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Real-Time Changes in the Comfort of a Toric, Monthly, Soft Contact Lens Over a Long Day of Wear

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Purpose: The purpose of this work was to determine the comfort performance of a toric, monthly, silicon hydrogel CL (lehfilcon A; TOTAL30 for Astigmatism) over a long day of wear.

Methods: This was a 1-month, 3-visit, prospective, single-arm study. Adult, 18- to 45-year-old CL wearers with good vision who were minimally symptomatic (CLDEQ-8 scores ≤12) were enrolled. Subjects were required to have astigmatism ranging from −0.75 D to −2.50 D in each eye and were required to wear the study CLs from about 8:00 AM until 12:00 AM each day. Comfort data with the study CL throughout the wear day were collected via text messaging.

Results: A total of 47 subjects who had a mean ± SD age of 29.5 ± 7.0 years were analyzed. Within a specified time point across the month of wear, CL comfort did not vary (all p-value ≥ 0.82), yet CL comfort did decrease across the wear day for all days evaluated (all p-value <0.001). Most subjects found their CLs to be comfortable with only 1.8% of subjects reporting an uncomfortable score at CL application and only 8.5% of subjects reporting an uncomfortable score after 16 hours of CL wear.

Conclusion: A high level of consistency and predictability in comfort was found within the first month of wearing lehfilcon A CLs. This suggests that patients with minimal CL-related discomfort at initial fitting of a lehfilcon A CL may likely tolerate longer wear time with minimal discomfort across the entire month of wear.

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Keywords: comfort, contact Lenses, lehfilcon A, toric, visual analog scale

Introduction

The leading cause of contact lens (CL) dropout is CL dryness and/or discomfort.[1–4] Soft CL wearers experience dryness at double the rate of non-CL wearers,[5] which oftentimes leads to discomfort and ultimately CL dropout.[2] Other reasons for CL dropout include poor vision, handling, and cost of CLs.[6] A recent review has found that the frequency of CL dropout ranges from 12.0% to 27.4% with this dropout frequency staying relatively stable over the past 20 plus years.[1,7] This static frequency of CL dropout is surprising since there have been a number of dramatic soft CL innovations during this time frame (eg, widely available daily disposable CLs, silicone hydrogel CL materials with high oxygen transmissibility, new CL surface coatings).[2] There is particularly more discomfort towards the end of the day, which accounts for 43% to 72% of CL dropouts.[6] Furthermore, toric soft CLs have a higher incidence of dryness than an equivalent spherical CL (40% vs 13%, respectively).[8] Many factors come into play regarding longevity and CL wear retention, including but not limited to equivalent water content, CL material, replacement frequency, tear film stability, eyelid interaction, wetting agents, toric design, CL handling, care system, and patient compliance.[2]

Maldonado et al determined a connection between visual blur and ocular discomfort, with the authors finding that there was a stronger positive correlation between comfort and subjective vision quality compared with comfort and

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measured visual acuity.[9,10] While eyecare providers generally make visual acuity the top priority, patients will often be most satisfied with CLs that feel comfortable in their eyes, even at the expense of optimal vision.[11] CL discomfort is a difficult entity to measure even with the use of a validated questionnaire such as the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8).[12] Newer studies, including this one, are attempting to ascertain real-time CL comfort throughout the day by having subjects report on comfort at regular intervals of wear time, as is the case with this study at application and at about 8, 10, 12, 14, and 16 hours of CL wear. In a 2023 study, Call et al demonstrated that although the comfort of spherical soft CL tended to decrease throughout the day, subjects reported good comfort (positive scores) for the duration of the study.[13]

Since it is common that CL wearers experience discomfort symptoms towards the end of the wear day, it is of the upmost importance to map this phenomenon in real-time.[3] While comfortable wear times vary from patient to patient, Terry et al have suggested that patients should be able to comfortably wear their CLs for at least 12 hours per day for at least 6 days per week.[4] Nevertheless, many patients prefer to wear their CLs for even more hours per day, and the literature currently lacks sufficient data to fully comment on the full day wearing experience in toric CL wearers, which for many patients may be 16 hours per day,[13] especially if they have demanding careers. While some studies have analyzed the experience of spherical CL wearers, there has been limited data on the comfort of toric CLs, which more frequently struggles with CLs than spherical wearers.[14] Thus, this study investigated the comfort of a relatively new water gradient, monthly, toric CL (TOTAL30 for Astigmatism; lehfilcon A; Alcon; Fort Worth, TX, USA) across long days of wear over 30 days. The present work set out to determine if this toric 30-day replacement daily wear CL provides adequate comfort to be worn for a 16-hour day. The overarching purpose of this study was to map comfort over the full wear day in established, asymptomatic to minimally symptomatic, soft CL wearers wearing the new study CLs. These data are not only important for judging the performance of this particular CL, but they will provide some of the first insights into the full day CL wearing experience of a toric CL over one month.

Materials and Methods

Subjects

This study followed a similar methodology to a study previously completed by the investigators.[13] This 1-month, 3-visit prospective, single arm, multi-center, clinical trial was conducted at the Southern College of Optometry (Memphis, TN, USA), Kannarr Eye Care (Pittsburg, KS), and Coldwater Vision Center (Coldwater, MS, USA). The study was approved by the Institutional Review Board of the Southern College of Optometry, and this study conformed to the tenets of the Declaration of Helsinki. This study was registered with ClinicalTrials.gov (NCT06052046). All sites were virtually trained by the lead investigator, and all sites followed the same protocol. Subjects were recruited via clinic records, email, and fliers. Subjects were screened prior to the study visit with an Institutional Review Board (IRB) approved phone screening survey. Adult, 18- to 45-year-old, CL wearers who had 20/20 equivalent visual acuity or better in both eyes (Logarithm of the Minimum Angle of Resolution [logMAR] ≤0.00) and who were asymptomatic or minimally symptomatic were recruited (CLDEQ-8 <10).[15,16] Subjects were required to be able to wear the study CLs, and they were required to have a smartphone with text messaging capabilities to be able to answer electronic survey questions. Subjects were required to have astigmatism ranging from −0.75 D to −2.50 D in each eye, were required to have regularly worn 2 week or monthly CLs within the past 6 months and were required to be a current CL wearer. Subjects were required to provide a glasses prescription that was less than 2 years old. Subjects were required to be willing to start wearing their CLs between 6:00 AM and 8:00 AM and wear their CLs until about 12:00 AM each day at least six days a week while in the study and during text message survey days. The 6:00 AM and 8:00 AM start time was required to help standardize message deployment for each subject. Subjects were excluded if they were a current or past hard CL wearers, had a known systemic health condition that was thought to alter tear film physiology or had a history of viral eye disease, ocular surgery, severe ocular trauma, active ocular infection, or active ocular inflammation. Subjects were also excluded if they were currently using isotretinoin-derivatives or ocular medications, rewetting drops, artificial tears, or if they were pregnant or breast feeding. Subjects were asked to discontinue usage of their current CLs one week prior to the initial visit to allow for a washout period.

Surveys and Clinical Tests

The baseline visit (Visit 1) started by verifying the IRB-approved phone screening survey data to ensure that each subject was still eligible for the study (Figure 1). Subjects' CLDEQ-8 questionnaire scores regarding their habitual CLs satisfaction over the 2 weeks of wear prior to the washout period were also verified to help ensure that the subjects were asymptomatic CL wearers. While subjects were asked to report to the visit without their CLs, they were asked to complete the CLDEQ-8 questionnaire as if they were wearing their habitual CLs. Patient demographics were collected via a questionnaire developed by the investigators. Non-eligible subjects were dismissed at this time or rescheduled depending upon the reason for ineligibility. Eligible subjects were enrolled, consented, and requested to sign Health Insurance Portability and Accountability Act (HIPAA) documentation. Visual acuity was then measured with a high-contrast LogMAR chart, and manifest refraction was determined via a phoropter with the investigator's preferred method. A binocular balance was performed if best-corrected visual acuity was equal between the eyes. The investigator then used a slit-lamp biomicroscope to document normal and/or remarkable findings of the anterior eye structures (eyelashes, eyelids, conjunctiva, and cornea). Subjects were then fit in the study CLs. The CLs were evaluated for centration, movement, coverage, and CL power adjustments were only made if they improved visual acuity. CLs were only released if the toric nature of the CLs was stable and aligning at the correct orientation. Subjects were then given a 1-month supply of CLEAR CARE® CL solution, and they were educated on how to use the solution.

All subjects were encouraged to wear their CLs for at least 16 hours per day and to start wearing their CLs between 6:00 AM and 8:00 AM on days that they were being requested to complete text messaging surveys. This wear scheduled was expected throughout the study and required for all days when text messaging data were collected. CL compliance was reinforced at all visits, and compliance was recorded on the noted text message days. Subjects were educated that they would be required to complete Research Electronic Data Capture (REDCap) surveys on their phone.[17,18] Subjects were asked to complete the following test message question before they left the baseline visit to make sure that the system was compatible with their phone: "Current contact lens comfort?". The survey response to this test message also served as a measure of initial CL comfort. REDCap surveys asked subjects about their eye comfort with a visual analog scale (VAS; slider scale with 0 as neutral comfort, −50 extremely uncomfortable, and +50 extremely comfortable; VAS scores below 0 were considered uncomfortable and scores above 0 were considered comfortable) before CL application, directly after CL application, and at 8-, 10-, 12-, 14-, and 16-hours post-lens application on the first 5 full days of the study.[13] Subjects were likewise asked about their CL comfort directly after CL removal. This same system was used to monitor how many hours subjects wore their CLs each day. Subjects were also asked to complete these surveys at 2 weeks and 1 day prior to their 1-month visit (1 month) to understand comfort over the life of the CLs. Subjects were called the day before the 2-week and 1-month scheduled surveys to remind them about the upcoming requests. Subjects

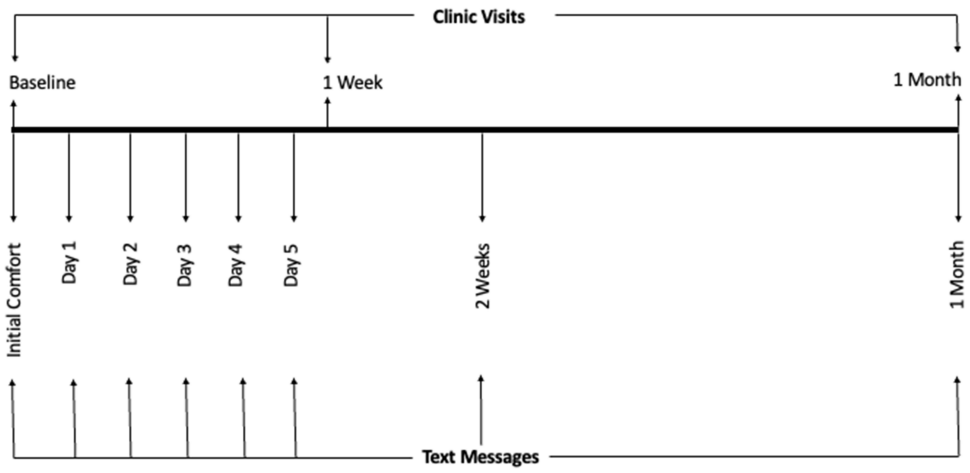

Figure 1 Study Flow Diagram.

were allowed to schedule their 2-week and 1-month surveys within 3 days of these time points to allow for better compliance.

Subjects reported to Visit 2 one week later (±1 day) where they repeated high-contrast LogMAR visual acuity and an ocular health evaluation with a slit-lamp biomicroscope. Subjects also had their CLs evaluated for centration, movement, and coverage, and CL power (sphere and cylinder power). CL power adjustments were only made if they improved visual acuity by a line or more, and good and stable vision was required while wearing the CLs. After Visit 2, subjects were asked to return for an evaluation 1 month after the baseline visit (±1 day). Subjects again completed high-contrast LogMAR visual acuity, a slit-lamp biomicroscope exam, and a CL evaluation. The subjects were then compensated and released from the study.

Sample Size and Statistical Analysis

All data were analyzed with Stata/BE 18 (StataCorp LLC; TX, USA), and all data were captured with REDCap. This study aimed to understand CL comfort throughout the day in monthly, toric, soft CL wearers. VAS comfort scores served as the primary endpoint and were reported for each timepoint. No formal sample size calculation was completed before the study given the limited data related to real-time comfort in monthly, soft, toric CL wearers; thus, this was a pilot study. The authors estimate that 50 subjects were needed to gain a general understanding of ocular comfort across the entire day based upon past research (40 subjects plus 10 subjects to account for subject attrition and missing data).[13] Descriptive statistics, such as means and standard deviations (SD) or percentages, were used to describe trends. Comfort comparisons across visits or across the wear day were evaluated via ANOVA tests. Comparisons were considered statistically significant when p-values were <0.05.

Results

A total of 50 subjects who had a mean ± SD age of 29.6 ± 7.2 years were enrolled; 68% of these subjects reported being female. None of the enrolled subjects were active TOTAL30 CL wearers prior to enrollment, yet all were active CL wearers. One subject dropped out of the study after Visit 1, and one subject dropped out of the study after Visit 2 with the reasons being a lack of time to attend to follow-up visits and text-survey questions. One subject required a −0.25 D sphere change in both eyes at Visit 2. Since the primary goal of this study was to understand the performance of a single CL over 1 month, the visual acuity and comfort analyses were limited to subjects who completed the full study with a single CL (n = 47). Analyzed subjects had a mean CLDEQ-8 score of 7.1 ± 2.6 units. The mean logMAR visual acuities while wearing the study CLs for the right eye for Visits 1, 2, and 3 were −0.04 ± 0.07, −0.4 ± 0.06, and −0.03 ± 0.06 (p = 0.78), while the mean logMAR visual acuities while wearing the study CLs for the left eye for Visits 1, 2, and 3 were −0.04 ± 0.06, −0.04 ± 0.05, and −0.03 ± 0.06 (p = 0.29). The mean CL sphere and astigmatic power for the right eye was −2.71 ± 2.26 D and −1.23 ± 0.50 D, respectively, while these values for the left eye were −2.62 ± 2.41 D and −1.33 ± 0.55 D, respectively. Compliance was high among the subjects who completed the study with 1971 of the 1974 (>99.9%) VAS surveys within the text messages being completed. No subjects self-reported any adverse events in this study, and no clinically meaningful abnormal slit-lamp findings were detected at any study visit.

The mean initial CL comfort at the time of the baseline visit was 38.79 ± 16.25 units. The mean hours of CL wear for days 1, 2, 3, 4, 5, and 2 weeks and 1 month were about 16 hours per day with the CL wear times not significantly differing over the life of the study (Figure 2; p = 0.22). CL comfort decreased across the wear day when considering comfort at the time of waking until after CL removal (all p-value <0.001); CL comfort also significantly decreased across the wear day when only considering times when the CL was being worn (all p-value <0.001). However, within a given time point (eg, initial CL comfort each day), CL comfort did not vary across the study (all p-value ≥0.82; Table 1). Most subjects found their CLs to be comfortable with only 1.8% of subject reporting an uncomfortable score at CL application and only 8.5% of subjects reporting an uncomfortable score after 16 hours of CL wear (Table 1).

Discussion

While it may be appealing to attribute measured comfort benefits to the higher oxygen transmissibility of the silicone hydrogel CL material, a recent meta-analysis has determined no discernable differences in comfort between silicone

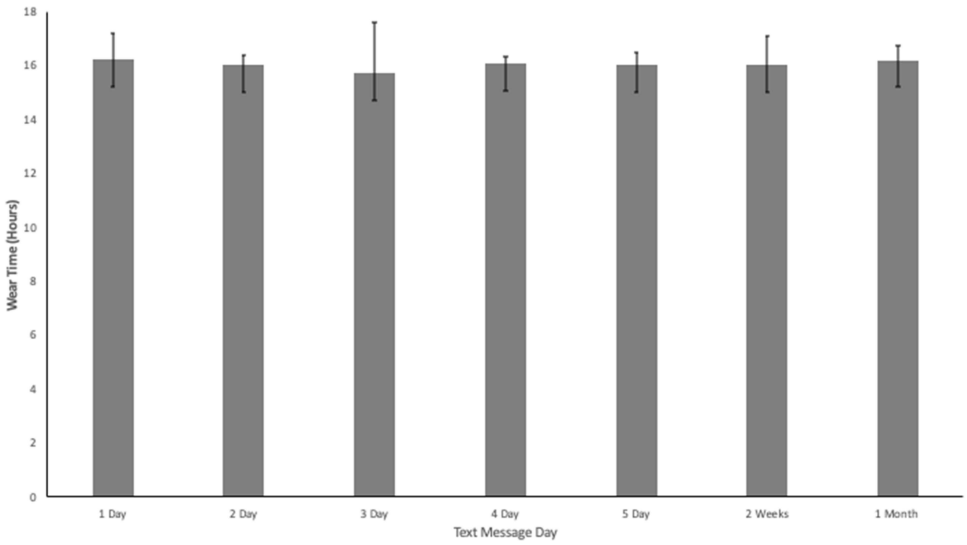

Figure 2 Contact Lens Wear Times by Study Event.

hydrogel and hydrogel CLs, which suggests that other factors are driving the comfort response; one of these factors could be a hydrophilic CL surface component.[19,20] The lehfilcon A study CL material offers a hybrid technology with a silicone hydrogel core with a water content of 55%. Unlike other homogenous CL materials, the material chemistry of the study lens changes gradually towards the surface of the lens causing the water content to also gradually increase, approaching 100% at the CL's surface. The comfort of lehfilcon A is supported by the current study with it determining that while comfort decreases across the day while wearing the study CL, the comfort of the CL at the same time of day across the entire wear month was stable. Furthermore, while the comfort of the study CL decreased across the wear day, which is to be expected,[1–4] the comfort of the study CL rarely decreased to the point where the CL became subjectively uncomfortable.

The results of the current study are supported by a recent study by Chaudhry et al who found that satisfied monthly CL wearers could be successfully refit into a daily CL with water gradient surface technology.[21,22] While this study was mainly looking at CL modality (daily disposable vs monthly reusable CLs), their results could suggest that patients would also be successful in a monthly CL that incorporates water gradient surface technology.[21] A related study of astigmatism correction in CL wearers with different levels of astigmatism found that comfort was a contributing factor in over half of all failed toric lens fits,[22] and in a separate study, Morgan et al established that patients are willing to pay more for a toric CL than a spherical CL if there was an equal improvement in vision and comfort, yet when comfort was worse, the subjects were less likely to pay more for a toric CL even if there was an improvement in vision, which further reinforces the importance of comfort when wearing a toric CL.[23]

The comfort of a lehfilcon A monthly CL has been previously evaluated by Call et al (n = 48), yet they only evaluated spherical CL wearers.[13] This study determined while using the same ±50 VAS as the current study that comfort was stable across a specific time of day (eg, comfort at application) for the duration of the 1-month study, yet comfort across the wear day (eg, comfort at application vs comfort at 16 hours of wear) significantly decreased for each day that was evaluated.[13] The current study found that at any given point few subjects found the study CLs uncomfortable with the highest percentage of subjects finding the CLs uncomfortable at 16 hours of wear (8.5%), which is not unexpected given the long duration of wear. Interestingly, only 1.8% of subjects found the CLs to be uncomfortable at CL application. This might be because of the initial shielding of the eye by the CL from the environment. The current study came to the same conclusion as Call et al while evaluating toric CLs made of the same material, and the two studies appeared to have numerically similar VAS scores for each time point evaluated. Nevertheless, a statistical comparison would be required to make a true determination. Alternatively, a recent study by Fogt and Patton (n = 30) evaluated the real-time comfort of a toric daily disposable CL wearers (verofilcon A).[1] The authors specifically utilized a forced-choice 1 to 10 grading

Table 1 Eye Comfort Visual Analog Scale (VAS) Scores by Event

Day of Wear	Comfort at Waking (Mean ± SD)	Comfort at Application (Mean ± SD)	Comfort at Hour 8 (Mean ± SD)	Comfort at Hour 10 (Mean ± SD)	Comfort at Hour 12 (Mean ± SD)	Comfort at Hour 14 (Mean ± SD)	Comfort at Hour 16 (Mean ± SD)	Comfort After Removal (Mean ± SD)	P-value#	P-value*
Day 1	35.74 ± 22.28	36.49 ± 16.30	42.02 ± 14.65	39.51 ± 15.94	37.15 ± 16.97	32.51 ± 17.66	27.74 ± 22.18	31.98 ± 17.87	<0.001	<0.001
Day 2	38.64 ± 19.91	36.28 ± 17.50	41.51 ± 14.67	37.26 ± 16.83	37.06 ± 16.42	31.51 ± 18.74	27.85 ± 21.16	30.71 ± 17.87	<0.001	<0.001
Day 3	36.15 ± 21.37	35.72 ± 17.46	38.81 ± 16.35	36.57 ± 17.77	34.89 ± 17.91	28.04 ± 20.22	24.77 ± 23.78	30.28 ± 19.02	<0.001	<0.001
Day 4	35.72 ± 21.60	36.34 ± 16.98	38.62 ± 15.65	38.04 ± 17.07	35.38 ± 18.45	31.00 ± 18.15	26.04 ± 22.17	30.49 ± 18.32	<0.001	<0.001
Day 5	35.72 ± 21.43	36.34 ± 16.18	40.43 ± 14.46	39.57 ± 15.04	34.57 ± 17.29	32.64 ± 16.40	27.81 ± 18.86	29.22 ± 20.80	<0.001	<0.001
2 weeks	40.55 ± 17.88	39.49 ± 12.39	39.15 ± 15.71	38.62 ± 14.20	36.83 ± 14.53	30.89 ± 17.77	26.68 ± 22.84	31.89 ± 16.36	<0.001	<0.001
1 Month	39.13 ± 18.46	39.49 ± 15.03	39.36 ± 17.07	35.17 ± 18.32	33.15 ± 15.63	28.36 ± 17.85	24.28 ± 21.47	31.21 ± 17.16	<0.001	<0.001
P-value	0.84	0.83	0.91	0.85	0.89	0.82	0.97	0.99	N/A	N/A
Negative Scores	5.8%	1.8%	3.0%	1.2%	3.3%	4.0%	8.5%	2.4%	N/A	N/A

Note: #Comfort at Waking through Comfort After Contact Lens Removal; *Comfort at Contact Lens Application through Comfort at Hour 16 of Contact Lens Wear.

scale (10 = excellent comfort), which was electronically sent to the subjects at 10, 12, 14, and 16 hours of CL wear for 5 weekdays, and the authors found median comfort scores of these time points to range between 8 and 10, which again signified excellent comfort. While additional work is needed to evaluate the real-time comfort of modern CLs, all these studies have been promising.

The increased CL diameters and thickness profiles of toric CLs compared to spherical CLs have the potential to negatively impact comfort. The added complexities relating to rotation and rotational stability of the CLs may also affect perceived vision.[10] This point is supported by Chaudhry et al who compared visual acuity, comfort, and patient preference in a soft toric CL versus soft spherical CL in low astigmats and found that toric CL wearers had better vision, improved visual quality, and significantly lower fatigue scores.[21] Because astigmatism correction with a toric soft CL relies on CL orientation and stability, it is crucial to assess vision, fit, and rotation after allowing the CLs to settle after insertion. Rotation may occur due to anatomical variations in corneal curvature or eyelid position that require compensatory adjustments to the axis.[1] This can be largely dependent on the toric CL design. Using a more contemporary prism ballasted, non-truncated design, Cho et al found no significant difference in comfort between this type of toric design and its spherical equivalent, which suggests that patients with lower amounts of astigmatism might benefit from being fit in a toric CL design.[24] The monthly toric soft CL evaluated in this study utilizes a modified prism-ballast that incorporates anchor points at 8:00 and 4:00 for improved lens stability. This thinner edge profile at the inferior portion of the CL likely improves comfort by reducing lower eyelid interaction. Hoekel et al identified a relationship between reduced on-eye lens movement and greater CL comfort, supporting the importance of CL stability.[25,26]

Sulley et al found that there was no significant difference in CL retention rate based on replacement frequency (eg, daily disposable vs reusable CLs).[14] This suggests that most CL wearers can be successful in a monthly replacement CL when appropriately prescribed for optimal fit and vision, which is perhaps contradictory to the tendency of eye care providers to fit most first-time wearers or those experiencing discomfort issues into a daily disposable CL. Patients using monthly reusable CLs may report more discomfort toward the end of the month as they are approaching the time for CL replacement, but this may depend on multiple factors such CL care system and compliance with CL care and replacement schedule. Nevertheless, the subjects enrolled in the current study did not experience this decrease in comfort towards the end of the wearing month, which suggests that a systematic approach evaluating other modern CLs is warranted to determine which CLs have comfort longevity.

While this study benefited from an exceptional survey response rate (>99% of texts completed), a homogenous group of subjects (eg, similar refractive error and age) and comfort tool that can easily discern between comfortable and uncomfortable CL wearing experiences, this study is not without limitations. The primary limitation of this study was that it only evaluated a single toric CL in a group of initially comfortable CL wearers. This approach was taken to help understand the performance of a new toric CL while minimizing variability among the subject pool. Work from Woods et al suggests that symptomatic and asymptomatic CL wearers respond differently when refit into an alternative CL material.[27] The authors specifically found that while CL material (silicone vs hydrogel materials) was not a factor in comfort across the wear day, subjects who were habitually asymptomatic tended to not have a decrease in comfort across the wear day, while symptomatic wearers tended to have a decrease in comfort across the wear day. Thus, this study should be repeated in subjects who have CL discomfort to see if the study CL can improve their comfort, and it should be repeated with additional brands of toric CLs to better understand the performance of the full menu of toric CLs in the market. These data could likewise help uncover if factors such as CL stabilization approaches or CL diameters have an impact on CL comfort. Work related to understanding how CL care systems and wear schedules impact real-time comfort could likewise be beneficial to the CL community. An additional limitation of this study is that it was a pilot study given that there was limited data related to the real-time comfort of a monthly, toric, soft CL wearer, yet if one uses the data from the current study, it can be assumed that there were enough subjects in this study. The current study specifically obtained an initial CL comfort of 38.79 ± 16.25 units at the baseline visit, and if one assumes a clinically meaningful difference of 6.8 units on a 100 units scale ($\alpha = 0.05$; power = 80%), only 47 subjects would need to demonstrate no difference within a subject a 2 different time points.[28]

Conclusions

Results from the present work found that the comfort of a monthly, toric, soft CL slightly decreased over the long wearing day, which is to be expected, yet this decrease was still in the comfortable range for most subjects. This result may be at least partially attributed to the modified ballast design of the study CL. The consistency and predictability in comfort with the study CL is reassuring for the CL fitter and the patients who wear these CLs. As previously noted, within any specific time point, CL comfort did not vary significantly across the entire study for the first full month of wearing the CL. This result indicates that how a patient feels in the study CL early in the fitting process is likely to be predictive of how the patient will feel in the study CL after the fit is finalized. Overall, most subjects found their CLs to be comfortable with less than 2% of subjects reporting an uncomfortable score upon application and less than 9% of subjects reporting an uncomfortable score after 16 hours of wear. While these initial results are promising, additional work is needed to understand how the study CLs perform after the first month of wear and how other CLs perform in real time during the first month of wear.

Data Sharing Statement

Upon written request to the corresponding author, deidentified participant information can be shared in regard to survey data and ocular health data collected in the present work. These data can be shared on a spreadsheet for all subjects analyzed. These data will be available 12 months after publication.

Acknowledgments

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Disclosure

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Spouse of PI/Corresponding Author is an employee of Alcon Vision Care. Research was approved by the Southern College of Optometry Institutional Review Board (IRB00006753/FWA00013872).

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