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CLINICAL TRIAL REPORT

Investigation of Delefilcon A Contact Lenses for Symptomatic Daily Disposable Contact Lens Wearers with Dry Eye Disease: A Prospective Comparative Study

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Purpose: This prospective comparative study aimed to assess the effects on contact lens comfort, dryness, and wear time when symptomatic daily disposable (DD) contact lens (CL) wearers were refit with delefilcon A (DT1) lenses.

Patients and Methods: Thirty five symptomatic DD CL wearers with dry eye disease as determined according to the TFOS DEWS 2 guidelines, were enrolled and completed the study. Participants wore their habitual DD CLs during an initial assessment and were subsequently refit with DT1 for 1 month. Participants were masked to the study lens type. Subjective ratings of end-of-day comfort and dryness, average wear time, and comfortable wear time were evaluated as primary endpoints.

Results: Of the 35 participants, two participants were classified as aqueous deficient dry eye, while the remaining participants exhibited symptoms primarily due to evaporative causes. The median CLDEQ-8 score for dryness significantly improved from 17 (fair) with habitual lenses to 13 (good) with DT1 lenses ($p < 0.01$). Participants reported significantly better end-of-day comfort ($p = 0.01$) and less end-of-day dryness ($p = 0.01$) with DT1 compared to their habitual DD lenses. The comfortable wear time was significantly longer with DT1 (8.5 ± 4.1 hours) compared to habitual DD lenses (6.7 ± 3.2 hours) ($p = 0.04$). No significant differences were observed in vision ratings ($p = 0.07$).

Conclusion: Refitting symptomatic DD CL wearers with DT1 resulted in improved end-of-day comfort, reduced end-of-day dryness, and extended comfortable wear time compared to their habitual lenses. These findings suggest that DT1 may offer benefits for symptomatic DD wearers with dry eye disease.

Keywords: contact lenses, daily disposable, delefilcon A, dry eye symptoms, comfort, wear time

Introduction

Contact lens discomfort affects a substantial number of users, with estimates suggesting that up to 50% of wearers experience some level of discomfort.[1] Discomfort continues to be an issue despite increased adoption of the daily disposable (DD) modality and is not only detrimental to the user experience but also leads to a significant number of drop-outs.[2] The challenge is particularly acute for individuals with Dry Eye Disease (DED), as their condition may exacerbate the discomfort associated with lens wear, underscoring the importance of identifying and managing the factors contributing to discomfort in this group.[1,3–5]

A thorough examination of the factors leading to contact lens discomfort has been described in the Dry Eye Workshop II (DEWS II) report by the Tear Film & Ocular Surface Society[6] (TFOS). It provides a comprehensive overview of dry eye disease, including its implications for contact lens wear. DED, characterized by inadequate tear production or increased tear evaporation, is also a significant factor in contact lens discomfort.[1,3] While patients with severe DED would be unlikely to successfully wear contact lenses, addressing the specific issues faced by contact lens wearers with

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concurrent mild-to-moderate DED is essential for improving their wearing experience.[7] Effective strategies for mitigating discomfort include the careful selection of lens materials and designs that promote ocular surface wettability and tear film stability, ensuring proper lens fit, and modifying environmental and lifestyle factors that may contribute to dry eye and discomfort.[8] One approach that has been frequently reported in the literature is refitting these individuals with DD contact lenses.[9–14] DD lenses offer several potential advantages over other lens modalities, including reduced accumulation of deposits, improved ocular hygiene, and enhanced convenience.[15,16] Delefilcon A (DAILIES TOTAL 1®; DT1) DD contact lenses have been reported as a suitable option for novice[17] or lapsed contact lens wearers.[12] The lens has been described to employ water gradient technology, where the water content increases from 33% at the core to >80% at the surface, resulting in a lens material that provides high oxygen transmissibility.[12,17–22]

Previous studies have not yet examined the classification of DED subtypes and assessed the performance of DT1 lenses using the TFOS DEWS II guidelines[3] in symptomatic DD lens wearers. Therefore, this study not only fills this gap in the literature but also aims to provide valuable insights into the management of contact lens discomfort and dry eye symptoms in this specific population.

In this study, the dry eye subclassification guidelines provided by TFOS DEWS II[3] were employed to qualify and characterize the DED subtypes in these individuals to identify the primary underlying causes contributing to their discomfort. The primary endpoints of this study included subjective ratings of end-of-day comfort and dryness, average wear time, and comfortable wear time. Comparing these endpoints between habitual DD lenses and DT1 lenses will allow evidence-based recommendations for lens selection and management in this specific population.

Material and Methods

This study was conducted in compliance with the tenets of the Declaration of Helsinki and Good Clinical Practice. Ethics clearance was received from a University of Waterloo Research Ethics Board (Waterloo, Canada) prior to commencement of the study. Written informed consent was obtained from all participants prior to their enrollment in the study and prior to data collection.

Study Design

This was a prospective, single site, non-randomized, participant-masked, comparative dispensing study with three study visits (clinicaltrials.gov registration NCT04105842) to determine if DT1 lenses would provide equivalent or improved end-of-day comfort and longer comfortable wear time compared to participants' habitual lenses. Participant masking of the study lenses was facilitated by attaching individual strongly adhesive over-labels to each blister dispensed. Participant eligibility and trial lens fitting of DT1 lenses was performed at the screening visit (V1), which participants attended wearing their habitual spectacles. Eligible participants were then asked to wear their habitual lenses for 6 to 14 days before attending a follow-up visit (V2) at which the performance of the habitual lenses was assessed, and they were dispensed with over-labelled DT1 lenses to be worn for 1 month. Participants attended the 1-month follow-up visit (V3) after having worn the DT1 lenses for 29–34 days.

Subjects and Sample Size

The sample size required for a 2-tailed matched paired *t*-test to detect a difference of at least 5 points in subjective ratings, with alpha = 0.05, power 95% and diff/SD = 0.60 was 39. The final sample size achieved was 35, which provided greater than 90% power and this was considered sufficient.

To be eligible, participants needed to have healthy eyes (free of any inflammation or infection requiring therapeutic intervention) and not habitually wear the study lenses; be at least 17 years old and current wearers of spherical daily disposable contact lenses (power between +6.00D and −10.00D); have astigmatism of ≤1.00DC in each eye and achieve a best corrected visual acuity of ≤0.20 logMAR in each eye with both habitual and study contact lenses; demonstrate symptoms and signs of dry eye disease according to the TFOS DEWS II DED criteria;[3] and report dryness while wearing their habitual DD CLs with a Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)[23] score ≥12 and ≤20;[24,25] and be willing to wear the study lens for at least 3 days per week and 6 hours per day throughout the study.

Dry-Eye Assessments

The recommendations of the TFOS DEWS II Diagnostic Methodology report[3] were followed to confirm participant eligibility and to establish the dry eye sub-classification for each participant. To be eligible, participants were required to have symptoms and signs of DED if they had an Ocular Surface Disease Index (OSDI)[26] score of ≥13 and at least one of the following signs in at least one eye: Tear osmolarity ≥308mOsm/L or interocular difference >8 mOsm/L OR Non-invasive tear breakup time of <10 seconds OR More than 5 spots of corneal staining or >9 conjunctival spots.

Tear osmolarity was determined using the TearLab osmolarity system (Trukera Medical, Temecula, California, USA) by collecting ~50nL of tears from the lower lateral tear meniscus of each eye, without making direct contact with the eye.

Non-invasive tear break-up time (NITBUT) was captured with the Keratograph 5M (K5M; OCULUS Optikgeräte GmbH, Wetzlar, Germany) after two blinks, a video of the participant's tear film layer was recorded and subsequently analyzed for changes in the tear film reflections by the K5M's automated NITBUT feature. Three recordings were taken for each eye to obtain an average automated NITBUT value.

Tear meniscus height (TMH) measurements were taken at the Keratograph 5M; one image for each eye was captured and subsequently analyzed using the built-in caliper tool of the K5M. Three measurements within 1mm to the left and right directly below the pupil centre were recorded and averaged.

Corneal and conjunctival staining as well as lid wiper epitheliopathy (LWE) were assessed after a 1mg sodium fluorescein strip (DIOFLUOR™; Dioptic Laboratories Inc. Toronto, Canada), wetted with a few drops of saline, was applied to the superior bulbar conjunctiva of both eyes. Staining was graded for each corneal zone and conjunctival quadrant using the Efron grading scale (0 to 4, 0 = normal) in 0.1 scale increments, while viewing with cobalt blue light through a Wratten no. 12 barrier filter, followed by the LWE assessment. The horizontal length and sagittal width of the fluorescein staining were graded (0 to 3 scale) following the classification proposed by Korb et al.[27]

Meibomian gland expressibility was assessed at the slit-lamp biomicroscope to determine the ease of expression and the quality of the expressed meibum. The TearScience™ Meibomian Gland Evaluator[28] (Johnson & Johnson Vision, Jacksonville Florida, USA) was used to apply a pressure of 1.2g/mm^2 to the lower eyelid just inferior to the lid margin in three areas – nasal, central and temporal. Five consecutive glands in each area were assessed for expressibility and graded as follows: 0: blocked, 1: inspissated (toothpaste), 2: cloudy with debris, 3: clear.[29] The results for each location assessed for meibomian gland expressibility were summed to determine a Meibomian gland score (0–45) for each eye; these summed scores were also used to categorize participants into Meibomian Gland Dysfunction (MGD) groups, where a score of 40–45 represented "None – minimal clinical signs", 32–39 represented "Mild – mildly altered secretions", 23–31 represented "Moderate – moderately altered secretions" and 0–22 represented "Severe – no glands express".

Following a sphero-cylindrical and best-sphere refraction to verify the prescription, the participants were trial-fitted with DT1 lenses to confirm acceptable lens fit and vision criteria were met.

Lens Performance Assessments

The lens performance of habitual DD and DT1 lenses was quantified by means of subjective questionnaires and clinical assessments of overall fit acceptance, taking into consideration lens wettability and deposits, lens tightness and centration on the eye (0–4 scale, 0=Lens should not be worn, 4=Perfect fit).

Total CL wear time and comfortable CL wear time on a typical lens wear day as well as subjective symptom scores just prior to lens removal for comfort, dryness and vision (0–100 scale, with 100 being best) were collected at the follow-up visits for habitual DD lenses (after 6–14 days of wear) and DT1 lenses (after 29–34 days of wear), respectively.

Visual acuity and measures of lens fit were collected with both habitual and study lenses at the respective follow-up visits. The CLDEQ-8 questionnaire was completed at the screening visit relating to the habitual lens wearing experience and at the final visit relating to the study lens wear experience. Ocular health was assessed relating to lens wear for both habitual and study lenses.

Data Analysis

Analysis was conducted using Statistica 13 (TIBCO Software Inc, Palo Alto, CA). The data were not normally distributed; therefore, a non-parametric analysis (Wilcoxon Matched Pairs Test) was conducted. Data are reported as mean, standard deviation, median, and range.

Descriptive statistics are provided on information regarding baseline variables (e.g., age, sex). Differences between the lenses were compared using Wilcoxon matched pairs; statistical significance was set at 5%.

Results

In total, 35 symptomatic DD lens wearers (27 female, 8 male) completed the study. The habitual daily disposable lenses of the participants are shown in Table 1.

Participants were screened to assess dry eye criteria following the DEWS II guidelines[3] (Table 2). The mean OSDI score of the study population at study entry was 28, which would be classified as moderate dry eye, with the range of scores varying from 13 (mild) to 55 (severe).[3] Mean NITBUT, tear osmolarity, and TMH per eye were not dissimilar to healthy eye values, though the range of responses include values consistent with dry eye symptoms.[3]

Considering the DED criteria used for inclusion, 19 participants had a mean NITBUT of <10 seconds in at least one eye. Nine participants had an osmolarity of >308 mOsm/L in at least one eye. Further nine participants had values ≤308 mOsm/L but a difference of >8 mOsm/L between eyes. Twenty-six participants had more than 5 spots of corneal staining or > 9 conjunctival spots in at least one eye. Out of all 35 participants, 12 qualified with one dry eye sign, 18 qualified with two dry eye signs and five qualified with all three signs.

Three participants presented with a TMH of ≤0.20mm in both eyes, which would be classified as aqueous deficient, and seven more participants had a TMH of ≤0.20mm in at least one eye. However, of these 10 participants only two presented with a mildly reduced Meibomian Gland Score and unimpeded meibum expressibility, while the other eight participants had more severe signs of MGD. This means that only two out of 35 participants, or six per cent, could be truly classified as presenting with aqueous deficient dry eye, while all others experienced dry eye symptoms primarily due a combination of aqueous deficiency and evaporative MGD. For LWE, less than half of all participants had a non-zero grading for the upper lid and approximately half had a non-zero grading in the lower lid.

Median daily wear time with the DT1 lenses was not significantly different than with participant's habitual DD lenses (12.5 hours vs 12.0 hours, p = 0.11; Table 3, Figure 1); however, median comfortable wear time (8.5 hours vs 6.0 hours, p = 0.04; Table 3, Figure 1) was statistically significantly better with DT1 compared to habitual DD lenses. Median end-

Table 1 Habitual Lenses Worn by Participants at Study Entry (n = 35)

Habitual lens types		
Silicone Hydrogel	ACUVUE® OASYS 1-Day (Johnson & Johnson Vision)	10
	MyDay® (CooperVision)	3
	1-DAY ACUVUE® TruEye® (Johnson & Johnson Vision)	2
	clariti® 1 day (CooperVision)	2
	Ultra® ONE DAY (Bausch + Lomb)	2
Hydrogel	1-DAY ACUVUE® MOIST (Johnson & Johnson Vision)	7
	DAILIES® AquaComfort Plus® (Alcon)	4
	Proclear® 1 day (CooperVision)	2
	1-DAY ACUVUE® DEFINE® (Johnson & Johnson Vision)	1
	DAILIES® COLORS (Alcon)	1
	Zeiss Contact Day 1 Spheric (Carl Zeiss)	1

Table 2 Summary of Dry Eye Assessments Determined at the Screening (Mean ± SD (Median) [Range]) (n = 35)

Dry eye assessments	OD		OS	
OSDI	28 ± 10 (25) [13 to 55]			
NITBUT (s)	11 ± 6 (9) [3–25]		12 ± 5 (11) [4–21]	
Tear Osmolarity (mOsm/L)	300 ± 10 (300) [279–319]		297 ± 10 (296) [281–327]	
TMH (mm)	0.28 ± 0.07 (0.28) [0.12–0.42]		0.28 ± 0.08 (0.27) [0.16–0.48]	
		N		**N**
Lid wiper epitheliopathy (LWE) (≥2mm length and ≥25% width)	Upper lid Upper lid	13 18	Upper lid Upper lid	14 21
Meibomian Gland score (sum of all 15 glands, 0–45 scale) 0: blocked 1: inspissated (toothpaste) 2: cloudy with debris 3: clear	26 ± 9 (26) [8–43]		24 ± 8 (24) [11–45]	
Meibum Expressibility (5 central glands, 0–3 scale)[29]	**Score**	**N**	**Score**	**N**
0: all glands express; 1: three to four glands express 2: one to two glands express 3: no glands express	0 1 2 3	11 11 12 1	0 1 2 3	10 11 12 2
Meibum quality (0–45 range)[29]		**N**		**N**
45–40: minimal clinical signs 39–32: mildly altered secretions 31–23: moderately altered secretions 22–0: severely altered secretions	None Mild Moderate Severe	5 3 13 14	None Mild Moderate Severe	2 3 14 16

Table 3 Daily Wear Time, Comfortable Wear Time, CLDEQ-8 and Subjecting Ratings of End-of-Day Comfort, Dryness and Vision (Mean ± SD (Median) [Range]) (n = 35)

	Habitual DD	DT1
Daily wear time	11.4 ± 3.1 (12.0) [3.2–16.5]	12.0 ± 2.7 (12.5) [6.5–17.0]
Comfortable wear time	6.7 ± 3.2 (6.0) [1.0–12.5]	8.5 ± 4.1 (8.5) [1.0–17.0]
End-of-day comfort	71 ± 19 (75) [25–90]	80 ± 16 (80) [40–100]
End-of-day dryness	66 ± 19 (70) [20–95]	78 ± 16 (80) [40–100]
End-of-day vision	85 ± 11 (85) [60–100]	87 ± 13 (90) [50–100]
CLDEQ-8	17 ± 2 (17) [12–20]	13 ± 6 (13) [2–29]

of-day comfort ratings across all participants were significantly higher for DT1 compared to habitual DD lenses (80 vs 75, p = 0.01; Table 3, Figure 2). Similarly, median CLDEQ-8 scores (13 vs 17, p < 0.01; Table 3, Figure 3) were statistically significantly better with DT1 compared to habitual DD lenses.

Participant-reported dryness just before lens removal was lower with DT1 compared to their own lenses (80 vs 70, p = 0.01; Table 3, Figure 4), and no difference in vision (90 vs 85, p = 0.07; Table 3, Figure 5).

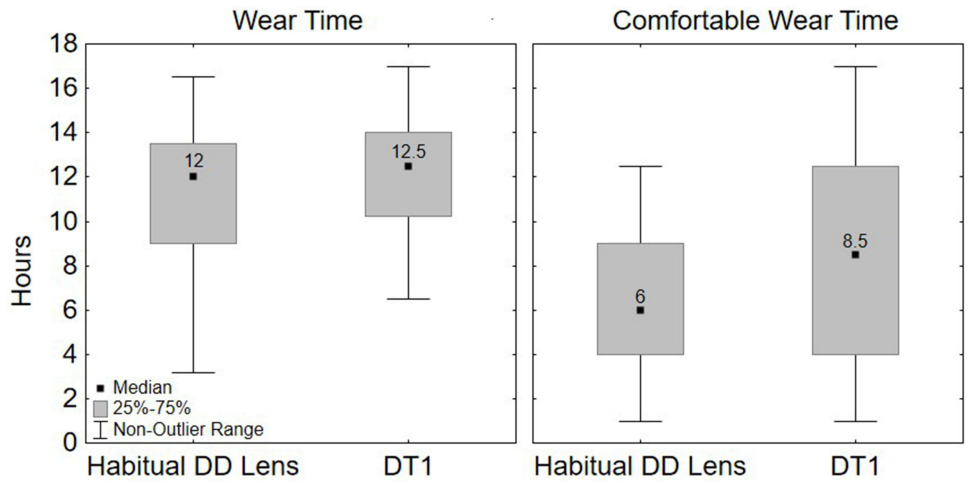

Figure 1 Daily wear time with habitual DD lenses and DT1 and comfortable wear time with habitual DD lenses and DT1 (n=35).

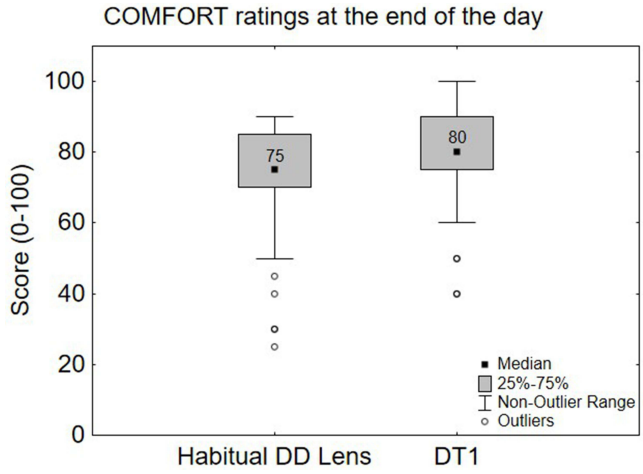

Figure 2 Subjective ratings of end-of-day comfort with habitual DD lenses and DT1 (n=35).

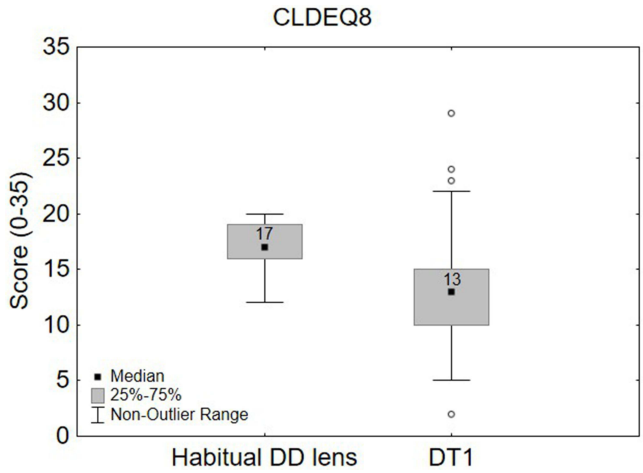

Figure 3 CLDEQ-8 with habitual DD lenses and DT1 (n=35).

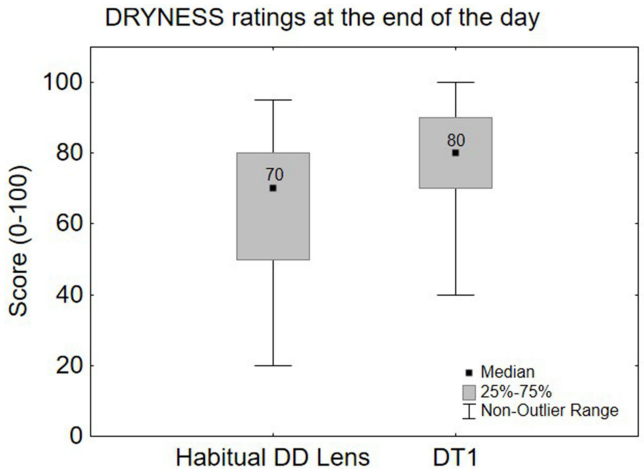

Figure 4 Subjective ratings of end-of-day dryness with habitual DD lenses and DT1 (n=35).

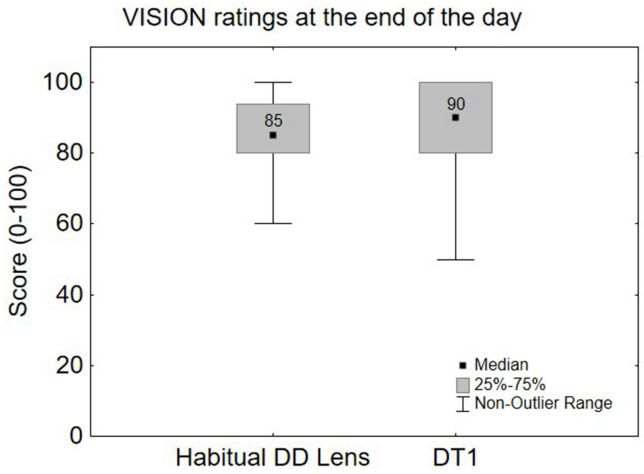

Figure 5 Subjective ratings of end-of-day vision with habitual DD lenses and DT1 (n=35).

Both habitual and study lenses had acceptable fit with no clinically relevant differences. There were no lens-related ocular findings or differences between habitual CL and after wearing DT1 for 1 month.

Discussion

Dry eye disease is very prevalent and impacts 5% to 50% of the population.[30] It is likely the primary reason for complaints of contact lens dryness and discomfort, however lens discomfort can also be found in asymptomatic patients when they are caused by lens-related or environmental factors.[31] This study investigated a cohort of participants who were habitual wearers of DD lenses and also present with signs and symptoms of DED to determine the performance of delefilcon A lenses. We hypothesized that delefilcon A lenses would provide equivalent or improved end-of-day comfort and longer comfortable wear time compared to participants' habitual lenses. Our findings support this hypothesis, demonstrating significant improvements in comfort, dryness, and comfortable wear time with delefilcon A lenses.

One important aspect of our study was the characterization of DED subtypes in the enrolled participants. While most participants experienced dry eye symptoms primarily due to evaporative causes or a mixture of evaporative and aqueous deficient causes, six percent (two participants) were classified as suffering from aqueous deficient dry eye alone, which is in agreement with previous findings where 10–11% prevalence was reported.[32,33]

The subjective ratings of comfort and dryness showed significant improvements with delefilcon A lenses compared to participants' habitual DD lenses and the CLDEQ-8 scores decreased after 1 month of delefilcon A lens wear, indicating a shift from "fair" (a score of 17) to "good" (a score of 13) levels of dryness symptoms based on the CLDEQ-8 validation of Chalmers et al.[23] A change of 4 points is considered a "change in overall opinion".[23]

End-of-day comfort ratings and dryness scores were significantly improved with delefilcon A lenses compared to habitual DD lenses and the difference in dryness of 10 points on a 0–100 scale would be considered a clinically meaningful difference.[34] Importantly, our study demonstrated that participants were able to wear delefilcon A lenses comfortably for a longer period during the day compared to their habitual DD lenses. The comfortable wear time with delefilcon A lenses was more than 2 hours longer, which reached statistical and clinical significance and may improve overall lens-wear satisfaction and could reduce dropout rates.

There were no significant differences in vision ratings between delefilcon A lenses and habitual DD lenses, indicating comparable visual performance. Lens fit parameters showed no clinically meaningful differences between the two lens types.

These findings align with previous studies that have demonstrated the performance of delefilcon A lenses in enhancing comfort and reducing dryness in various contact lens wearer populations.[11,17,35,36]

It is important to acknowledge certain limitations of the study. The relatively small sample size and the inclusion of participants with mainly MGD DED subtypes may limit the generalizability of the results to those with solely aqueous deficient DED. Future research with larger sample sizes in each dry eye subgroup would provide further insights into the effectiveness of delefilcon A lenses in each specific DED subtype. In addition, it is possible that the study design (non-crossover) may have caused a moderate placebo effect.[37] Additionally, the study duration of 1 month may not capture the long-term effects of delefilcon A lens wear. Long-term studies are warranted to evaluate the sustainability of the observed improvements in comfort and dryness. It should be noted that the package insert for delefilcon A lists "insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear" as a contraindication, which was not applicable to participants in this study given that they were current wearers of DD contact lenses. Thus, they were categorized as mild-to-moderate sufferers of DED, with levels of DED insufficient to interfere with lens wear.

Conclusion

This study demonstrated that DT1 lenses offered superior comfort, reduced dryness symptoms, and extended comfortable wear time compared to habitual DD lenses in symptomatic DD lens wearers with signs and symptoms of DED. These findings have important implications for eye care practitioners in their management of contact lens discomfort and DED. Refitting symptomatic DD lens wearers into DT1 lenses may provide an effective solution to enhance patient comfort and alleviate dry eye symptoms.

Abbreviations

DD, daily disposable; CL, contact lens; DT1, DAILIES TOTAL 1, delefilcon A; TFOS, Tear Film & Ocular Surface Society; DEWS II, The Dry Eye Workshop II; DED, Dry Eye Disease; OSDI, Ocular Surface Disease Index; SD, standard deviation; NITBUT, Non-invasive tear break-up time; K5M, Keratograph 5M; TMH, Tear Meniscus Height; LWE, lid wiper epitheliopathy; MGD, Meibomian Gland Dysfunction; CLDEQ-8, Contact Lens Dry Eye Questionnaire 8.

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This data was presented at both the 2020 American Academy of Optometry Meeting (interim results) and the 2023 American Optometric Conference (full results) as a poster presentation.

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Disclosure

Ms Jill Woods reports personal fees from CooperVision; grants to CORE from Alcon, and Johnson & Johnson Vision, outside the submitted work. Dr Lyndon Jones reports personal fees from Alcon, CooperVision, and Johnson & Johnson Vision, outside the submitted work. He is also involved in contracted research for Azura Ophthalmics, Bausch + Lomb, Essilor, Hoya, IMedPharma, Integral Biosystems, Novartis, Ophtecs, Ote Pharma, Santen, SightGlass, SightSage, Topcon, and Visioneering, outside the submitted work. The authors report no other conflicts of interest in this work.

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