


A Clinical Study Evaluating How Delefilcon A Contact Lenses Perform in Satisfied Senofilcon A Contact Lens Wearers



Chris Lievens^{1,2,*} , Andrew D. Pucker³, Morgan Bromley¹, Brad Giedd^{2,4}, Gina Wesley^{2,5}, Jason Miller^{2,6} and Quentin X. Franklin⁷

¹Southern College of Optometry, Memphis, TN, USA

²Eye Research Associates, LLC, Pittsburg, KS, USA

³Eminent Ophthalmic Services, Milledgeville, GA, USA

⁴Maitland Vision, Maitland, FL, USA

⁵Complete Eyecare of Medina, Medina, MN, USA

⁶Eyecare Professionals of Powell, Powell, OH, USA

⁷University of Alabama at Birmingham, Birmingham, AL, USA

Abstract:

Introduction: To investigate whether satisfied daily disposable Contact Lens (CL) wearers can switch CL brands and remain satisfied as CL wearers.

Methods: This 2-month, 4-visit switch study (NCT06847230) recruited 18- to 40-year-old subjects who were currently satisfied Acuvue® Oasys MAX (MAX; senofilcon A) CL wearers (CLDEQ-8 score <12). Visits 1 and 2 confirmed that subjects had well-fit MAX CLs. Subjects were then refitted into Dailies Total1® (DT1; delefilcon A) CLs and were asked to start wearing them at Visit 3. Subjects then returned 1 month later to have their DT1 CLs evaluated with the CLDEQ-8, Visual Analog Scales (VAS), and the Impact of Dry Eye on Everyday Life (IDEEL) Quality Of Life (QoL) domains.

Results: This study enrolled 36 CL wearers, with a median (interquartile range) age of 30.5 (11.0) years (69.4% female). After switching to DT1, the study found a median CLDEQ-8 score of 8.5 (10.5) (asymptomatic level).

Discussion: Median IDEEL questionnaire scores while wearing DT1 were good, with daily activities at 97.8 (8.9) units, feelings at 97.9 (7.3) units, and work scores at 100 (10) units. Subjects likewise rated their end-of-day eye comfort (35.0 [32.5] units), eye dryness (25.0 [58.0] units), and clarity of vision (44.5 [18.0] units) as good with a ± 5.0 VAS (positive = comfortable; negative = uncomfortable).

Conclusion: This study found that most subjects were able to remain satisfied CL wearers and had a positive CL wearing experience after switching CL brands, suggesting that clinicians can have confidence when switching patients from senofilcon A to delefilcon A daily disposable CLs.

Keywords: Delefilcon A, Senofilcon A, Contact lens, Comfort, Vision, Daily disposable.

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*Address correspondence to this author at the Southern College of Optometry, Memphis, TN, USA and Eye Research Associates, LLC, Pittsburg, KS, USA; E-mail: clievens@sco.edu

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1. INTRODUCTION

Refitting patients into a different Contact Lens (CL) is a common practice for troubleshooting CL discomfort and dissatisfaction [1]. Several CL materials have demonstrated success in re-engaging previously unsatisfied patients in CL wear [1-3]. However, there is much less literature regarding the refitting of currently satisfied CL wearers. Many practitioners may be reluctant to refit their currently satisfied CL wearers, even when newer, more advanced technology is available or when patients can benefit from a cost perspective while having a similar wearing experience. The main reason for this stance may be fear of upsetting the patient and jeopardizing their retention [4]. Recent studies have shown potential for successfully refitting a previously satisfied CL wearer, as similar on-eye performance between CL materials has been reported [5-8].

The Dailies Total1® CL (DT1; delefilcon A; Alcon; Fort Worth, Tx, USA) is a daily disposable CL that has a core modulus of 0.76 Minimum Protection Area (MPA) and an oxygen transmissibility of 156 dk/t. The water content of the CL gradually increases, starting at 33% in the core and approaching 100% at the surface. DT1 CLs featuring this Water Gradient Technology were reported to have a reduced Thin Aqueous Layer Break (TALB) and an increased Non-Invasive Tear-Break Up Time (NIBUT) compared to the CLs when using another conventional silicone hydrogel material in CL wearers [9]. This CL also releases phosphatidylcholine during wear, which is a polar lipid that can be found in natural tears. This type of tear film lipid has been reported to help with tear film stability [10]. This CL material has been recently found to provide adequate comfort to wearers who had previously discontinued CL wear due to dryness and discomfort [1]. In Lievens *et al.*, the subjects reported high satisfaction with their vision, comfort at the end of the day, and overall satisfaction while wearing the study CL. At the end of the 1-month study period, nearly 90% of the subjects reported that they were likely to continue wearing the study CL, and an even greater percentage was willing to recommend it to a friend [1]. Similar rates of satisfaction and a decrease in dryness have also been found in DT1 CL when compared to other CL materials [11, 12]. Acuvue® Oasys MAX (MAX; Senofilcon A; Johnson & Johnson Vision Care, Inc.; Jacksonville, FL, USA) is the newest version of the Acuvue material that has also shown good comfort [8]. MAX is a daily disposable CL that has a comparable core modulus of 0.74 MPA and oxygen transmissibility of 121 dk/t. The water content is 38% throughout the CL. It is designed with TEARSTABLE™ technology, which enhances the stability of the tear film by distributing Polyvinylpyrrolidone (PPV) throughout the CL, resulting in reduced *in-vitro* evaporative dehydration. This lens also features OPTIBLUE™ LIGHT FILTER (blue-violet and ultraviolet filtering) for protection throughout the day [13].

Despite these advancements in the CL field, the definition of satisfied CL wear remains ill-defined, likely because its subjective nature makes it difficult to quantify. It is often better understood once broken down into the factors that most strongly impact it. The Cornea and Contact Lens Research Unit (CCLRU) defined successful CL use based on wear time, comfort, and vision [14]. These standards require

12 hours of wear each day, for at least 6 days per week, with visual acuity within one line of correction with spectacles, and no reports of ocular discomfort. Other factors, such as ease of handling, have also been found to influence CL satisfaction [5]. However, Diec *et al.* agree that comfort and vision satisfaction are the most impactful, as they found that when either was unsatisfactory, only 50% of subjects would continue wearing the CL, and if both were unsatisfactory, no subjects wished to continue wearing it [12]. Therefore, the purpose of the current study was to investigate whether successful patients in one lens material (senofilcon A) could be successfully switched to another (delefilcon A). The results of the study may also provide clinical evidence to further expand the utility of DT1 for some clinicians who primarily reserve the lens as a problem-solving refit solution.

2. METHODS

2.1. Subjects

This 2-month, 4-visit study was conducted at the Southern College of Optometry (Memphis, TN, USA), Maitland Vision (Maitland, FL, USA), Complete Eyecare of Medina (Medina, MN, USA), and Eyecare Professionals of Powell (Powell, OH, USA). This study obtained Institutional Review Board (IRB) approval from the Southern College of Optometry, USA and adhered to the principles outlined in the Declaration of Helsinki. This study was registered with ClinicalTrials.gov (NCT06847230). Subjects were included based on the criteria that they were between 18 and 40 years old and wore MAX CLs. Subjects were required to have 20/20 or better visual acuity while wearing their MAX CLs and to have worn the MAX CLs for at least 3 months in the past year and be currently wearing MAX CLs at the time of the baseline visit. All subjects were required to have a Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) score <12 while wearing MAX CLs and explicitly indicate that they were satisfied with the MAX CLs [15, 16]. While in the study, subjects were required to be willing and able to wear the DT1 CL (astigmatism <0.75 OD and OS) for 12 or more hours per day with at least 8 hours of electronic device use while wearing the CLs, and not to wear the CLs overnight. Exclusion criteria included individuals with a history of viral eye disease, ocular surgery, severe ocular trauma, corneal dystrophies, active infection, currently using ocular medications, or those who were pregnant or breastfeeding. Subjects were also excluded if they had a history of dry eye disease, ocular allergies, or systemic conditions that were thought to alter the tear film. Subjects were additionally excluded if their CL history included DT1 wear for longer than 1 week in the past, previous rigid CL wear, or need for a near add for presbyopia. Subjects were released from the study if their visual acuity worsened by a line or more at Visit 2 compared to Visit 1 while wearing CLs.

2.2. Surveys and Clinical Tests

Subjects were instructed to wear their habitual MAX CLs to the baseline visit (visit 1), during which a CLDEQ-8 score of <12 was confirmed. Subjects began the baseline visit by verifying eligibility and having their demographic information collected. Visual acuity was evaluated with a high-contrast Bailey-Lovie chart. Manifest refraction was then completed with the investigator's standard method

after having the subjects remove their CLs; no more than 1.00 D of sphere of change was allowed beyond the initial blur balance starting point. A slit-lamp biomicroscopy exam for general ocular health was then completed (eyelashes, eyelids, conjunctiva, and cornea). A CL fitting was then performed to ensure an optimized fit with the MAX CLs (centration, movement, coverage, and CL power), and each subject was given 10 days' worth of MAX CLs.

Subjects returned 1 week later (visit 2), and their visual acuity was evaluated, and a slit-lamp biomicroscopy examination was performed. Subjects were also required to indicate "yes" to the following question to continue the study. Are you currently satisfied with the comfort of your (MAX) contact lenses? A CL evaluation was then performed to ensure centration, movement, coverage, and power appropriateness while wearing the MAX CLs. If the CLs were optimal with the recorded visual acuity within 1 line of what was previously recorded at Visit 1, they were refitted into DT1 CLs. If acuity dropped 1 line or more from the previously recorded measurement, the subject was exited from the study. The DT1 CLs were evaluated for centration, movement, coverage, and CL power, and power adjustments were only made if visual acuity significantly improved. Subjects were then educated on the washout period, including instructions to stop wearing MAX CLs and refrain from wearing any CL for 1 week.

Subjects returned 1 week later (visit 3), at which point the DT1 CLs were dispensed. Visual acuity was assessed, a slit-lamp biomicroscopy exam was performed, and the CL fit was confirmed. Additionally, they were provided with a one-month supply of DT1 CLs and educated on their use. Subsequently, one month later, the participants returned for the 4th visit, and again the visual acuity with the CLs was evaluated, a slit-lamp biomicroscopy exam was performed, and the CLs were evaluated for fit and condition. Only subjects with an optimal CL fit were allowed to complete the subjective outcome measures. The CLDEQ-8 questionnaire was then completed. A set of Visual Analog Scales (VAS) regarding comfort, eye dryness, and clarity of vision was administered, and an investigator-developed Likert survey was completed, which explored vision, dryness, comfortable wear time, willingness to continue wearing the DT1 CLs, digital device usage, and general lifestyle. The Impact of Dry Eye on Everyday Life (IDEEL) and Quality of Life (QoL) domains were lastly completed. All subjects were then compensated for their time and released from the study.

2.3. Data Analysis

All data were collected using Research Electronic Data Capture (REDCap; Vanderbilt University, Nashville, TN, USA) [17, 18] and analyzed with Stata/BE 18 (StataCorp LLC, TX, USA). Non-parametric statistics (medians, interquartile ranges [IQR]) were used to evaluate visual acuity, refractive error, CLDEQ-8 scores, IDEEL scores, Likert data, and VAS scores because of the likely skewed nature of the data. With the primary goal of evaluating whether satisfied MAX CL wearers could become satisfied DT1 CL wearers, comparisons were generally not made between the two brands. However, CLDEQ-8 scores were compared

using the Wilcoxon signed-rank test to determine if subjects remained satisfied with their CLs after switching brands. No formal sample size calculation was performed for this single-arm study, given its descriptive nature. A cohort of 29 subjects has been shown to be sufficient in a prior evaluation of patient-reported outcomes [19, 20].

3. RESULTS

This study enrolled 36 participants who were satisfied MAX CL wearers based on self-report and had a median (IQR) CLDEQ-8 score of 8.0 (8.0) units at the baseline visit (Fig. 1). The median age of the enrolled participants was 30.5 (11.0) years, and 69.4% were female participants. Regarding ethnicity and race, the total sample reported 8.3% being Hispanic, with 2.8%, 88.9%, 5.6%, and 2.8% identifying as Black or African American, White, more than one race, or unknown or not reported, respectively. Manifest refraction at the baseline visit found right eyes to have a median (IQR) sphere and cylinder power of -3.00 (1.88) D and 0.0 (0.5) D, respectively, while manifest refraction at the baseline visit found left eyes to have a median (IQR) sphere and cylinder power of -3.00 (2.25) D and 0.00 (0.25) D, respectively. Visual acuity with manifest refraction was -0.10 (0.05) logMAR for the right eye and -0.10 (0.00) logMAR for the left eye. None of the subjects reported any adverse events, and all slit-lamp examination findings remained normal throughout the study.

At baseline, subjects had their MAX fits confirmed. When evaluating the MAX CLs, all CLs had acceptable coverage, centration, and movement. The power of the MAX CLs was found to be satisfactory, with none of the subjects requiring a change in CL power. The subjects also exhibited good visual acuity while wearing the CLs (Tables 1 and 2). When subjects returned for visit 2, 1 week later, their MAX CLs were again evaluated and were found to have efficient coverage, centration, and movement, with no power changes needed, as well as good visual acuity while wearing the CLs (Table 1). Moreover, all subjects indicated that they were satisfied with the comfort of the MAX CLs. At visit 2, the evaluations of the DT1 CLs revealed that all CLs had good coverage, centration, and movement. Visual acuity while wearing the CLs was also satisfactory, and their DT1 CLs had a similar power compared to the MAX CLs (Tables 1 and 2). Subjects then returned for visit 3, 1 week later, and they were dispensed their DT1 CLs. When evaluating the dispensed DT1 CLs, all were found to have good coverage, centration, and movement. Additionally, the subjects exhibited good visual acuity while wearing the CLs (Table 1). Ultimately, subjects then returned for visit 4, one month later, and their CLs were reevaluated. The investigators determined that all subjects had good visual acuity, along with good coverage, centration, and movement while wearing DT1 CLs (Table 1).

The subject's wearing experience with the DT1 CLs was evaluated at visit 4. The subjects were found to have a median CLDEQ-8 score of 8.5 (10.5) units while wearing DT1 CLs. A Wilcoxon signed-rank test demonstrated that the CLDEQ-8 score while wearing DT1 lenses was significantly different from the baseline score with habitual MAX CLs ($p = 0.004$).

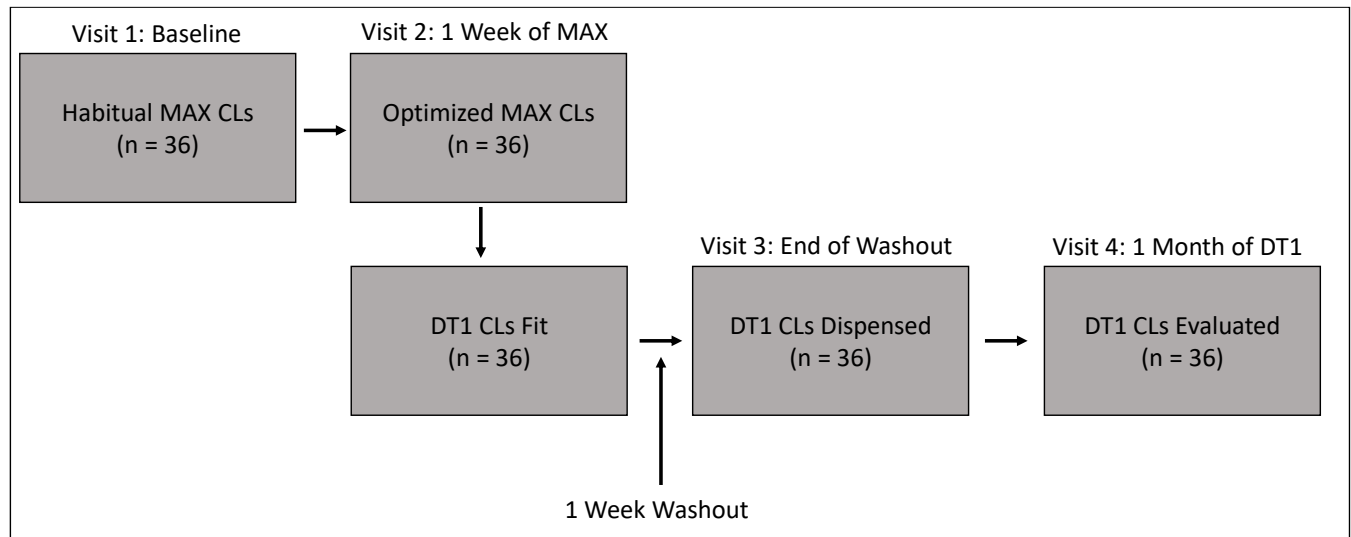


Fig. (1). Study flow diagram.
Note: *CL = Contact Lens; DT1 = Dailies Total1®; MAX = Acuvue® Oasys MAX.

Table 1. Visual acuity with contact lenses by visit.

Visit	Contact Lens	Right Eye (Median ± Interquartile Range)	Left Eye (Median ± Interquartile Range)
1	ACUVUE® OASYS MAX 1-Day	-0.10 (0.10)	-0.10 (0.00)
2	ACUVUE® OASYS MAX 1-Day	-0.10 (0.00)	-0.10 (0.00)
2	Dailies Total1®	-0.10 (0.15)	-0.10 (0.15)
3	Dailies Total1®	-0.10 (0.00)	-0.10 (0.00)
4	Dailies Total1®	-0.10 (0.00)	-0.10 (0.00)

Table 2. Contact lens powers.

Visit	Correction Type	Right Eye (Median ± Interquartile Range)	Left Eye (Median ± Interquartile Range)
1	ACUVUE® OASYS MAX 1-Day	-3.00 (1.75) D	-3.00 (2.13) D
2	Dailies Total1®	-3.00 (1.50) D	-3.00 (2.00) D

The absolute difference of 8.0 units (CLDEQ-8 score) for MAX CLs *versus* 8.5 units for DT1 was not clinically meaningful. DT1 CLs were furthermore found to have exceptionally positive IDEEL questionnaire scores, with this study finding IDEEL daily activities, feelings, and work scores of 97.8 (8.9) units, 97.9 (7.3) units, and 100 (10) units, respectively. When the subjects were asked Likert questions about their DT1 CL wearing experience (Table 3), they indicated that they strongly agreed or agreed that they would continuing wearing the CLs after the study ends (58.3%), 69.4% showed satisfaction with wearing the CLs, 80.6% were confident with their vision while wearing the CLs, 61.1% were satisfied with their end of day eye comfort while wearing the CLs, 80.6% were satisfied with their end of day vision while wearing the CLs, 69.4% were satisfied with their overall eye comfort while wearing the CLs, 80.6% were satisfied with their ability to play sports and perform

fitness activities while wearing the CLs, 80.6% were satisfied with their ability to use digital devices while wearing the CLs, and 66.7% would recommend the CLs to a friend. Furthermore, the subjects were asked to rate their end of day eye comfort (35.0 [32.5] units), eye dryness (25.0 [58.0] units), and clarity of vision (44.5 [18.0] units) after wearing DT1 CLs on a ±50 visual analog scale (VAS) with the results indicating overall good/positive scores for each of these metrics.

4. DISCUSSION

Clinicians commonly refit patients into alternative CLs when they are struggling with factors such as comfort or vision, yet they might hesitate to switch patients into a different CL brand when patients are happy with their current CLs. A CL switch in a satisfied CL wearer may be driven by considerations such as the release of a newer CL material

into the market, a negative clinical sign noticed by the clinician but not the patient, the discontinuation of a CL brand, or cost factors. The current study found that when switching a successful daily disposable CL wearer to an alternative daily disposable CL, most subjects were able to remain satisfied, maintain excellent visual acuity, and experience a high overall visual quality of life.

Table 3. Investigator-developed likert questionnaire responses.

Question	Response (Percent)
1. I am likely to continue wearing the study contact lens after the study ends.	Strongly Agree: 27.8% Agree: 30.6% Neither Agree nor Disagree: 11.1% Disagree: 25.0% Strongly Disagree: 5.6%
2. I am satisfied with wearing the study contact lens.	Very Satisfied: 27.8% Satisfied: 41.7% Indifferent: 5.6% Unsatisfied: 25.0% Very Unsatisfied: 0.0%
3. I am satisfied with my vision while wearing the study contact lens.	Very Satisfied: 36.1% Satisfied: 44.4% Indifferent: 13.9% Unsatisfied: 5.6% Very Unsatisfied: 0.0%
4. I am satisfied with my end-of-day eye comfort while wearing the study contact lens.	Very Satisfied: 16.7% Satisfied: 44.4% Indifferent: 16.7% Unsatisfied: 16.7% Very Unsatisfied: 5.6%
5. I am satisfied with my end-of-day vision while wearing the study contact lens.	Very Satisfied: 33.3% Satisfied: 47.2% Indifferent: 11.1% Unsatisfied: 8.2% Very Unsatisfied: 0.0%
6. I am satisfied with my overall eye comfort while wearing the study contact lens.	Very Satisfied: 27.8% Satisfied: 41.7% Indifferent: 2.8% Unsatisfied: 27.8% Very Unsatisfied: 0.0%
7. I am satisfied with my ability to play sports and perform fitness activities while wearing the study contact lens.	Very Satisfied: 38.9% Satisfied: 41.7% Indifferent: 16.7% Unsatisfied: 2.8% Very Unsatisfied: 0.0%
8. I am satisfied with my ability to use digital devices (e.g., smartphones, computers) while wearing the study contact lens.	Very Satisfied: 27.8% Satisfied: 52.8% Indifferent: 13.9% Unsatisfied: 5.6% Very Unsatisfied: 0.0%
9. I would recommend the study contact lenses to a friend.	Strongly Agree: 25.0% Agree: 41.7% Neither Agree nor Disagree: 16.7% Disagree: 16.7% Strongly Disagree: 0.0%

In the current study, all subjects initially started wearing MAX CLs, having done so for at least 3 months in the past year and continuing to wear them at the study's outset. These subjects were then switched to DT1 CLs. While there is limited data in the literature related to the MAX CL, Buch *et al.* have previously compared the MAX CL to the DT1 CLs in a prospective, parallel design study [13]. Buch *et al.*'s

study specifically randomized habitual soft CL wearers to wear MAX CL or DT1 CLs for 2 weeks [13]. The authors then asked these subjects to rate questions related to both visual and physical comfort and found that the MAX CL wearers had a higher odds of indicating that the worn CLs had excellent or very good visual and physical comfort compared to the DT1 CL wearers. While the current study had a completely different study design, which prevents a direct comparisons between the current research and Buch *et al.*'s work, the current study determined that satisfied MAX CL wearers could be successfully refit into DT1 CLs while also allowing the subjects to have low/good CLDEQ-8 scores, excellent IDEEL QoL scores, and positive/comfortable VAS scores. Subjects also strongly agreed that the DT1 CLs had a positive impact on their lives.

An additional unique aspect of the current study was that it evaluated subjects who used an electronic device at least 8 hours per day. While one might hypothesize that digital devices may stress the ocular surface of CL wearers because patients who use digital devices blink far fewer times per minute than patients who are in unstimulated gaze (~16 blinks/minute vs. ~6 blinks/minute) [21], the literature suggests the typical CL wearer can use digital devices without additional issue [22-24]. This statement is supported by Meyer *et al.*, who evaluated CL and non-CL wearers who used digital devices for at least 4 hours per day with an investigator-developed questionnaire that evaluated 10 symptoms related to eye fatigue and found both groups had similar symptomatology overall [22-24]. Nevertheless, the authors did note that the CL wearers had less severe and less frequent eye strain/pain and more severe and more frequent dry eye symptoms than non-CL wearers [22-24]. Sphere DT1 CLs used in the current study did not have blue light filtration, whereas MAX CLs filter ~60% of short-wave visible light between 380 and 450 nm. However, there is no conclusive evidence to support that blue light filtering benefits digital device users who have healthy eyes [25-27]. The present study found that the vast majority of subjects who switched CLs were satisfied with their ability to use digital devices while wearing the DT1 CLs and continued using their devices at least 8 hours per day.

While this study was strengthened by having a rigorous visit schedule that helped ensure that the subjects were truly satisfied with the MAX CLs at the start of the study, the multiple approaches used to evaluate the subjects' wearing experience (e.g., CLDEQ-8 scores, IDEEL scores, Likert responses), and a defined washout period between CLs to help ensure that results of the study lens was truly independent, this study does have limitations that should be acknowledged. The first key limitation is that this study only evaluated subjects who were habitually satisfied with the MAX CL. This study may have reached a different conclusion if a mix of happy and unhappy MAX CL wearers had been evaluated. This approach was taken to help ensure consistency among the subjects enrolled in this study. Nevertheless, future studies should determine whether unhappy MAX CL wearers will remain unhappy if they are switched to the DT1 CLs or if they would become satisfied CL wearers when given an alternative CL option. This study also evaluated only one CL brand at the start and offered

subjects only one alternative CL brand at the switching point. Thus, the results from this study can only be applied to patients who start with MAX CLs and who are switched to DT1 CLs. Repeating this study with additional CL options that have different wear schedule options (*e.g.*, patients who are satisfied with multiple CL brands and are willing to switch to a different brand) could provide additional data to either support or refute the practice of switching satisfied CL wearers to a different CL.

CONCLUSION

This study evaluated subjects who were happy with their habitual, premium, daily disposable CL and refitted them into an alternative premium daily disposable CL and found that these subjects remained satisfied CL wearers, as indicated by them having excellent visual acuity, a high visual quality of life, and great patient-reported outcomes. These outcomes occurred despite all the subjects being frequent digital device users. These data provide confidence for practitioners to switch satisfied senofilcon A (MAX) CL wearers to delefilcon A (DT1). While this study has provided data about satisfaction when switched to a novel CL material, additional work is needed to determine how dissatisfied CL wearers of one brand may respond to a refit with a different CL brand. Similar research should be expanded to include various brands and/or modalities of CLs, providing clinicians with more comprehensive data.

AUTHORS' CONTRIBUTIONS

The authors confirm their contributions to the paper as follows: B.G., G.W., J.M.: Data collection; M.B., Q.F.: Data curation; A.P.: Data analysis and interpretation of results; C.L.: Investigation. All authors reviewed the results and approved the final version of the manuscript.

LIST OF ABBREVIATIONS

IDEEL	=	Impact of Dry Eye on Everyday Life
CL	=	Contact Lens
MPA	=	Minimum Protection Area
TALB	=	Thin Aqueous Layer Break
NIBUT	=	Non-Invasive Tear-Break Up Time
PPV	=	Polyvinylpyrrolidone
IQR	=	Interquartile Ranges

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study obtained Institutional Review Board (IRB) approval from the Southern College of Optometry, Memphis, TN, USA.

HUMAN AND ANIMAL RIGHTS

All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

All participants provided written informed consent.

AVAILABILITY OF DATA AND MATERIALS

The data supporting the findings of the article is available from the Southern College of Optometry and is available after email request to the corresponding author.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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