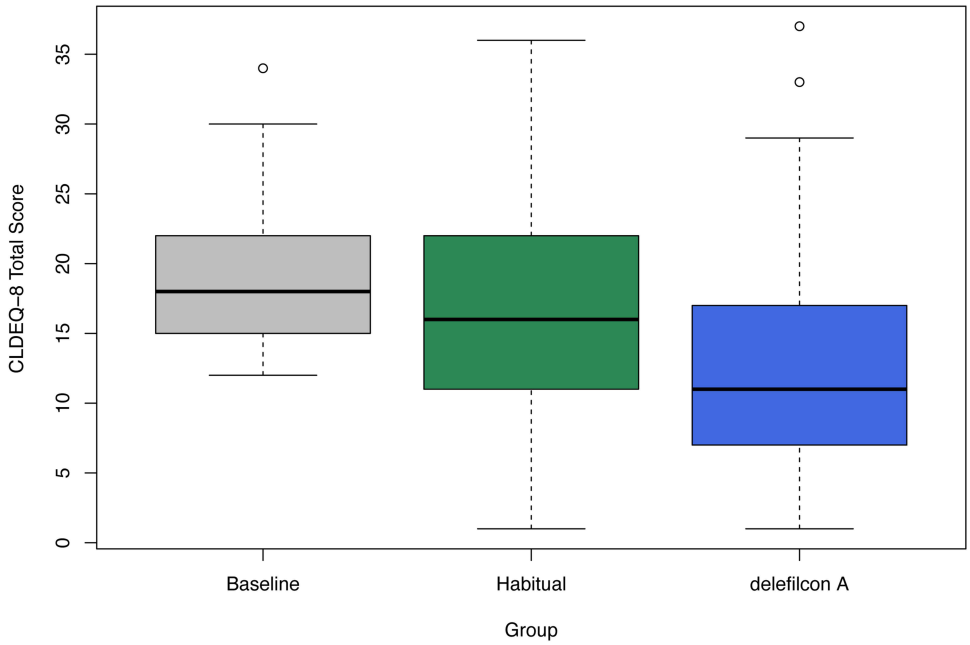

Figure 1 Box-and-whiskers plot of total scores on the CLDEQ-8 at baseline and between groups. The upper and lower extremities of the box represent the 75th and 25th percentiles, the bar within the box represents the median, and the whiskers represent the full extent of the data ranges. CLDEQ-8 = contact lens dry eye questionnaire.

symptomatic when refit with habitual lenses, but not symptomatic when refit with delefilcon A lenses. This difference was statistically significant ($p < 0.0001$).

Responses to individual questions on the CLDEQ-8 about intensity of symptoms were also compared. A summary is shown in Table 4. With delefilcon A toric lenses, 78.9% of subjects reported little to no intensity of eye discomfort (responding 0, 1, or 2) compared to 51.7% for the habitual toric lenses and this difference was statistically significant (p =

Table 3 Symptomatic (CLDEQ-8 ≥ 12) and Non-Symptomatic (CLDEQ-8 < 12) Scores on the CLDEQ-8 After Refits (n=85)

	Refit with Delefilcon A Lens		
Refit with Habitual Lens	**Symptomatic n (%)**	**Non-Symptomatic n (%)**	**Total n (%)**
Symptomatic n (%) Non-Symptomatic n (%)	28 (33) 7 (8)	33 (39) 17 (20)	61 (72) 24 (28)
Total n (%)	35 (41)	50 (59)	85 (100)

Abbreviation: CLDEQ-8, contact lens dry eye questionnaire.

Table 4 Distribution of Responses About Intensity of Symptoms from the CLDEQ-8

Question		**Distribution of Responses (%)**					
		0	**1**	**2**	**3**	**4**	**5**
When your eyes felt discomfort with your contact lenses, how intense was this feeling of discomfort	Delefilcon A toric	11.8	40	27.1	8.2	9.4	3.5
	Habitual toric	8.2	18.8	24.7	23.5	20	4.7
When your eyes felt dry, how intense was this feeling of dryness	Delefilcon A toric	18.8	31.8	27.1	15.3	3.5	3.5
	Habitual toric	8.2	15.3	27.1	23.5	18.8	7.1
When your vision was blurry, how noticeable was the changeable, blurry, or foggy vision	Delefilcon A toric	21.2	27.1	16.5	23.5	8.2	3.5
	Habitual toric	16.5	20	17.6	23.5	16.5	5.9

Abbreviations: 0, Never have it; 1, Not at All Intense; 5, Very Intense.

0.007). In addition, 77.7% of subjects reported little to no intensity of dryness (responding 0, 1, or 2) with delefilcon A toric lenses compared to 50.6% for the habitual toric lenses and the difference was statistically significant ($p = 0.02$). For delefilcon A toric lenses, 64.8% of subjects reported little to noticeable change between clear to blurry or foggy vision (responding 0, 1, or 2), compared to 54.1% for the habitual lenses, and the differences in responses were not significant ($p > 0.05$).

Other endpoints included CLCDVA and the number of hours of comfortable wear. Mean monocular CLCDVA was 0.00 ± 0.09 while wearing delefilcon A toric lenses and 0.05 ± 0.12 while wearing the habitual toric lenses. This difference was statistically significant ($p < 0.001$), but not clinically relevant. The mean reported hours of comfortable wear for delefilcon A toric lenses was 9.0 ± 4.0 compared to 8.0 ± 4.1 for the habitual lenses, however this difference was not statistically significant ($p > 0.05$).

Discussion

Reducing contact lens discomfort may help lower the rates of dropout with current lens wearers. Compared to spherical lenses, toric lens wearers have been reported to discontinue lens wear at higher rates,[17] which may be caused by increased discomfort.[18] In this study, we evaluated subject comfort of symptomatic reusable toric contact lens wearers before and after refits from their optimized habitual lenses to delefilcon A toric lenses. There was a statistically significant improvement in CLDEQ-8 scores after refit with delefilcon A toric lenses, compared to the habitual toric lenses. The mean of the differences was 4.3 ± 10.4, which was above the threshold for clinical significance (≥ 3).[20] To the best of our knowledge, this is the first report of comfort with the toric version of delefilcon A, although, there have been reports of comfort with the spherical version of this lens. Garaszczuk et al[21] observed minimal differences in total CLDEQ-8 scores for subjects refit with either delefilcon A or omafilcon A daily disposable lenses compared to their habitual lenses (94% of which were frequent replacement). The authors pooled the CLDEQ-8 results from refits with both delefilcon A (68% of refits) and omafilcon A (32% of refits), and their results suggest that refitting with daily disposable lenses reduced tear osmolarity, but did not significantly impact ocular surface disease index or CLDEQ-8 scores compared to baseline. However, Garaszczuk et al[21] had a lower sample size ($n = 50$) compared to our study, and enrolled subjects that were not symptomatic (CLDEQ-8 < 12 at baseline), which may explain why they did not observe a significant difference in CLDEQ-8 scores.

Arroyo-Del Arroyo et al[22] also investigated CLDEQ-8 scores after refits with delefilcon A daily disposable lenses. The authors split 31 participants into 2 groups: a study group that was refit with delefilcon A ($n = 14$) for 1 month, and a control group where refits were first done with the habitual lenses for 1 month, then with delefilcon A for 1 month ($n = 17$). Clinically significant differences were observed on the CLDEQ-8 total scores (≥ 3) between baseline and refits with delefilcon A in both groups. However, only statistically significant differences were noted in the study group. The results reported by Arroyo-Del Arroyo et al[22] are similar to that of our study, however we observed statistically significant differences in CLDEQ-8 scores. This difference may be explained by the larger sample size in our study (85 vs. 17). Arroyo-Del Arroyo et al[22] also noted an improvement in CLDEQ-8 scores when participants were refit with their habitual lenses, which we observed in our study as well. The authors attributed the improvement to a placebo effect with contact lens refitting, which may explain the improvement in CLDEQ-8 score in our study for refits with habitual lenses. The improvement for refits with habitual lenses compared to baseline in our study (approximately 2) was below the threshold for clinical significance (≥ 3).[20] In contrast, the improvement for refits with delefilcon A lenses compared to baseline in our study (approximately 6) was above the threshold for clinical significance.

Mean reported hours of comfortable wear was higher when refitted with delefilcon A, compared to refits with habitual lenses. This would make sense given the lower CLDEQ-8 total score for refits with delefilcon A. However, this result was not statistically significant. Post-hoc power analysis revealed a power of 65%, which may explain why the difference was not statistically significant despite appearing clinically relevant. It is also worthwhile to note that despite clinically significant improvements in CLDEQ-8 scores, subjects were still symptomatic for dry eye (CLDEQ-8 score ≥ 12) in both refit groups.

We investigated if there were specific factors that may explain any differences in CLDEQ-8 total score between the habitual toric and delefilcon A toric lenses. A statistically significant higher percentage of respondents indicated that

feelings of discomfort and dryness were less intense with delefilcon A toric lenses compared to the habitual toric lenses, however there was no statistically significant difference in the percentage of respondents for a noticeable change between clear to blurry or foggy vision. Other studies have reported that delefilcon A may provide a longer non-invasive tear break-up time[14,16,23] and higher subjective comfort[15] compared to other lens materials. These results and the results of our study suggest that delefilcon A toric lenses may offer improved comfort and less dryness when symptomatic reusable toric wearers are refit to this lens. However, it is important to note that from our study, we are not able report the cause of the improved comfort. It could be the delefilcon A material (as suggested by other studies),[14–16,23] the replacement schedule (switching from frequent replacement to daily disposables), the lack of contact lens cleaning solutions when switching to a daily disposable, or a combination of these or other factors.

This study had a few limitations. First, there was no direct comparison of delefilcon A to different lens materials, including other daily disposables. A direct comparison to daily disposables would eliminate confounding factors such as replacement schedule and contact lens care systems. Second, subjects were also not masked to their habitual toric lenses or delefilcon A toric lenses, which could introduce bias, although it would be impossible to mask the subjects from a reusable and daily disposable lens replacement schedule. Third, there was also no randomization as subjects were dispensed their habitual lenses first, then delefilcon A. Finally, the follow up period for the habitual lenses and delefilcon A was 2 to 4 weeks, thus we cannot draw any conclusions about the long-term effect of refits with habitual toric lenses or delefilcon A toric lenses.

In conclusion, the subjective comfort in symptomatic reusable toric lens wearers was improved by refitting with delefilcon A toric lenses. This lens may be a good option for practitioners to dispense for patients with toric contact lens discomfort, as patients are likely to experience improved comfort compared to their habitual lenses.

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Disclosure

Brad Hall reports that he has received consulting fees from Ace Vision Group outside the submitted work. The authors report no other conflict of interest for this work.

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