Clinical Performance Comparison of Two Commercially Available Daily Disposable Soft Contact Lenses: Verofilcon A versus Somofilcon A

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INTRODUCTION

- Soft contact lenses (SCLs) accounted for >70% of new fits/refits in the United States in 2021; further, 46% of SCLs were prescribed in a daily disposable modality[1]
- About 83% of all SCLs prescribed in the US are silicone hydrogel materials[1]
- Verofilcon A is a daily disposable silicone hydrogel contact lens, with 51% water content at the core and a modulus of 0.6MPa that helps in easy handling[2]

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

METHODS

Study design

- A prospective, randomized, controlled, double-masked, bilateral, crossover, daily wear, multicenter clinical study was conducted at 8 sites in the United States (ClinicalTrial.gov Identifier: NCT04865354)
- Subjects were randomized (1:1 ratio; single crossover) to wear verofilcon A or somofilcon A SCLs bilaterally for ≥10 hours/day for 8 (-0/+3) days
- On the day prior to visits 2 and 3, subjects were instructed to wear the study lenses for ≥16 hours and complete take-home questionnaires at various time points (after lens insertion, and at 12 and 16 hours following insertion)

Study visits

Visit 1 Screening/Baseline/ Dispense lens 1 → **Visit 2** Week 1 follow-up lens 1/ Dispense lens 2 → **Visit 3** Week 1 follow-up lens 2/ Exit

Key eligibility criteria

Inclusion criteria

- Subjects aged ≥18 years
- Spherical soft lens wearing experience of ≥3 months, with wearing time of ≥5 days/week and ≥10 hours/day
- Subjects needing vision correction in spherical range from -1.00 to -6.00 D with best corrected visual acuity of 20/25 or better in each eye
- Manifest cylinder of ≤0.75 D in each eye
- Willing to wear contact lenses for at least 16 hours on one of the days

Exclusion criteria

- Habitual contact lens wearers in an extended wear modality
- Monovision and multifocal lens wearers
- Symptomatic subjects as determined using the symptomatology questionnaire

Study endpoints

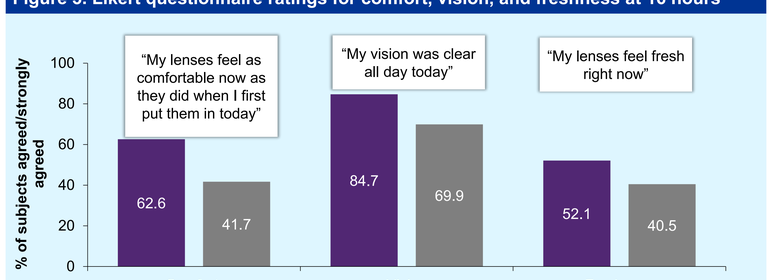
- **Primary endpoint**: Distance visual acuity (logMAR) at week 1
- **Exploratory endpoints**:
  - Subjective ratings for comfort after lens insertion, and at 12 and 16 hours (visual analog scale [VAS] ratings: 0=causes pain to 100=excellent)
  - Subjective ratings for overall impression at 16 hours (VAS ratings: 0-100: 0=extremely poor to 100 =excellent)
  - Likert questionnaire ratings for comfort, vision, and freshness at 16 hours (5-point scale; strongly agree to strongly disagree)
  - Overall preference at the 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)
  - Lens movement at week 1 (at primary and peripheral gazes; 5-point scale: - 2=unacceptably tight to + 2=unacceptably loose)
  - Lens position at week 1 (3-point scale: 0=optimal lens centration to 2=unacceptable decentration)

Statistical analysis

- All statistical analyses were performed using SAS® software (SAS Institute Inc., Cary, NC)
- Distance visual acuity (non-inferiority margin=0.05 logMAR) and VAS ratings were analyzed using mixed effects repeated measures models; Likert questionnaire ratings were analyzed by generalized linear model; overall preference was analyzed by exact binomial test

RESULTS

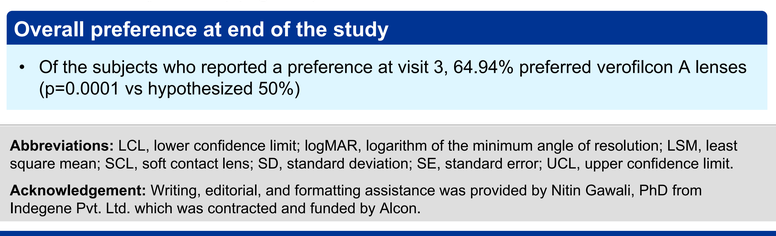
Figure 1. Distance visual acuity at week 1



Error bars indicate standard deviation.

- Verofilcon A was noninferior to somofilcon A SCLs in distance visual acuity at week 1 **(Figure 1)**

Figure 2. Subjective ratings for comfort and overall impression



Error bars indicate standard deviation.

- Verofilcon A at 12 hours was noninferior to somofilcon A lenses after insertion, for comfort (95% LCL for LSM difference > -7)
- At 16 hours, VAS ratings for overall impression and comfort were significantly higher for verofilcon A than somofilcon A lenses (**Figure 2**)

Figure 3. Likert questionnaire ratings for comfort, vision, and freshness at 16 hours

- At 16 hours, higher percentage of subjects wearing verofilcon A (vs somofilcon A) lenses strongly agreed/agreed for the statements on lens comfort ($p<0.0001$), vision ($p=0.0003$), and freshness ($p=0.0051$) (**Figure 3**)

Overall preference at end of the study

- Of the subjects who reported a preference at visit 3, 64.94% preferred verofilcon A lenses (p=0.0001 vs hypothesized 50%)

RESULTS

- A total of 170 subjects were enrolled in the study, of which 167 subjects were randomized (screen failure, n=3)
  - Of these subjects, 164 completed the study (discontinued, n=3)
- Overall, mean±SD age of the subjects was 31.4±8.2 years, with 69.5% being female
- Majority of subjects were of White race and of Not Hispanic or Latino ethnicity (**Table 1**)

Table 1. Demographic characteristics of subjects

Characteristics	Overall (n=167)
Age, mean±SD years	31.4±8.2
Age Group, 18 – 64, n (%)	167 (100.0)
Sex, n (%)	
Male	51 (30.5)
Female	116 (69.5)
Race, n (%)	
White	136 (81.4)
Asian	25 (15.0)
Black or African American	4 (2.4)
Other	2 (1.2)
Ethnicity, n (%)	
Hispanic or Latino	13 (7.8)
Not Hispanic or Latino	154 (92.2)

Table 2. Lens movement and lens position at week 1

Lens fit characteristics	Verofilcon A (n=328)	Somofilcon A (n=328)
Lens movement – primary gaze, n (%)		
Unacceptably tight	0 (0.0)	0 (0.0)
Acceptably tight	29 (8.8)	62 (18.9)
Optimal fit/movement	281 (85.7)	240 (73.2)
Acceptably loose	18 (5.5)	24 (7.3)
Unacceptably loose	0 (0.0)	2 (0.6)
Lens movement – peripheral gazes, n (%)		
Unacceptably tight	0 (0.0)	0 (0.0)
Acceptably tight	13 (4.0)	32 (9.8)
Optimal fit/movement	290 (88.4)	273 (83.2)
Acceptably loose	25 (7.6)	21 (6.4)
Unacceptably loose	0 (0.0)	2 (0.6)
Lens position, n (%)		
Optimal lens centration	299 (91.2)	226 (68.9)
Acceptable decentration	29 (8.8)	100 (30.5)
Unacceptable decentration	0 (0.0)	2 (0.6)

- At week 1, all lenses had optimal/acceptable lens movement (for both primary and peripheral gazes) and optimal lens centration/acceptable decentration (**Table 2**)

CONCLUSION

- Verofilcon A performed better than somofilcon A lenses with respect to comfort and overall impression even after 16 hours of wear
- More verofilcon A wearers agreed for statements on lens comfort, vision and freshness assessed using Likert questionnaires
- Both verofilcon A and somofilcon A lenses had optimal/acceptable lens movement and centration at week 1

References:
1. Morgan PB, et al. *Cont Lens Spectrum.* 2022;37:32-38.
2. Miller J, Giedd B, Subbaraman LN. *Clinical Ophthalmol (Auckland, NZ).* 2021;15:4339.

Abbreviations: LCL, lower confidence limit; 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.

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

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