Clinical Performance of a Novel Toric Silicone Hydrogel Contact Lens

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INTRODUCTION

- Soft contact lenses are among the most prescribed contact lenses worldwide, accounting for 74% of new fits and 81% of refits in the United States in 2021[1]
- Daily disposable contact lenses are extensively prescribed by eye care professionals, which offer several advantages such as hygiene, convenience, compliance, and lower rates of corneal infiltrative events[2,3]
- Silicone hydrogel contact lenses account for 74% of all soft contact lenses globally[1]
- Verofilcon A toric lens is a novel silicone hydrogel contact lens consisting of a material (verofilcon A) that combines high oxygen transmissibility with a low modulus of elasticity
- Verofilcon A toric lens is intended for the optical correction of astigmatism in subjects with healthy eyes with or without refractive ametropia

PURPOSE: To obtain on-eye clinical performance data and assess the characteristics of contact lens alignment and fit of a novel daily disposable toric silicone hydrogel contact lens (verofilcon A) for astigmatism

METHODS

Study design

- A prospective, open-label, single-arm, bilateral, multicenter, non-dispense clinical study conducted across five clinical practice sites in the United States (NCT04464044)
- Eligible subjects with healthy eyes were exposed to study lenses for approximately 1 hour

Total subjects
N=39 (78 eyes)

Study period
20 July 2020 – 6 August 2020

Key eligibility criteria

Inclusion criteria

- Age ≥18 years
- Habitual wearers of spherical or toric soft contact lenses for the past 3 months, for ≥5 days/week, and ≥8 hours/day
- Best corrected distance visual acuity of 20/25 or better in each eye, with a cylindrical correction of –0.75 D or –1.25 D (at axis 90° or 180°) and a sphere component of –1.00 D or –3.00 D

Exclusion criteria

- Habitual contact lens wearers in an extended wear modality (sleeping with lenses for ≥1 night/week) over last 3 months
- History of ocular or intraocular surgery, including refractive surgery within the previous 12 months
- Any anterior segment infection, inflammation or disease (including systemic)
- Biomicroscopy findings at screening of ≥Grade 3, corneal vascularization of ≥Grade 2, or any infiltrates

Study product

- Subjects were fitted with verofilcon A toric lens (8.5 mm base curve and 14.5 mm diameter)
- The following lens powers were available in this study:

–1.00 / –0.75 x 90	–1.00 / –0.75 x 180	–1.00 / –1.25 x 90	–1.00 / –1.25 x 180
–3.00 / –0.75 x 90	–3.25 / –0.75 x 175	–3.00 / –1.25 x 90	–3.00 / –1.25 x 175

Effectiveness and safety measures

Lens alignment:

- Lens settling time: The amount of time taken (in seconds) for the scribe mark orientation to reach its resting (settled) position
- Absolute axis orientation: Measured in degrees relative to the 6 o'clock position at 1, 2, 3, 5, and 10 minutes after lens insertion
- Percentage of lenses with axis orientation within ±20°, ±10°, and ±5° from the intended axis (90°), after 1, 2, 3, 5, and 10 minutes following lens insertion
- Lens oscillation with blink on a 4-point scale (none, <3°, 3° to 5°, and >5°)
- Scribe mark visibility (0, not visible; 1, somewhat visible; 2, easily visible)

Lens fit characteristics:

- Lens movement (5-point scale: –2, unacceptably tight; –1, acceptably tight; 0, optimal fit; +1, acceptably loose; and +2, unacceptably loose)
- Lens position (3-point scale: 0, optimal centration; 1, acceptable decentration; and 2, unacceptable decentration)

Lens alignment and fit characteristics

Lens alignment

Figure 1. Percentage of lenses within 5°, 10°, and 20° of intended orientation, at 10 min post insertion (n=78)

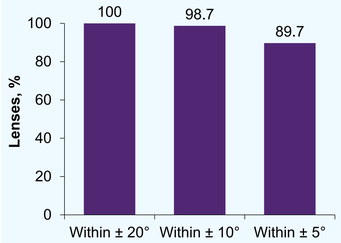
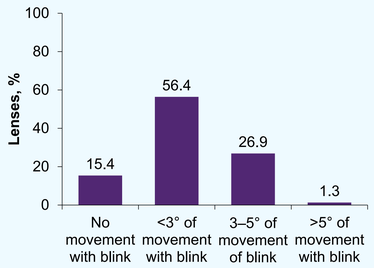
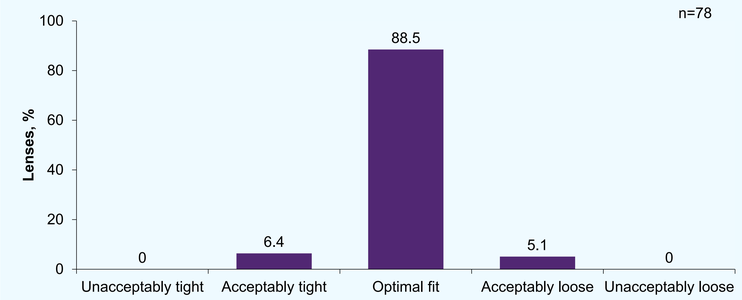


Figure 2. Distribution of lens oscillation with blink (n=78)



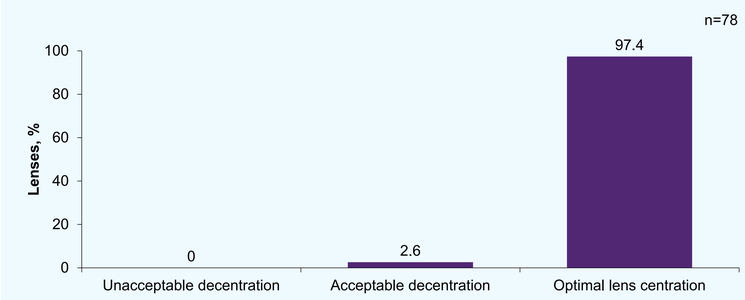
- At 10 minutes after lens insertion, the proportion of lenses orientating within ±20°, ±10°, and ±5° from the intended axis were 100%, 98.7%, and 89.7%, respectively (**Figure 1**)
- At all time-points (1, 2, 3, 5, and 10 minutes post insertion), at least 94.9% of lenses were within ±10° from the intended orientation
- The majority of the lenses (98.7%) had ≤5° of oscillation with blink (**Figure 2**)
- All lenses showed visible scribe marks; and were easily visible in 96.2% of the lenses

Figure 3. Lens movement



- Majority of the lenses achieved optimal fit (88.5%), while 11.5% had acceptably tight/loose fit **(Figure 3)**

Figure 4. Lens position



- The majority of lenses achieved optimal centration (97.4%), while 2.6% achieved acceptable decentration **(Figure 4)**

Safety measures:

- Adverse events, biomicroscopy findings, and device deficiencies

Statistical analysis

- All statistical analyses were performed using SAS® software (SAS Institute Inc., Cary, NC)
- Categorical variables were summarized as counts and percentages, and continuous data as mean (SD)

RESULTS

- Overall, subjects had a mean age of 34.1 years, with 66.7% being female, and majority being of White race (92.3%) (**Table 1**)
- The mean±SD lens settling time was 40.1±56.8 seconds
- Mean absolute axis orientation post lens insertion was <10° at all time points (1, 2, 3, 5, and 10 minutes)
- The mean axis orientation was stable from 2 minutes to 10 minutes post insertion, with the means ranging from 2.2° to 2.7°

Table 1. Demographic characteristics of subjects

Characteristics	n=39
Age (years), mean±SD	34.1±10.8
Age group (years), n (%)	
18–64	39 (100)
Sex, n (%)	
Male	13 (33.3)
Female	26 (66.7)
Race, n (%)	
White	36 (92.3)
Black or African American	1 (2.6)
American Indian or Alaska Native	0 (0.0)
Asian	1 (2.6)
Native Hawaiian or other Pacific Islander	0 (0.0)
Other	1 (2.6)
Ethnicity, n (%)	
Hispanic or Latino	6 (15.4)
Not Hispanic or Latino	33 (84.6)

SD, standard deviation

Safety endpoints

- No adverse events, device deficiencies, or clinically relevant worsening of biomicroscopic findings were reported

CONCLUSION

- The novel daily disposable toric verofilcon A contact lens showed optimal alignment and fit without any safety concerns.
- The unique material features, advanced surface technology, and optimal alignment and fitting characteristics of this lens could offer a better contact lens wearing experience for individuals with astigmatism.

References

1. Morgan PB, Woods CA, Tranoudis IG, et al. International contact lens prescribing in 2021. *Cont Lens Spectrum.* 2022;37:32-38. **2.** Sulley A, Dumbleton K. Silicone hydrogel daily disposable benefits: The evidence. *Cont Lens Anterior Eye.* 2020;43:298-307. **3.** Orsborn G, Dumbleton K. Eye care professionals' perceptions of the benefits of daily disposable silicone hydrogel contact lenses. *Cont Lens Anterior Eye.* 2019;42:373-379.

Abbreviations: D, diopter; SD, standard deviation

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Conflict of interest: Lakshman Subbaraman is employee of Alcon. Susan Whaley is a paid principal investigator for Alcon and Johnson and Johnson. Britt Gustafson and Bradley Giedd are clinical investigators for Alcon.

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