# COMFORT OF DAILIES TOTAL1® FOR ASTIGMATISM IN SYMPTOMATIC HABITUAL REUSABLE TORIC LENS WEARERS

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## CL Dropout

Contact lens (CL) dropout occurs in approximately 20% of CL wearers annually with the top reasons being discomfort and dryness.[1] The replacement schedule of a CL may be a factor for discomfort, with lenses replaced daily (daily disposables) offering advantages over those replaced weekly or monthly (frequent replacement). One benefit with daily disposable lenses is that accumulation of surface deposits from the tear film may be lower than with frequent replacement lenses.[2,3] In addition, daily disposable lenses are not exposed to care solutions and storage cases, and thus have less potential to absorb components from each.[4,5] For patients experiencing CL discomfort with their frequent replacement lenses, refitting with daily disposable lenses may offer relief and help prevent CL discontinuation.[6,7] Different CL brands can have distinct material properties and interactions with the ocular environment that may also affect CL comfort in different ways.[2,4,7-9] With the recent introduction of DAILIES TOTAL1® for Astigmatism, there is little comfort data on this lens in those who are symptomatic that are switched from their habitual reusable toric lenses to DAILIES TOTAL1® for Astigmatism.

## DAILIES TOTAL1® Contact Lens Technology

DAILIES TOTAL1® (delefilcon A) with Water Gradient Technology are unique in that the chemistry is different than any other soft CL on the market. Unlike other traditional soft CL materials that are homogenous, or the same composition from core to surface, DAILIES TOTAL1® is a two-phase (biphasic) CL with a surface chemistry that is different from the core material.[10] This is important because the surface of the lens is ultimately what interacts with the tissues of the eye.

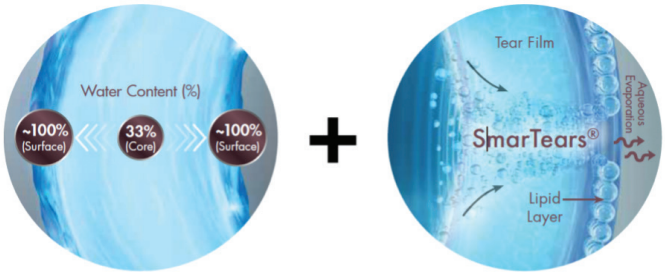
The core of the lens is a standard homogenous SiHy material with 33% water content which gradually transitions into a water gradient with nearly 100% water at the lens surface, based on in vitro measurements of unworn lenses (Figure 1).[11] The water gradient is not simply a surface treatment, but instead is integrated and anchored into the bulk lens material and remains intact during wear. The material is so unique that it does not easily fit into traditional lens categorizations – it is not simply a silicone hydrogel lens as it has characteristics of both silicone hydrogel (at the core) and hydrogel lenses (at the surface).[10]

DAILIES TOTAL1® CLs also feature SmarTears® Technology, which releases phosphatidylcholine (PC), an ingredient found naturally in tears. PC in the tears is important to help stabilize the lipid layer of the tear film in order to help prevent tear film evaporation.[12] The release of this ingredient from the CL is not continuous, but instead is based on diffusion in response to the concentration of PC in the surrounding tear film throughout the day (Figure 1).[12,13]

The Water Gradient and SmarTears® Technologies of DAILIES TOTAL1® CLs provide a lens surface that is highly wettable, soft, and lubricious.*,[14-20] In fact, DAILIES TOTAL1® has outperformed other homogenous lens materials in in vitro studies looking at lens surface wettability, softness, lubricity, and shear stress demonstrating just how different water surface materials are from others.*,†,‡,§,[21-28]

## Clinical Study to Determine Comfort of DAILIES TOTAL1® for Astigmatism in Symptomatic Habitual Reusable Toric Lens Wearers

In a recent investigator-initiated study, comfort with DAILIES TOTAL1® for Astigmatism CLs compared to other reusable soft toric CLs in symptomatic wearers was assessed.[29] This was a




**Water Gradient Technology**
Thick layer of moisture that reaches nearly 100% water at the surface, based on in vitro measurements of unworn lenses.[11]

**SmarTears® Technology**
Lens releases phosphatidylcholine (PC), an ingredient found naturally in tears that helps to stabilize the lipid layer of the tear film[12]

**Figure 1: DAILIES TOTAL1® Technologies**

**TABLE 1: DEMOGRAPHIC AND BASELINE (HABITUAL LENS) DATA**

| Baseline Factor | Outcomes* |
|---|---|
| Eyes (participants) | 170 (85) |
| Sex | |
| Female | 58 (68.2) |
| Male | 27 (31.8) |
| Age (years) | 28.5 ± 5.9 (18 to 38) |
| Cylinder (D) | -1.39 ± 0.58 (-3.00 to -0.50) |
| MRSE (D) | -3.48 ± 2.31 (-10.12 to 0.88) |
| CLDEQ-8 Total Score | 18.45 ± 4.88 (12.0 to 34.0) |

***Presented as Mean ± SD (Range) or n (%). Abbreviations:** CLDEQ-8 contact lens dry eye questionaire; D, diopters; MRSE, manifest refraction spherical equivalent; SD, standard deviation.

three visit study that recruited current reusable soft toric lens wearers who wore the lenses at least 5 days per week and ≥10 hours per day, and who had a minimum score of 12 on the CLDEQ-8 questionnaire. The distribution of habitual CL brands that were included represented the current reusable market share by percentage. Participants were given new habitual lenses with an optimized prescription in order to ensure that symptoms were not due to an old lens or an incorrect lens power. Participants wore the new lenses as daily wear and according to the recommended wear schedule for that brand (2 weeks or 4 weeks) before being switched to DAILIES TOTAL1® for Astigmatism which were worn as daily wear for 2 weeks. Masking and randomization of lenses was not attempted given that it would be impossible to mask the subjects from a reusable and daily disposable lens replacement schedule.[29]

The primary endpoint of this study was the total CLDEQ-8 score after 2 or 4 weeks of wear with optimized habitual toric lenses compared to 2 weeks of DAILIES TOTAL1® for Astigmatism lens wear. Other endpoints included responses to individual questions of the CLDEQ-8 and DVA with CLs.[29]

Eighty-five symptomatic subjects (170 eyes) completed the study, were aged 18-38 (mean + SD: 28.5 + 5.9) and were 68% female. MRSE ranged from 0.88D to -10.12D (mean + SD: -3.48 + 2.31) and cylinder ranged from -0.50D to -3.00D (mean + SD: -1.39 + 0.58). The mean baseline CLDEQ-8 score with original habitual contact lenses was 18.45 + 4.88 (Table 1).[29]

There was a significant improvement in CLDEQ-8 scores after being fit with DAILIES TOTAL1® for Astigmatism as compared to the optimized habitual toric lens. The mean score for subjects refit with new and optimized habitual toric lenses was 16.8 ± 8.1 and for subjects refit with DAILIES TOTAL1® for Astigmatism toric lenses was 12.4 ± 7.5 and was statistically significantly different between the groups ($P < 0.001$).[29]

Responses to individual questions on the CLDEQ-8 about intensity of symptoms were also compared. With DAILIES TOTAL1® for Astigmatism lenses, 78.9% of subjects reported little to no intensity of eye discomfort (responding 0, 1, or 2) compared to 51.7% for the optimized habitual toric lenses and this difference was statistically significant ($P = 0.007$). In addition, 77.7% of subjects reported little to no intensity of dryness (responding 0, 1, or 2) with DAILIES TOTAL1® for Astigmatism lenses compared to 50.6% for the optimized habitual toric lenses and the difference was statistically significant ($P = 0.02$). No difference was seen for intensity of blurriness when it did occur.[29]

Distance visual acuity was similar between the lenses with mean ±SD LogMAR of 0.00 ± 0.09 with DAILIES TOTAL1® for Astigmatism lenses and 0.05 ± 0.12 with optimized habitual toric lenses.

## Conclusions

DAILIES TOTAL1® for Astigmatism daily disposable contact lenses feature Water Gradient and SmarTears® Technologies, which provide a lens surface that is nearly 100% water based on in vitro measurements of unworn lenses, highly wettable, soft, and lubricious.*,†,‡,§,[21-28] These surface characteristics are important because the surface of the lens is what interacts with the tissues of the eye to help provide comfort during wear. The study results presented here showed that the subjective comfort and dryness in symptomatic habitual reusable toric contact lens wearers was improved by refitting with DAILIES TOTAL1® for Astigmatism.[29] This data suggests that DAILIES TOTAL1® for Astigmatism lenses should be considered as an alternative lens option for reusable lens wearers who are symptomatic. ■

*Based on in vitro studies on delefilcon A sphere lenses wherein wettability was measured using the iDDrop System (p<0.001). All lenses were tested in an identical manner, soaked in a PBS (phosphate-buffered saline solution) for 16 hours +/- 2 hours (p<0.001).
†Based on surface modulus measured with AFM nanoindentation studies with delefilcon A material (DAILIES TOTAL1 sphere lenses); compared to ACUVUE OASYS 1-DAY, ACUVUE OASYS MAX 1-DAY, 1-DAY ACUVUE MOIST, clariti 1day and MyDay sphere contact lenses; p<0.01.
‡Sphere contact lenses were placed on a membrane-covered probe and slid across live ocular epithelial cells for 1,000 cycles, at forces that mimic typical ocular pressures. Friction coefficient was calculated for each cycle and recorded for the duration of the experiment; compared to ACUVUE OASYS MAX 1-DAY, 1-DAY ACUVUE MOIST, clariti 1day, and MyDay sphere contact lenses; p<0.01.
§Contact lenses were placed on a membrane-covered probe and slid across live ocular epithelial cells for 1,000 cycles, at forces that mimic typical
ocular pressures. Fluorescence microscopy imagery shows that DAILIES TOTAL1 sphere contact lenses resulted in a far lower amount of epithelial cell damage compared to the lenses tested (p<0.001).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