Clinical Performance of Two Daily Disposable Toric Soft Contact Lenses Verofilcon A versus Etafilcon A

INTRODUCTION

METHODS

- Toric soft contact lenses (SCLs) accounted for 32% of all SCLs prescribed worldwide in 2021
- Silicone hydrogel daily disposable contact lenses are considered as the lenses of choice in patients requiring toric designs and long wearing times²
- Verofilcon A SCL, a silicone hydrogel daily disposable contact lens, has been reported to have high ratings in terms of vision quality, comfort, and handling³
- Etafilcon A is a widely used conventional hydrogel contact lens that has been available in the market for a long time⁴

Purpose: To compare clinical performance of two commercially available daily disposable toric soft contact lenses, verofilcon A and etafilcon A

Study design

- A prospective, randomized, controlled, double-masked, crossover, clinical study conducted at 8 sites in the US (July-September 2021; NCT04908488)
- Eligible subjects were randomized (1:1 ratio; single crossover) to bilaterally wear verofilcon A toric (test) or etafilcon A toric (control) lenses for lenses for ≥10 hours/day for 8 to 11 days in a daily disposable modality
- On/after day 7 of the study lens wear, subjects were asked to wear the study lenses for at least 16 hours on 1 day and complete take-home questionnaires

Study visits

Visit 1 Screening/ Trial lens fitting and evaluation

Visit 2 **Baseline**/ **Dispense lens 1** (2-6 days after visit 1)

Visit 3 1 Week follow-up lens 1/ Dispense lens 2 (8-11 days after visit 2)

Key eligibility criteria

Inclusion criteria

- Subjects aged ≥18 years
- Successful wearers of toric soft contact lenses in both eyes (≥5 days/week and ≥10 hours/day) during the past 3 months
- Subjects willing to wear study contact lenses \geq 16 hours/day on one of the days

Visit 4 1 Week follow-up lens 2/ Exit (8-11 days after visit 3) **Exclusion criteria** Current/previous habitual wearers of verofilcon A or etafilcon A toric lenses • Any current spherical monovision and multifocal contact lens wearers • Ocular or intraocular surgery within the

- last 12 months

Study endpoints

- **Primary endpoint:** Distance visual acuity (logMAR) at week 1 (noninferiority margin = 0.05) logMAR)
- **Exploratory endpoints:**
- Subjective ratings for overall preference at end of the study (5-point scale: strongly prefer lens 1, somewhat prefer lens 1, no preference, somewhat prefer lens 2, strongly prefer lens 2)
- Subjective ratings for insertion handling, insertion comfort, and overall comfort at 16 hours (10-point scale: 1=poor to 10=excellent)
- Lens position at week 1 (3-point scale: 0=optimal lens centration to 2=unacceptable decentration)
- Lens movement at week 1 (at primary and peripheral gazes; 5-point scale: -2=unacceptably tight to +2=unacceptably loose)

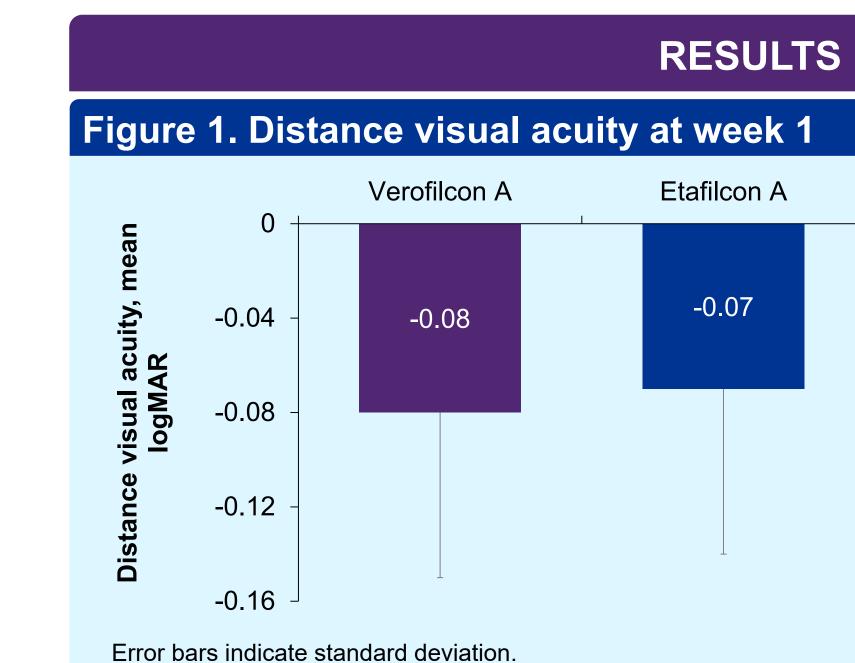
Statistical analysis

- All statistical analyses were performed using SAS[®] software (SAS Institute Inc., Cary, NC)
- A mixed effects repeated measures model was utilized to test the visual acuity and subjective ratings
- Overall preference was analyzed by the exact binomial test

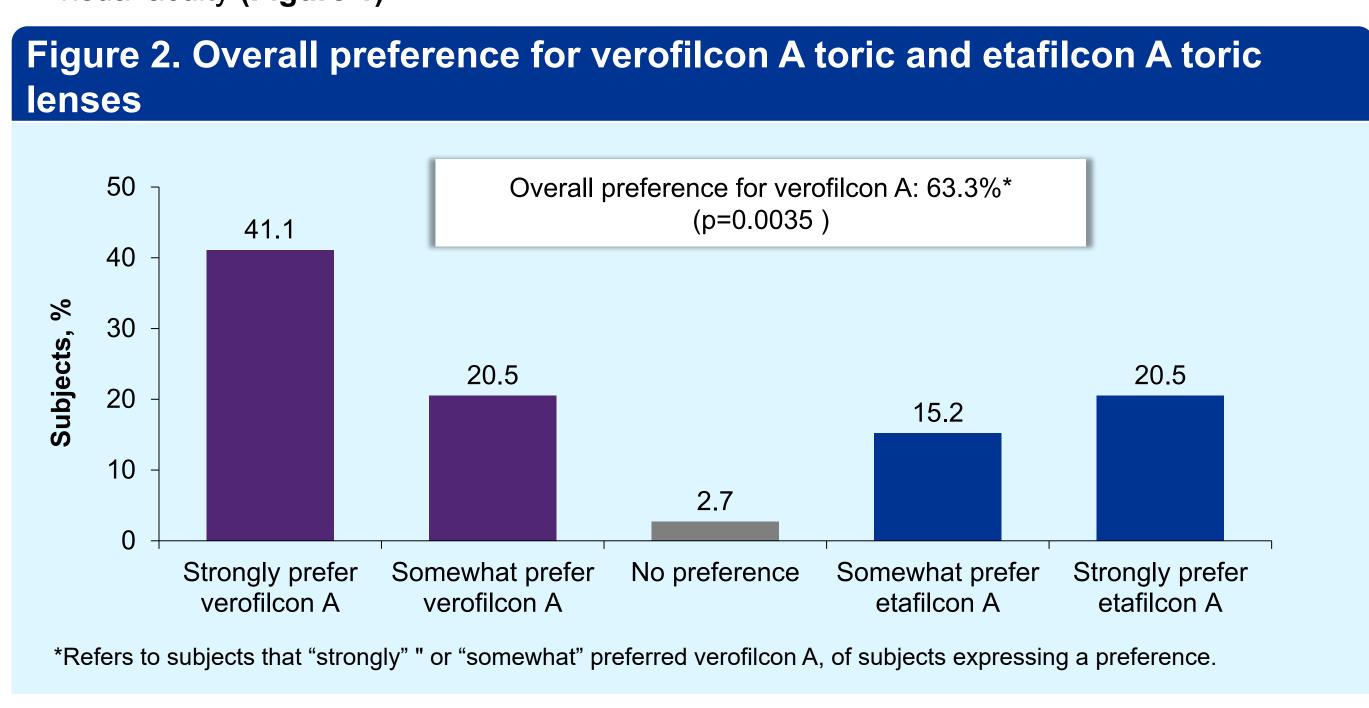
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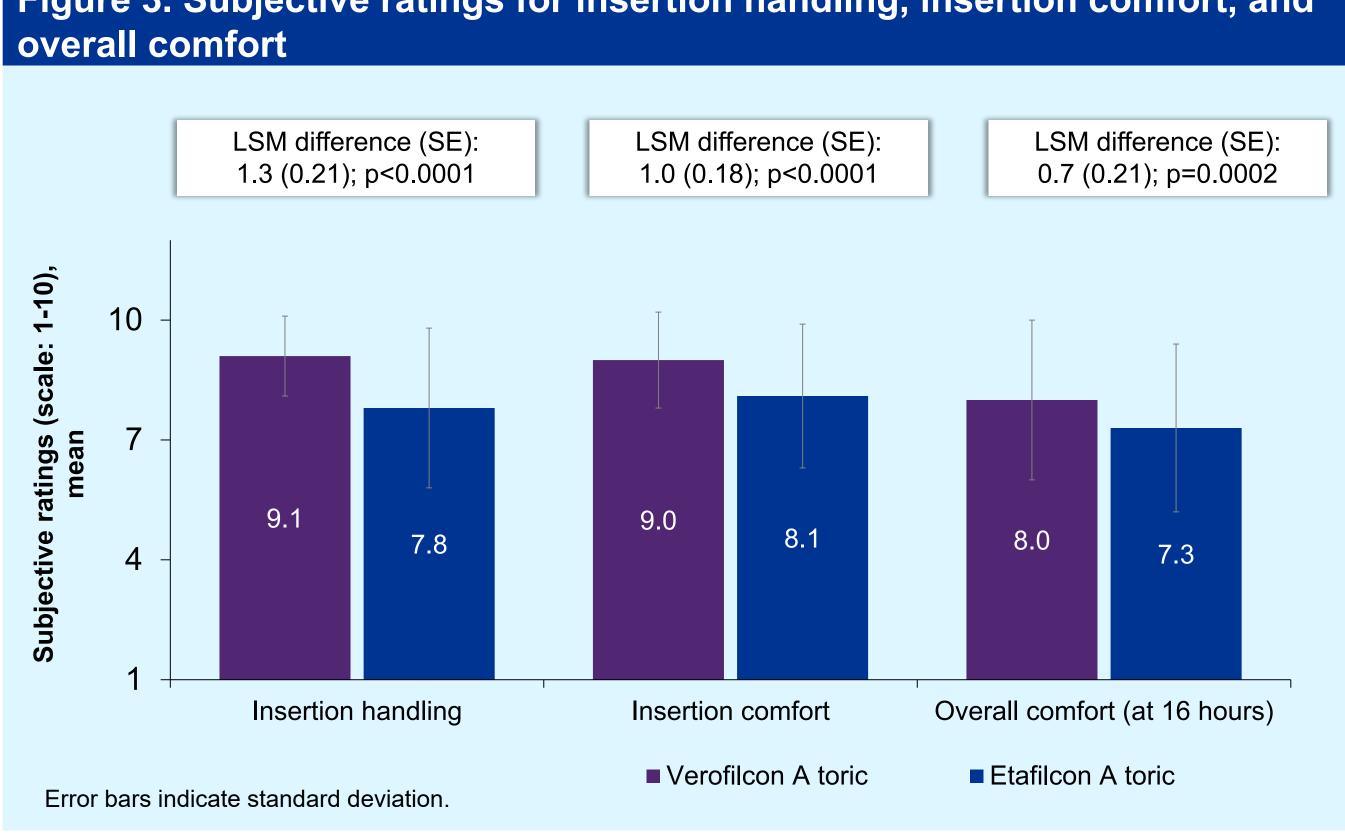


• At week 1, verofilcon A toric lenses were noninferior to etafilcon A toric lenses for distance visual acuity (Figure 1)



• Of subjects who reported preference, 63.3% preferred verofilcon A toric lenses at end of the study (p=0.0035 vs hypothesized 50.0%) (Figure 2)

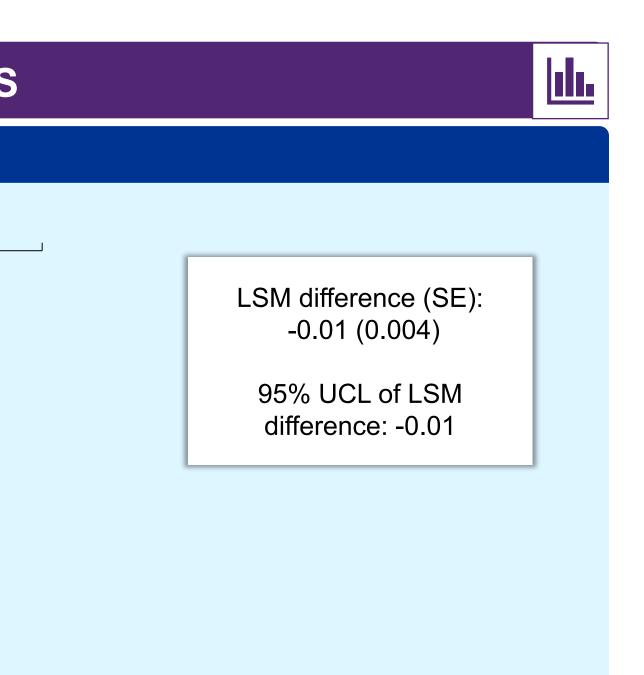
Figure 3. Subjective ratings for insertion handling, insertion comfort, and



• Verofilcon A toric lenses had higher ratings than etafilcon A toric lenses for insertion handling, insertion comfort, and overall comfort at 16 hours (Figure 3)

Abbreviations: logMAR, logarithm of the minimum angle of resolution; LSM, least square mean; SCL, soft contact lens; SD, standard deviation; SE, standard error; UCL, upper confidence limit. Acknowledgement: Authors thank David Evans, Glen Corbin, Elsa Pao, and Jennifer Chin for their support as clinical investigator of the study. Writing, editorial, and formatting assistance was provided by Janet Oommen, PharmD, from Indegene Pvt. Ltd. which was contracted and funded by Alcon.

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- wear study lenses (screen failure, n=1)
- Of these, 112 subjects completed the study (discontinuation; adverse event, n=1;
- withdrawal by subject, n=1)

Table 1. Demographic characteristics of subjects

| Overall (n=114) | | |
|------------------|--|--|
| 32.3±10.1 | | |
| | | |
| 44 (38.6) | | |
| 70 (61.4) | | |
| · | | |
| 67 (58.8) | | |
| 23 (20.2) | | |
| 23 (20.2) | | |
| 1 (0.9) | | |
| Ethnicity, n (%) | | |
| 19 (16.7) | | |
| 94 (82.5) | | |
| 1 (0.9) | | |
| | | |

Table 2. Lens fit evaluation at week 1

Lens fit characteristics

- Lens movement primary gaze,
- Unacceptably tight
- Acceptably tight
- **Optimal fit/movement**
- Acceptably loose
- Unacceptably loose

Lens movement - peripheral gaz

- Unacceptably tight
- Acceptably tight
- **Optimal fit/movement**
- Acceptably loose
- Unacceptably loose
- Lens position, n (%)
- Optimal lens centration
- Acceptable decentration
- Unacceptable decentration

- handling, insertion comfort, and overall comfort at 16 hours
- decentration and optimal/acceptable lens movement at week 1
- Funding: This study was funded by Alcon Research, LLC.

Conflict of interest: Lakshman Subbaraman is employee of Alcon. All other authors are clinical investigators for Alcon. There is no other conflict of interest to declare.

RESULTS

• Overall, 115 subjects were enrolled in the study, of which 114 subjects were randomized to

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• Overall, mean±SD age was 32.3±10.1 years, with 61.4% being female (Table 1)

| S | Verofilcon A (n=224) | Etafilcon A (n=220) |
|------------|----------------------|---------------------|
| n (%) | | |
| | 0 (0.0) | 0 (0.0) |
| | 15 (6.7) | 2 (0.9) |
| | 202 (90.2) | 205 (93.2) |
| | 7 (3.1) | 13 (5.9) |
| | 0 (0.0) | 0 (0.0) |
| zes, n (%) | · | |
| | 0 (0.0) | 0 (0.0) |
| | 15 (6.7) | 0 (0.0) |
| | 201 (89.7) | 190 (86.4) |
| | 8 (3.6) | 30 (13.6) |
| | 0 (0.0) | 0 (0.0) |
| | | |
| | 224 (100.0) | 213 (96.8) |
| | 0 (0.0) | 7 (3.2) |
| | 0 (0.0) | 0 (0.0) |

• At week 1, both toric lenses demonstrated optimal lens centration/acceptable decentration and optimal/acceptable lens movement in both primary and peripheral gazes (Table 2)

CONCLUSION

• Verofilcon A toric lenses performed better than etafilcon A toric lenses for insertion Both daily disposable toric soft contact lenses showed optimal lens centration/acceptable