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ORIGINAL RESEARCH

Subjective Wearing Experience of Lehfilcon A Among Satisfied Comfilcon A Toric Lens Wearers

Jay Mashouf[1], Keith Wan[1], Brad Hall[2]

[1]Scripps Optometric Group, San Diego, CA, USA; [2]Sengi, Penniac, NB, Canada

Correspondence: Jay Mashouf, Scripps Optometric Group, 10549 Scripps Poway Pkwy, Ste. G, San Diego, CA, 92131, USA, Tel +1-858-530-2800, Email jaymashouf@gmail.com

Purpose: To evaluate the subjective wearing experience of lehfilcon A toric lenses among subjects who were already satisfied with their comfilcon A toric lenses.

Methods: This was an open-label, single arm study of currently satisfied comfilcon A soft toric contact lens (Biofinity Toric, CooperVision, Pleasanton, CA) wearers that were refit with lehfilcon A soft toric lenses (Total30® for Astigmatism; Alcon Vision LLC, Fort Worth, TX). Subjects were administered a questionnaire about satisfaction with comfort, visual performance, end of day comfort, and ease of handling with lehfilcon A toric lenses.

Results: A total of 40 subjects completed the study. After one month of wear the median and interquartile range (IQR) was 8 (2) for overall satisfaction with lehfilcon A comfort, 8 (1.25) for visual performance, 7 (3.25) for end of day comfort, 9 (2) for ease of handling, and finally 8 (2) for overall satisfaction.

Conclusion: A high proportion of subjects were satisfied with the subjective wearing experience with lehfilcon A toric lenses, including satisfaction with comfort, visual performance, end of day comfort, and ease of handling.

Plain Language Summary: There are many different types of contact lens materials and replacement schedules for patients to suit individual needs. Despite the diversity of options, contact lens dropout continues to be high, likely influenced by discomfort and poor vision. A new frequent replacement toric contact lens is available that may offer good subjective comfort for patients. However, there is minimal data on the performance of this lens. The purpose of this study was to evaluate the subjective wearing experience with the new contact lens among patients who were already satisfied with their current toric contact lenses. The results of this study suggest that a high proportion of patients were satisfied with the subjective wearing experience with the new toric contact lens, including satisfaction with comfort, visual performance, end of day comfort, and ease of handling.

Keywords: comfort, toric, contact lens, lehfilcon A, Total30 for Astigmatism

Introduction

Contact lenses are effective for the correction of refractive error. Today, there are many options for patients to choose from including different contact lens materials and replacement schedules. This variety is good, as there is no one combination of material and replacement schedule that would be suitable for all patients. Survey data suggests that 37% of contact lens wearers use daily disposable lenses and 48% use frequent replacement lenses (with a 2–4 week replacement schedule).[1] Despite the diversity of options for patients, contact lens dropout continues to be high. A recent analysis by Pucker and Tichenor[2] reported a pooled dropout rate of 22%. Contact lens discomfort and poor vision have been identified as the top factors contributing to dropout.[3,4] In addition, toric lens wearers may dropout at higher rates compared to spherical lens wearers,[5] which may be due to greater discomfort or uncorrected astigmatism.[6]

Wearing contact lenses can cause changes to the ocular surface and lead to discomfort for patients. In response, contact lens technology continues to advance in the pursuit of reducing contact lens discomfort. For example, delefilcon A lenses are daily disposables with a unique water gradient material that transitions from 33% water content in the core

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to nearly 100% water content at the lens surface.[7] In addition, high patient comfort with spherical and toric versions of delefilcon A lenses has been observed.[8–10] However, until recently, similar materials were not available in frequent replacement modalities. Similar to the delefilcon A daily disposable lens, the lehfilcon A material also features water gradient technology, but as a monthly replacement lens. The lehfilcon A material also incorporates 2-methacryloyloxyethyl phosphorylcholine (MPC), which may enhance comfort by creating a lubricious surface that helps resist deposits and bacterial adhesion.[11,12] Wesley et al[13] reported good performance of the spherical version of lehfilcon A compared to comfilcon A lenses. However, there is minimal data on the subjective comfort of lehfilcon A toric lenses. The purpose of this study was to evaluate the subjective wearing experience with lehfilcon A toric lenses among subjects who were already satisfied with their comfilcon A toric lenses.

Methods

This study was reviewed and approved by an independent institutional review board (Salus IRB, approval number JM-23-01). An independent institutional review board was used as this study was conducted at a private practice. All subjects gave written informed consent before participation. This study was registered on clinicaltrials.gov (NCT05938010) and conducted in compliance with International Harmonization (ICH) guidelines, the tenets of the Declaration of Helsinki, and Good Clinical Practice (GCP). Data are not available for sharing.

Subjects included were between the ages of 18–45, wearing comfilcon A toric lenses (Biofinity Toric, CooperVision, Pleasanton, CA) in both eyes at least 5 days per week, 10 hours per day, and currently satisfied with these lenses, sphere between −6.00 D and +4.00 D inclusive, cylinder between −0.75 D and −2.25 D inclusive, and vision correctable to 20/20 (0.0 logMAR) or better in each eye. Exclusion criteria were ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear, use of systemic or ocular medications for which contact lens wear could be contraindicated, fitted with only one contact lens, prior ocular surgery, and a history of herpetic keratitis, ocular surgery, or irregular cornea.

There were three total study visits, beginning with a baseline visit where informed consent was given. At the baseline visit, subjects were given new comfilcon A toric lenses with optimized prescriptions to eliminate uncorrected refractive error as a cause of subjective discomfort. Subjects returned one week later and were confirmed to be still satisfied with their comfilcon A toric lenses before being dispensed lehfilcon A toric lenses (Total30® for Astigmatism; Alcon Vision LLC, Fort Worth, TX) and instructed to continue to use their habitual contact lens storage and cleaning solution. The final visit occurred after four weeks of lehfilcon A wear. At this final visit, subjects were administered a questionnaire. The questionnaire asked respondents to provide answers to five questions using a scale of 0 to 10, as shown in Figure 1. The questions were: 1) "Overall, how satisfied are you with your comfort while wearing these lenses over the past 30 ± 3 days? (0 = not satisfied at all, 10 = extremely satisfied)", 2) "The visual performance of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory)", 3) "The end of day comfort of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory)", 4) "The ease of handling of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory)", and 5) "My overall satisfaction of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory)".

The primary endpoint was overall satisfaction with lehfilcon A toric lenses (question #1 on the questionnaire). Other endpoints included questions 2–5 on the questionnaire. Adverse events were also monitored at each visit.

All statistical analyses were performed using R (version 4.3.1; The R Foundation for Statistical Computing, Vienna, Austria). It was estimated that 40 subjects would provide sufficient data to characterize the subjective comfort of lehfilcon A toric lenses in this one arm, descriptive study.

Results

A total of 42 subjects were enrolled, and 40 completed the study. Two subjects were lost to follow up and were excluded from the analysis. Demographic and baseline data are summarized in Table 1. There were no adverse events reported.

Table 2 summarizes the median and frequency of responses on the questionnaire. A score of >5 was considered satisfied for each question. The primary endpoint was the subject-reported satisfaction with the comfort of lehfilcon A for astigmatism (question #1). The median and interquartile range (IQR) was 8 (2). In addition, a total of 82.5% of subjects

Please respond to the following five statements by circling a number to represent where on the scale your rating number would fall. There are no right or wrong answers.

1. Overall, how satisfied are you with your comfort while wearing these lenses over the past 30 ± 3 days? (0 = not satisfied at all, 10 = extremely satisfied)

0	1	2	3	4	5	6	7	8	9	10
Not satisfied										Extremely satisfied

2. The **visual performance** of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory).

0	1	2	3	4	5	6	7	8	9	10
Not satisfactory										Extremely satisfactory

3. The **end of day comfort** of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory).

0	1	2	3	4	5	6	7	8	9	10
Not satisfactory										Extremely satisfactory

4. The **ease of handling** of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory).

0	1	2	3	4	5	6	7	8	9	10
Not satisfactory										Extremely satisfactory

5. My **overall satisfaction** of the Total 30 for Astigmatism lens was (0 = not satisfactory at all and 10 = extremely satisfactory).

0	1	2	3	4	5	6	7	8	9	10
Not satisfactory										Extremely satisfactory

Figure 1 Study questionnaire for subjective comfort with lehfilcon A toric lenses.

were satisfied with the comfort of lehfilcon A. Other endpoints were the subject-reported responses to the other four questions on the questionnaire. The median and interquartile ranges (IQR) wwere 7 (3.25) for end of day comfort, 9 (2) for ease of handling, and 8 (2) for overall satisfaction. A total of 90% of subjects were satisfied with the visual performance of lehfilcon A. The end of day comfort had the lowest reported satisfaction of all questions, with 67.5% of subjects satisfied with the end of day comfort of lehfilcon A. A total of 87.5% of subjects were satisfied with the ease of handling of lehfilcon A. Finally, the overall reported satisfaction with lehfilcon A was 85%.

Table 1 Demographic and Baseline Data.

Baseline Factor	Outcomes*
Sex	
Female (n)	28 (70)
Male (n)	12 (30)
Age (years)	29.2 ± 5.6 (20 to 38)
Cylinder (D)	−1.39 ± 0.49 (−2.50 to −0.75)
MRSE (D)	−4.04 ± 1.82 (−7.12 to −0.88)
CDVA	0.00 ± 0.02 (−0.08.0 to 0.04)

Notes: *Presented as mean ± SD (range) or n (%).
Abbreviations: CDVA, corrected distance visual acuity; D, diopters; SD, standard deviation.

Table 2 Questionnaire Responses (n = 40).

Question	Median (IQR)	Frequency of Response (Percentage)					
		≤ 5	6	7	8	9	10
Satisfaction with comfort	8 (2)	7 (18)	2 (5)	8 (20)	7 (18)	10 (25)	6 (15)
Visual performance	8 (1.3)	4 (10)	0 (0)	2 (5)	15 (38)	9 (23)	10 (25)
End of day comfort	7 (3.3)	13 (33)	2 (5)	8 (20)	9 (23)	4 (10)	4 (10)
Ease of handling	9 (2)	5 (13)	1 (3)	3 (8)	8 (20)	8 (20)	15 (38)
Overall satisfaction	8 (2)	6 (15)	1 (3)	5 (13)	11 (28)	12 (30)	5 (13)

Abbreviation: IQR, interquartile range.

Discussion

The relatively high dropout rates of contact lens wearers may be related to contact lens discomfort,[3,4] poor vision,[6] and difficulty handling and inserting.[5] In this study, we evaluated the subjective wearing experience of lehfilcon A toric lenses among subjects who were already satisfied with their comfilcon A toric lenses. Current comfilcon A toric lens wearers were chosen as this toric lens has been reported to provide acceptable subjective comfort and vision,[14] and anecdotally, reliable stability on the eye. Mean overall satisfaction with the comfort of lehfilcon A toric lenses in this study was 82.5%. Capote-Puente et al[15] evaluated the comfort of lehfilcon A after refitting current daily or monthly silicone hydrogel contact lens wearers. The authors reported a reduction of scores on the contact lens dry eye questionnaire (CLDEQ-8),[16] which implies improved comfort after the refits, though the difference was below the clinical significance threshold (≥3).[17] Scores on the Standard Patient Evaluation of Eye Dryness (SPEED)[18] questionnaire were reduced as well, suggesting a reduction in dry eye symptoms after refits.

There are also published reports looking at comfort with the similar delefilcon A material (daily disposable). A large multicenter European study observed high subjective comfort for first-time contact lens wearers fitted with delefilcon A.[10] Wan et al[9] evaluated the subjective comfort of delefilcon A toric lenses with the CLDEQ-8 questionnaire. The authors observed that subjective comfort was improved by refitting symptomatic (CLDEQ-8 score ≥12) habitual reusable toric contact lens wearers with delefilcon A toric lenses. However, Garaszczuk et al[19] refit non-symptomatic (CLDEQ-8 score <12) subjects with either omafilcon A (32% of refits) or delefilcon A (68% of refits) and reported minimal improvement in comfort following refits. Additionally, Arroyo-Del Arroyo et al[20] also observed improvements in CLDEQ-8 scores when subjects were refit with delefilcon A lenses. Other studies have reported a high level of subjective comfort with delefilcon A lenses.[7,21,22]

All subjects were given new habitual lenses and had their prescriptions optimized to eliminate an old lens and uncorrected refractive error as a factor for subjective comfort. Overall reported satisfaction with the visual performance of lehfilcon A toric lenses was 90%. Wesley et al[13] observed that 99% of subjects had distance visual acuity 20/20 or better after three months of wear with lehfilcon A lenses. Marx et al[10] fit first time contact lens wearers with delefilcon A and evaluated subjective visual performance using a questionnaire. Subjects self-reported high quality of vision with delefilcon A lenses, and a preference for vision overall with delefilcon A lenses compared to spectacles. Varikooty et al[21] reported good visual performance with delefilcon A lenses.

Overall reported satisfaction with ease of handling lehfilcon A toric lenses was 87.5%. We are not aware of any other studies reporting on the ease of handling lehfilcon A lenses. However, Marx et al[10] observed that 95% of subjects "strongly agreed" or "agreed" that delefilcon A lenses were easy to insert.

The primary limitation of this study is that there was no direct comparison of subjective wearing performance with lehfilcon A toric lenses to comfilcon A toric lenses or other frequent replacement contact lenses. In addition, the follow up time was only one replacement schedule (one month), therefore we are not able to draw conclusions about the subjective wearing experience for longer time periods with the use of lehfilcon A toric contact lenses.

In conclusion, a high proportion of subjects were satisfied with the subjective wearing experience with lehfilcon A toric lenses after one month of wear, including satisfaction with comfort, visual performance, end of day comfort, and ease of handling.

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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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