

Patient Satisfaction with a Novel Daily Toric Contact Lens in Individuals with Previous Lens Failures

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Purpose: The primary purpose of this study is to assess the comfort and vision of Dailies Total1[®] for Astigmatism contact lenses in subjects dissatisfied with their previously worn toric contact lenses.

Patients and Methods: In this prospective, non-comparative study, subjects aged 18 to 39 years with a history of unsuccessful previous astigmatism contact lens wear were recruited. Subjects were allocated and fitted with varying astigmatism powers of the Dailies Total1[®] for Astigmatism contact lenses. After 30 days of wear, participants responded to a questionnaire consisting of a visual analog scale assessing overall comfort and vision and a Likert scale assessing comfort and vision throughout the day, at the end of the day (EOD), and as it pertains to real-world tasks.

Results: Sixty-five subjects (130 eyes) completed the study, of which 50 were female, and 15 were male, with a mean (\pm standard deviation) age of 29.5 ± 5 years. Overall, 87.69% of the subjects reported a positive rating for comfort and 92.31% for satisfaction with vision. 78% of respondents reported positive ratings for comfort throughout the day and 55% at the end of the day. Comfort while working on the computer and utilizing a cellphone was rated at 80% and 86%, respectively. 85% either agreed or strongly agreed that the lenses provided clear vision throughout the day, and 71% at the end of the day. Positive ratings for vision while on the computer and while using a cellphone were 87% and 91%, respectively. Of all participants, based on comfort and vision, 58% favored continuing to wear the lenses after the study.

Conclusion: The results suggest that Dailies Total1[®] for Astigmatism contact lenses offer favorable comfort and vision for individuals who had previously been dissatisfied with their toric lenses.

Keywords: Dailies Total1[®] for Astigmatism, astigmatism, contact lens, contact lens dropout

Introduction

The global prevalence of astigmatism in adults is estimated to be 40.4%, with the rate in the United States reaching 36.2%.^{1,2} Although contact lenses are a widely used solution for correcting refractive errors, including astigmatism, the contact lens industry is actively focused on addressing the high dropout rates, which average around 22% across multiple studies.³ This ongoing effort aims to improve patient satisfaction and reduce the factors that contribute to lens discontinuation.

Multiple studies have examined the primary factors for contact lens discontinuation, with discomfort and dissatisfaction with vision being commonly cited.^{3–6} Failure to correct for astigmatism in contact lenses in those with even low amounts of astigmatism (≤ 1 diopter) can contribute to dissatisfaction with vision.⁷ It has been found that only 25% of those with ≥ 0.75 D astigmatism were fitted in toric contact lenses.⁸ To further explore the impact of astigmatism correction, several studies have compared the performance of individuals with low to moderate astigmatism wearing astigmatism-correcting contact lenses versus spherical equivalent lenses, using a crossover study design. The results consistently showed that participants wearing toric lenses reported improved comfort and superior visual outcomes.^{9,10} These studies underscore the ongoing commitment to understanding the root causes of contact lens dropout while simultaneously equipping the contact lens industry with a better understanding of what technological advancements need to be focused on to reduce dropout rates and enhance patient satisfaction.

Recent advances in lens material and design aim to improve the vision and comfort of astigmatism-correcting contact lenses. When daily disposable contact lenses were initially introduced, they were composed of hydrogel, which is a hydrophilic material with a low tensile modulus. Although the hydrophilic composition allowed for improved wettability, the oxygen transmissibility was low, and the low tensile modulus made the lenses difficult to handle. More recently, the introduction of silicone hydrogel lenses allowed for an increase in oxygen transmissibility and an increase in the tensile modulus, making it easier to handle. Although there was an improvement in oxygen transmissibility, the hydrophobic nature of silicone hydrogel lenses resulted in poor wettability.^{11–13} To offset this and increase wettability, surface treatments and/or hydrophilic wetting agents were added to these lens materials.

The introduction of the delefilcon A daily disposable contact lens (Dailies Total1[®] for Astigmatism; Alcon Laboratories, Inc., Fort Worth, Texas, USA), a silicone hydrogel material, not only has maintained the advantageous qualities of the silicone hydrogel material, increased oxygen transmissibility and tensile modulus, but it has improved wettability secondary to the novel water gradient design.¹⁴ Notably, this lens stands out among commercially available daily contact lenses, boasting the highest oxygen permeability with a Dk value of 140—significantly higher than that of other daily lenses. In addition, its unique water gradient design, which transitions from a low water content at the core to nearly 100% water content at the surface, further enhances its distinction.¹⁵ This combination of advanced oxygen transmissibility and innovative moisture distribution sets this lens apart as a true innovation among toric daily lenses. Additionally, the SmarTears[®] Technology allows for improvement in the lipid layer of the tear film by releasing phosphatidylcholine, an ingredient naturally found in tears.¹⁶ Lastly, the lenses utilize an 8/4[®] lens balancing design that contributes to better vision stability and higher first-time fit success rate. Given the strong correlation between comfort, vision quality, and contact lens dropout, the introduction of this novel technology is designed to enhance both comfort and visual performance, ultimately aimed at improving patient satisfaction and reducing dropout rates.

The primary focus of this study is to assess patient satisfaction with this novel astigmatism-correcting daily lens in a population of contact lens dropouts. To our knowledge, no studies have evaluated the Dailies Total1[®] for Astigmatism (delefilcon A, Alcon Laboratories, Inc., Fort Worth, TX, USA) contact lens in subjects that previously discontinued wear due to dissatisfaction with either comfort, vision, or both. Furthermore, this study aims to assess the percentage of patients reporting satisfaction with the overall and end-of-day (EOD) comfort and vision of the lens under real-world conditions, specifically while on the computer and while using a cellphone. Also, a measurement of whether participants desired to remain in the lenses after the study was also evaluated.

Methods

This prospective, non-comparative, open-label post-market study was approved by an institutional review board (Salus IRB, Austin, TX, USA). The study was conducted in compliance with Good Clinical Practice (GCP), the tenets of the Declaration of Helsinki, and guidance from the International Conference on Harmonization (ICH). The study was registered at ClinicalTrials.gov (NCT05886452). All participants completed the informed consent process before participation.

The study enrolled participants that were between 18 and 39 years of age. Initially, subjects were asked screening questions regarding previous use of astigmatism-correcting (toric) soft contact lenses and whether they stopped wearing them because of poor or fluctuating vision, discomfort, or any other reasons. If they answered yes to any one of the reasons, they were deemed eligible.

Additional screening was undertaken to ensure participants met the following inclusion and exclusion criteria. They needed to be in good general health with 20/25 or better vision with habitual correction in each eye. Good general health was defined by prescription medication use that had not changed within the last month and the absence of medical conditions or treatments that were deemed confounding to the study endpoints. Exclusion criteria included previous ocular surgery, history of Accutane use, ocular surface disease that would interfere with contact lens wear, comorbidities such as autoimmune disorders and diabetes, irregular astigmatism as identified by topography measurements, amblyopia, strabismus and/or history of eye muscle surgery, monovision, pregnancy, or inability to be fit with the study lens design.

Following the initial recruitment visit, eligible participants were fit in both eyes at a follow-up visit (Visit 2) with the Dailies Total1[®] for Astigmatism contact lens. After allowing the lenses to settle for at least ten minutes in both eyes, the

fit and high-contrast visual acuity was assessed. Distance Snellen high contrast visual acuity was utilized throughout the study. For analysis, Snellen visual acuity was converted to LogMAR acuity.

Following thirty days of wear, participants returned for a final visit (Visit 3) at which visual acuity was again ascertained along with a comfort and vision questionnaire. Figure 1 provides a visualization of each visit in the study. The questionnaire was comprised of two sections. The first section included two visual analog scales (VAS) with which participants were asked to mark on a number line how satisfied they were with the overall comfort and vision while wearing the lenses over the past 30 ± 3 days. The left side of the scale began with 0 being not satisfied and the right side was 100 being extremely satisfied.

The second section consisted of nine Likert scales to assess comfort and vision under specific conditions with 5 responses ranging from strongly disagree to strongly agree. The Likert scale was used to assess comfort and vision throughout the day, at the end of the day, while on a computer or tablet, and while using a cellphone. An additional Likert scale assessed whether participants would like to continue wearing the lenses after the study ended.

Since the statistics are descriptive, the number of subjects enrolled was recruited to ensure that an adequate number of each power of astigmatism contact lens was represented. Consistent with the findings of Zhang et al, which reflect trends in the general population, fewer subjects were recruited for the higher astigmatism group, as high astigmatism occurs less frequently than mild or moderate forms.¹⁷ In this study, twenty subjects were recruited to be fit in -0.75 D cylinder lenses, twenty subjects in -1.25 D cylinder lenses, and twenty subjects in -1.75 D cylinder lenses. Five subjects were recruited to be fit in -2.25 D cylinder lenses.

Baseline demographic data and factors were evaluated using the statistical software R (version 4.4.0; The R Foundation for Statistical Computing, Vienna, Austria). For analysis of the VAS scales, Adobe Illustrator® (Adobe Systems Inc., San Jose, California, USA) was used to determine the length from 0 to 100 and from 0 to the response line to determine the score out of 100. The final score was calculated by dividing the length of the response line by the length of the entire line and then multiplying by 100. The Likert scale survey was analyzed as percentages of responses in each category and also by the proportion of those who agreed/strongly agreed to those who disagreed/strongly disagreed.

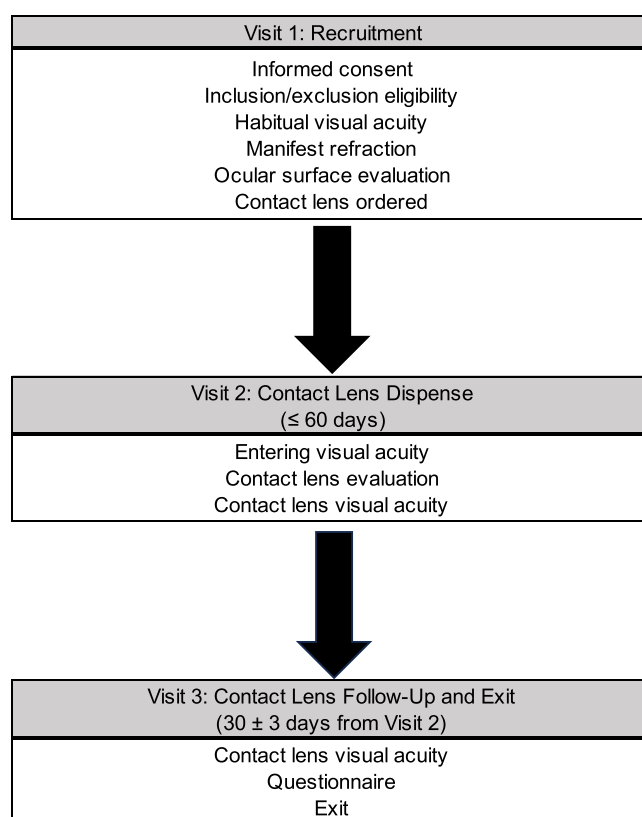


Figure 1 Study Design.

Results

Sixty-five subjects (130 eyes) completed the study. Throughout the study, there were no participants lost to follow-up and there were no adverse events. Fifty participants were female and 15 were male and the mean (\pm standard deviation) age was 29.5 ± 5 years old. Additional details regarding the demographics of participants are listed in Table 1. At Visit 1, manifest refraction was done to determine the appropriate contact lens power to be dispensed at Visit 2. Analysis of the manifest refraction from Visit 1 shows the mean sphere in the study was $-2.29 \text{ D} \pm 1.87 \text{ D}$, with a max myopia of -7.75 D and a max hyperopia of $+1.00 \text{ D}$. The mean refraction cylinder was $-1.42 \text{ D} \pm 0.57 \text{ D}$, with a range from -0.50 D cylinder to -3.00 D cylinder. Table 2 provides additional baseline manifest refraction details for the participants. The frequency distribution for manifest refraction astigmatism is further quantified in Table 3. Table 4 details the distance visual acuity at each of the three visits, with Visit 2 and 3 being distance visual acuity with the contact lens. At Visit 3, the mean LogMAR visual acuity was 0.01 ± 0.04 .

Table 1 Demographics

Factor	Outcome
Eyes (Participants)	130 (65)
Female	50 (77%)
Male	15 (23%)
Age (Years)*	29.5 ± 5 (20–39)

Note: *Mean \pm SD (Range).

Table 2 Visit 1 Manifest Refraction*

Factor	Mean	SD	Median	Min	Max
Sphere	-2.29	1.87	-2.00	-7.75	1.00
Cylinder	-1.42	0.57	-1.25	-3.00	-0.50
MRSE	-3.00	1.90	-2.88	-8.62	0.38

Note: *Diopters.

Table 3 Cylinder

Cylinder (Diopters)	Frequency
-3.00	2
-2.75	4
-2.50	5
-2.25	2
-2.00	5
-1.75	34
-1.50	5
-1.25	34
-1.00	7
-0.75	31
-0.50	1

Table 4 Visual Acuity*

Visit	Mean	SD	Median	Min	Max
Visit 1 BCVA (Manifest Refraction)	0.01	0.03	0.00	-0.12	0.10
Visit 2 (With Contact Lenses)	0.02	0.03	0.00	0.00	0.14
Visit 3 (With Contact Lenses)	0.01	0.04	0.00	-0.10	0.30

Note: *LogMAR acuity.

Analysis of the VAS scale assessing how satisfied participants were with the comfort while wearing the lenses throughout the month showed 87.69% of the subjects reporting a positive rating of >50 out of 100 with a mean score value of 78.15 ± 19.62 . The second VAS scale evaluating satisfaction of vision while wearing the lenses throughout the month indicated 92.31% of participants reporting a positive rating of >50 with a mean score value of 85.54 ± 18.53 . Table 5 provides details regarding the two scales.

Table 6 provides the analysis of the Likert scale survey as it pertains to statements about comfort and vision during the day and while performing common daily activities. Of note is that many of the responses given were neutral, where the subject neither agreed nor disagreed with the statement. Therefore, looking at the proportion of those who agreed/strongly agreed to those who disagreed/strongly disagreed helps to better understand the results, particularly in those responses that appear lower than expected. 78% of respondents agreed or strongly agreed that the study lenses were comfortable throughout the day, with a 4.6-fold higher rate of agreement compared to disagreement. 55% of participants agreed or strongly agreed that the study lenses remained comfortable at the end of the day, double those who disagreed or strongly disagreed. Those agreeing or strongly agreeing that the lenses were comfortable while working on the computer and utilizing a cellphone were 80% and 86%, respectively. Evaluation of the Likert survey pertaining to vision showed 85% either agreed or strongly agreed that the lenses provided clear vision throughout the day and 71% at the end of the day. Positive ratings for vision while on the computer and while using a cellphone were 87% and 91%, respectively. Of all participants, based on comfort and vision, 58% agreed or strongly agreed that they would continue to wear the lenses after the study. This was nearly three times higher than the number of participants who disagreed or strongly disagreed.

Table 5 Visual Analog Scale (VAS) Response for Overall Comfort and Vision*

Question	Response Score**	% > 50
Overall, how satisfied are you with your comfort while wearing these lenses over the past 30 ± 3 days	78.15 ± 19.62 (8–100)	87.69
Overall, how satisfied are you with your vision while wearing these lenses over the past 30 ± 3 days	85.54 ± 18.53 (8–100)	92.31

Notes: *VAS Score: Scale from 0 (Not Satisfied) to 100 (Extremely Satisfied). **Mean ± SD (Range).

Table 6 Questionnaire*

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree	Proportion Strongly Agreed or Agreed to Strongly Disagree or Disagree
The contact lenses were comfortable overall throughout the day	0	17	5	46	32	4.6
The contact lenses were comfortable at the end of the day	5	22	18	32	23	2.0
The contact lenses were comfortable while working on a computer or tablet	0	5	15	52	28	16.0
The contact lenses were comfortable while utilizing my cellphone	0	3	11	48	38	28.7
The contact lenses provided clear vision overall throughout the day	0	6	9	48	37	14.2
The contact lenses provided clear vision at the end of the day	2	15	12	43	28	4.2
The contact lenses provided clear vision while on a computer or tablet	0	3	9	55	32	29.0
The contact lenses provided clear vision while looking at my cellphone	0	3	6	49	42	30.3
Based on the comfort and visual performance of these contact lenses, I would like to continue wearing them on a daily basis after the study ends	6	15	20	29	29	2.8

Note: *The five responses are tabulated as percentages.

Discussion

Overall, the study found that the Dailies Total1® for Astigmatism contact lens, a daily disposable lens featuring enhanced wettability and stability technology, received positive feedback for both comfort and vision from participants who had previously discontinued contact lens use due to dissatisfaction. It is important to note that the study population consisted primarily of former contact lens users, who may represent a more challenging group to satisfy compared to the general population. Given this context, the positive feedback observed suggests that Dailies Total1® for Astigmatism could be a suitable option for patients who stopped using contact lenses due to discomfort or vision issues, as well as for those at risk of discontinuing lens wear.

Addressing common concerns such as discomfort and inadequate vision is key to reducing contact lens dropout rates. A literature review found that approximately 22% of contact lens wearers discontinue use, with discomfort and poor vision being the most frequent reasons.^{3,5} Additionally, analysis of dropout rates revealed that toric lens wearers tend to discontinue at higher rates than those wearing spherical lenses.⁴ When examining the relationship between comfort and vision, Maldonado-Codina et al found a significant association between discomfort and subjective vision quality. The results emphasize the importance of perceived vision quality as opposed to solely objective measures of vision and the relationship to discomfort.¹⁸ In this study, over 85% of participants rated the lenses as providing favorable vision and comfort (scoring above 50 on the VAS scale). The methodology and assessment highlight the crucial role of perception in evaluating a contact lens, suggesting it may be a key factor in reducing dropout rates.

Computers and cellphones are commonly used in households and while at work with estimates suggesting an increase in average duration over time.¹⁹ With this ever-increasing rate of screentime among the general population, having an astigmatism-correcting contact lens that provides good comfort and vision under these scenarios is crucial. This study assessed the contact lens wear experience while working on a computer and while using a cellphone and the results were favorable with the majority of responses being either agree or strongly agree for all questions.

Moreover, an evaluation of a contact lens in the clinic by a practitioner only provides an initial assessment of the comfort and vision of the lenses. An understanding of stability as it pertains to comfort and vision throughout the day and at the end of the day over some time is also critical and is a necessary step for a comprehensive contact lens evaluation. The majority of participants in this study reported that the lenses performed well throughout the day and at the end of the day, providing good comfort and vision. These lasting effects are important to reduce contact lens dropout rates. Additionally, the majority of participants responded favorably to wanting to continue with the lenses after the study, showing that the study lens can successfully bring astigmatic contact lens dropouts back into contact lens wear.

Two other studies have reported experiences with the delefilcon A for astigmatism lenses as compared to other contact lenses. Wan et al assessed the contact lens dry eye (CLDEQ-8) questionnaire results for symptomatic subjects in their habitual lenses compared to the delefilcon A for astigmatism lenses and found an improvement in CLDEQ-8 scores when participants were refitted with the delefilcon A for astigmatism lenses.²⁰ In evaluating, specifically, a cohort of symptomatic patients, the authors further supported the ability of the delefilcon A for astigmatism lens to improve dryness symptoms, and in turn, mitigate contact lens dropout in those with comfort concerns in their habitual contact lenses.

Another study by Fogt et al also assessed the delefilcon A for astigmatism lens compared to another commonly used, commercially available toric lens. Employing a crossover study design, subjects were initially randomized to wear either the delefilcon A for astigmatism daily disposable lens or the comfilcon A for astigmatism (Biofinity® Toric, Cooper Vision, Pleasanton, CA, USA) monthly reusable lens. After 30 days of wear, participants were refitted with the opposite lens. After the monthly trial of each lens, participants responded to a VAS survey assessing comfort and vision for each lens. Overall, the participants noted the delefilcon A lenses for astigmatism outperformed the comfilcon A astigmatism lenses for both comfort and vision.²¹ In comparison to the other lens, the delefilcon A for astigmatism lens was superior in comfort and vision. The current study described here adds to this knowledge by further evaluating delefilcon A in dissatisfied previous contact lens wearers and assessed critical factors such as vision and comfort overall, at the end of the day, and also importantly, under common real-world scenarios.

There were some limitations to the study. The majority of the participants were female, and female gender is a known risk factor for dry eye with some estimates showing females have a 50% higher risk of dry eye compared to males.²² Although the cohort consisted largely of female participants, along with the higher relative risk for dry eye, the data still showed favorable

results as it pertains to comfort and vision in the lenses. Therefore, this study may suggest that these lenses can perform well in those typically at higher risk for dry eye. However, to further analyze this, an additional prospective study comparing female versus male responses as it relates to dry eye would need to be completed. Additionally, the Likert scale results showed some participants remained neutral in their responses. One potential reason for this could be that some individuals may have needed more than one month to fully assess the lens. While clinicians typically provide 1–2 weeks of trial lenses for real-world evaluation, this study mitigated potential time-related biases by offering participants a one-month supply of lenses. Furthermore, while the 30-day follow-up period provides valuable insights, a longer follow-up would be needed to fully evaluate long-term satisfaction and potential issues. In typical clinical practice, follow-up visits generally occur one to two weeks after lens dispensing, allowing patients time to assess the lenses before making a final decision. Thus, the 30-day follow-up in this study is still sufficient to draw meaningful conclusions about patient satisfaction with this daily contact lens in real-world conditions. Despite these factors, it is important to emphasize that the overall ratio of positive to negative responses remained favorable, highlighting the lens's effectiveness and high acceptance among the majority of participants.

Conclusion

In conclusion, the results of this study demonstrated that the Dailies Total1® for Astigmatism contact lens is comfortable and provides satisfactory vision in those who were unapproving of their previous toric contact lenses. Furthermore, the data shows the study lens is a potential option for patients requiring astigmatic correction who have previously discontinued contact lens wear or may be at risk of dropping out.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Disclosure

Dr. Phillip Brunson received a grant from Alcon for the study and is a consultant for Tarsus Pharmaceuticals Inc. The authors report no other conflicts of interest in this work.

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