

Clinical Performance Results of a New Silicone Hydrogel Material (Lehfilcon A)

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INTRODUCTION

- Contact lens wearing schedule preferences vary among contact lens users. The most popular options are daily disposable and monthly replacement lenses¹
- Improvements in lens materials and their properties have been made over the years,^{2,3} however most of these improvements have been applied to daily disposable products
- It is particularly important to provide monthly replacement wearers with new and advanced options
- A sensible starting point for an optimized monthly reusable contact lens is water gradient technology found in delefilcon A
- Lehfilcon A (TOTAL30®), a new monthly replacement silicone hydrogel (SiHy) contact lens, with a core lens material containing 55% water that gradually transitions to nearly 100% water at the outer surface has been developed

PURPOSE

This study evaluated the clinical performance of a new silicone hydrogel (SiHy) material, lehfilcon A, with a core lens material containing 55% water that gradually transitions to nearly 100% water at the outer surface.

METHODS



Prospective, multi-center, bilateral, dispense study



Study period (30 day (±2 days))



Total subjects N = 66

Inclusion criteria

- Subjects aged ≥ 18 years fitted with lehfilcon A contact lenses
- Habitual spherical soft contact lens wearers with range of sphere power from -1.00 to -6.00D and a manifest cylinder of ≤ -0.75D
- Best corrected visual acuity of 20/25 or better in each eye

Measures

- On visit 1, the subjects were screened, baseline measurements were collected, and the contact lenses were dispensed. After 30 days (±2 days) of daily wear, the follow-up visit took place
- Clear Care solution was used for daily cleaning and disinfection
- Subjective agreement questions were asked on Day 1 and Day 30 and subjective lifestyle questions were asked on Day 30 using a 5-point Likert scale (1 = strongly agree; 5 = strongly disagree)
- 0–100 VAS scales (originally designed by Eurolens Research) were used to test Lens Cleanliness, Overall Impression, and Comfort
- The scales were anchored for Lens Cleanliness and Overall Impression: 0 = Extremely Poor; 20 = Very Poor; 40 = Poor; 60 = Good; 80 = Very Good; 100 = Excellent, and for Comfort: 0 = Causes Pain; 20 = Very Uncomfortable; 40 = Slightly Uncomfortable; 60 = Comfortable; 80 = Very Comfortable; 100 = Excellent

RESULTS

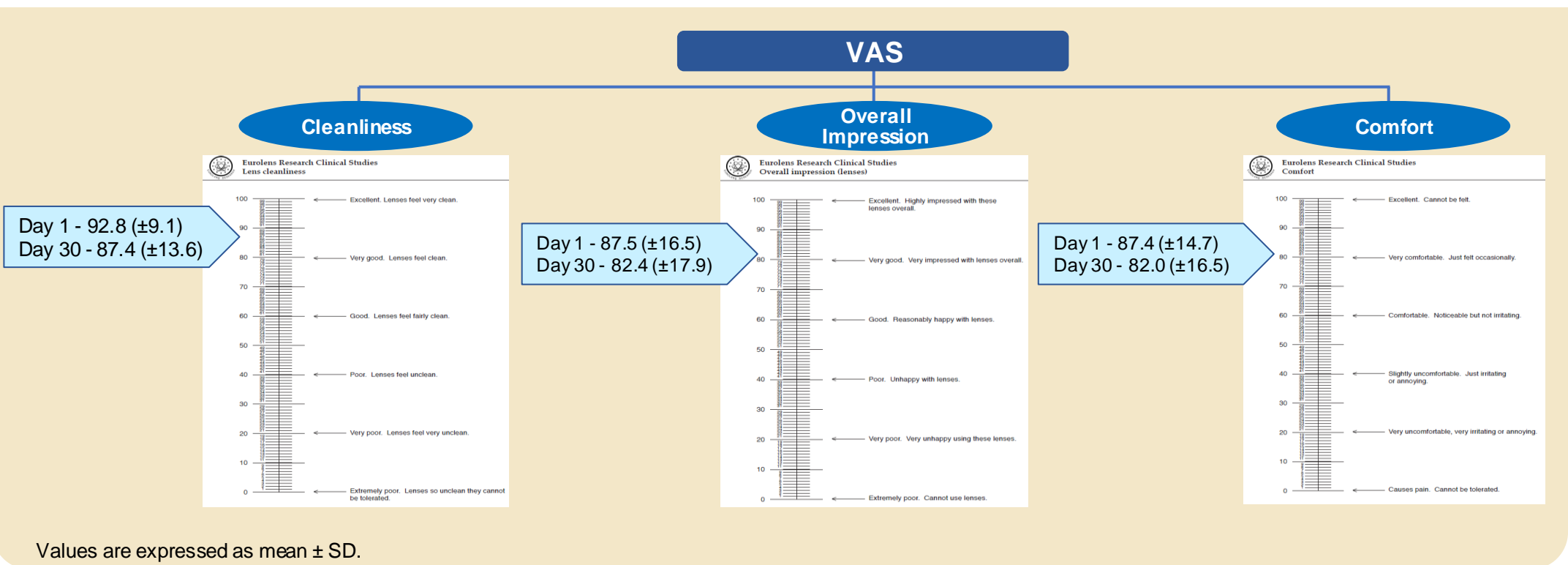
Demographics

Age (years)	Sex, n (%)	Race, n (%)
Mean: 33.2 (±8.3) Range: 20 – 53	Male, 14 (21.2) Female, 52 (78.8)	White, 64 (97) African American or black, 1 (1.5) Others, 1 (1.5)

Agreement Questions

Subjective Lifestyle Questions	Day 30 Strongly Agreed or Agreed %
These lenses were hassle free	87.7
These lenses did not distract me from living my life to the fullest	86.2
It was easy to remove my lenses	89.2

Subjective Agreement Questions	Day 1 Strongly Agreed or Agreed %	Day 30 Strongly Agreed or Agreed %
My lenses felt comfortable	93.8	89.2
My vision was clear	93.8	93.8
It was easy to put my lenses in	95.3	96.9



CONCLUSION

- Consistent clinical performance in terms of comfort, vision, overall impression, and ease of use was observed from Day 1 to Day 30 with this new lehfilcon A material

References

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Disclosure

Alcon Research, LLC, Johns Creek, GA, USA.
This data was originally presented at BCLA 2021.

Conflicts of interest

Carolina Kunnen is an employee of Alcon Research, LLC.
Other authors have no conflicts of interest to declare.