

# Subjective Performance of Hydrogel and Silicone Hydrogel Daily Disposable Contact Lenses

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## Purpose

The purpose of this study was to evaluate subjective performance of DAILIES® AquaComfort Plus™ (nelfilcon A with 69% water content and a blink-activated moisture system; Alcon Laboratories, Inc.) and Clarity™ 1-day (filcon II-3 with 56% water content; Sauflon Pharmaceuticals) in a population of daily disposable (DD) contact lens wearers.

## Methods

### Study Design

- ▶ This was a prospective, multicenter, subject-masked, randomized bilateral crossover study conducted at 22 study centers in Germany and the United Kingdom.
- ▶ Subjects were randomized to nelfilcon A/filcon II-3 or filcon II-3/nelfilcon A lens wear sequences and wore each brand bilaterally for 1 week.
- ▶ The study consisted of a baseline visit and 2 follow-up visits conducted 1 week after use of each lens.

### Subjects

- ▶ Eligible subjects were currently wearing any spherical DD lens except study lenses or private-labeled equivalent lenses and wore lenses ≥8 hours/day and ≥5 days/week.
- ▶ Key exclusion criteria: eye injury or surgery ≤12 weeks before enrollment; preexisting ocular irritation that would preclude lens fitting; any systemic or ocular abnormality, infection, or disease likely to affect successful wear of contact lenses; prior history of corneal or refractive surgery; current use of study lenses; monovision correction

### Outcomes

- ▶ The primary efficacy endpoints were subjective responses (ratings and preferences) regarding lens comfort, eye dryness, vision, lens handling, overall satisfaction and lens preference, purchase intent, and comfortable wearing time.
  - After 1 week of lens wear, subjects rated each variable on a 1–10 point scale: 1 = poor/very dry/difficult; 10 = excellent/not dry/easy.
- ▶ To evaluate noninferiority for the subjective responses recorded on 10-point scales, a 95% 1-sided confidence limit was computed for the paired difference between study lenses. A noninferiority margin of 0.5 units was used. A repeated measures model was fitted for paired differences, using Proc Mixed/GenMod in SAS software. Period (lens brand 1, lens brand 2) and sequence group (test followed by control, control followed by test) were included in the model. If the analysis result concluded that the test lens was not inferior to the control lens, then the lower bound of the confidence limit (LCL) was used to determine whether the test lens was superior to the control lens (ie, LCL above 0).
- ▶ Subjective preference and purchase intent were analyzed using Exact Binomial Tests.

## Results

### Subjects

- ▶ 310 of 316 enrolled subjects completed the study. The subjects, all habitual DD wearers, were wearing hydrogel lenses in the majority of cases, with only 11% wearing silicone hydrogel lenses (Table 1).

Table 1. Subject Demographics and Habitual Lens Brands

Parameter	Subjects (n=316)
Mean ± SD age, years	33.9±11.1
Sex, n (%)	
Female	197 (62.3)
Male	119 (37.7)
Habitual lens brands, n (%)	
Alcon (Focus Dailies All Day Comfort, Sehwert One Day, Focus Dailies Basic)	91 (28.8)
Johnson & Johnson (1-Day Acuvue Moist, 1-Day Acuvue Trueye, 1-Day Acuvue)	90 (28.5)
Cooper (Proclear 1 Day, Biomedics 1 Day)	81 (25.6)
Bausch & Lomb (Soflens Daily Disposable, Soflens One Day, Interlens One Day, Optosan Daily)	52 (16.4)
Sauflon (Bioclear One Day)	2 (0.6)
Mean ± SD habitual lens wear	
Hours per day (range)	12.5±2.6 (7–19)
Days per week (range)	6.1±1.1 (1–7)

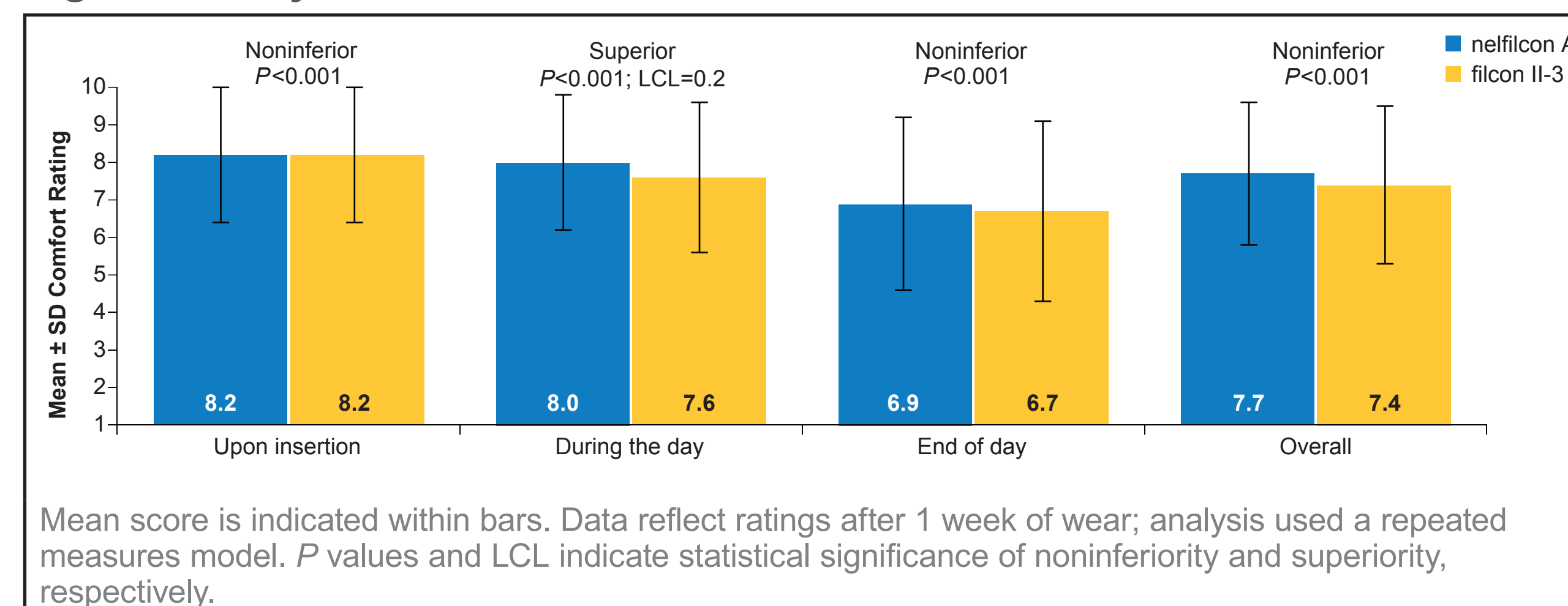
### Lens Wearing Time

- ▶ Mean ± SD subject-reported wear time was similar for both study lenses (nelfilcon A, 12.7±2.4 hours; filcon II-3, 12.4±2.6 hours).
- ▶ Mean ± SD subject-reported comfortable wear time with nelfilcon A and filcon II-3 lenses was 10.5±3.6 hours/day and 10.0±4.1 hours/day, respectively (P=0.065).

### Subjective Lens Ratings

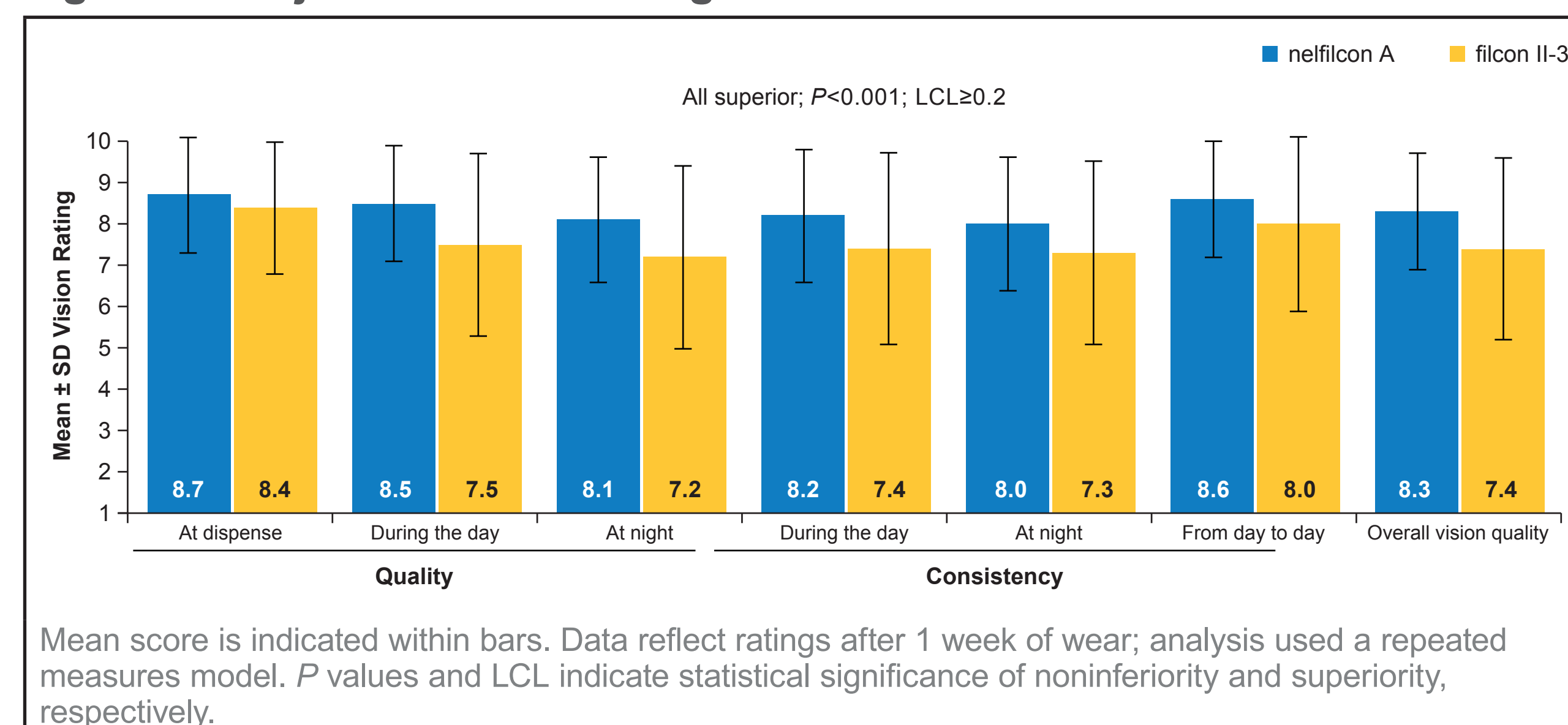
- ▶ Subjective comfort ratings after 1 week of wear (Figure 1) were noninferior for nelfilcon A vs filcon II-3 lenses for all items (P<0.001, repeated measures model) and were superior for nelfilcon A lenses in terms of comfort during the day (P<0.001, LCL=0.2).

Figure 1. Subjective Lens Comfort



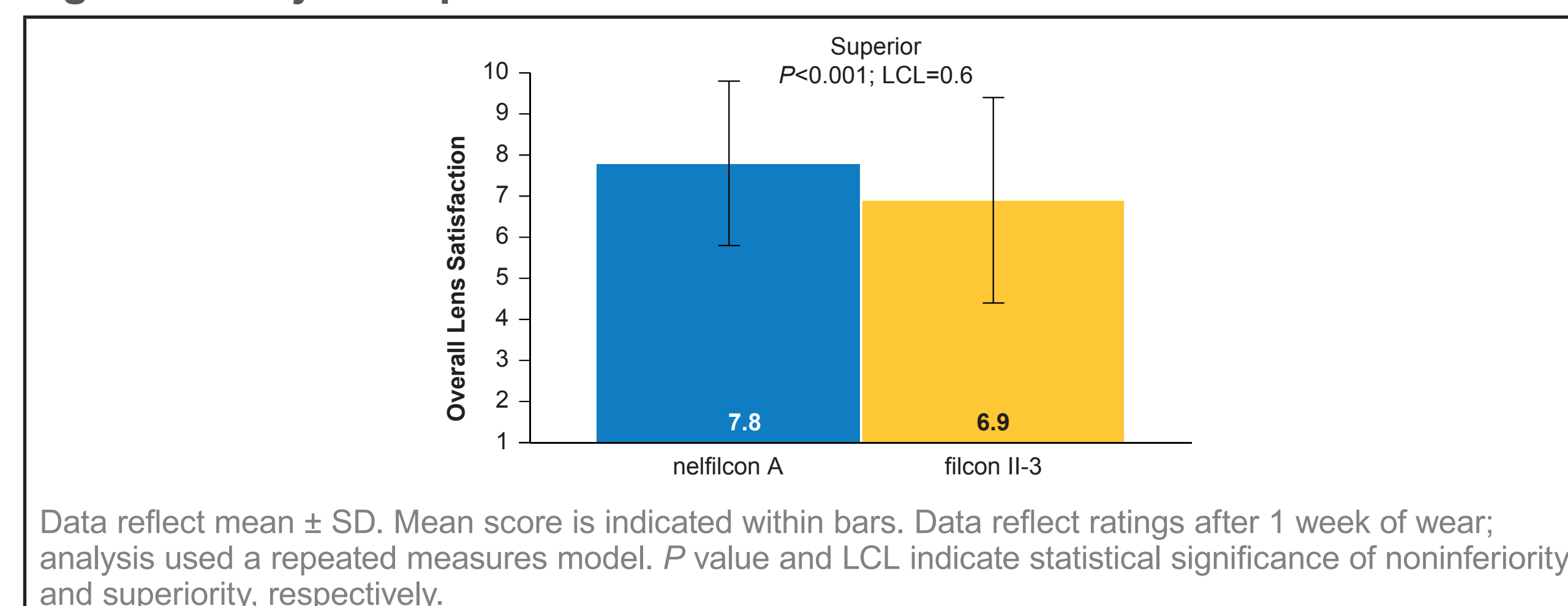
- ▶ Dryness ratings were noninferior for nelfilcon A vs filcon II-3 lenses and were superior for nelfilcon A lenses for daytime dryness.
  - Remains moist throughout the day: nelfilcon A, 7.2; filcon II-3, 7.0 (noninferior; P<0.001)
  - Dryness throughout the day: nelfilcon A, 7.7; filcon II-3, 7.3 (superior; P<0.001; LCL=0.1)
  - Dryness at the end of the day: nelfilcon A, 6.5; filcon II-3, 6.5 (noninferior; P=0.003)
- ▶ After 1 week of wear, vision ratings for nelfilcon A lenses were superior compared with filcon II-3 lenses for all variables assessed (Figure 2).

Figure 2. Subjective Vision Ratings



- ▶ Ratings for lens handling at insertion and overall were noninferior for nelfilcon A vs filcon II-3 lenses (P<0.001), and were superior for handling at removal (P<0.001; LCL=0.2).
- ▶ Overall lens satisfaction was superior with nelfilcon A lenses compared with filcon II-3 lenses (Figure 3).

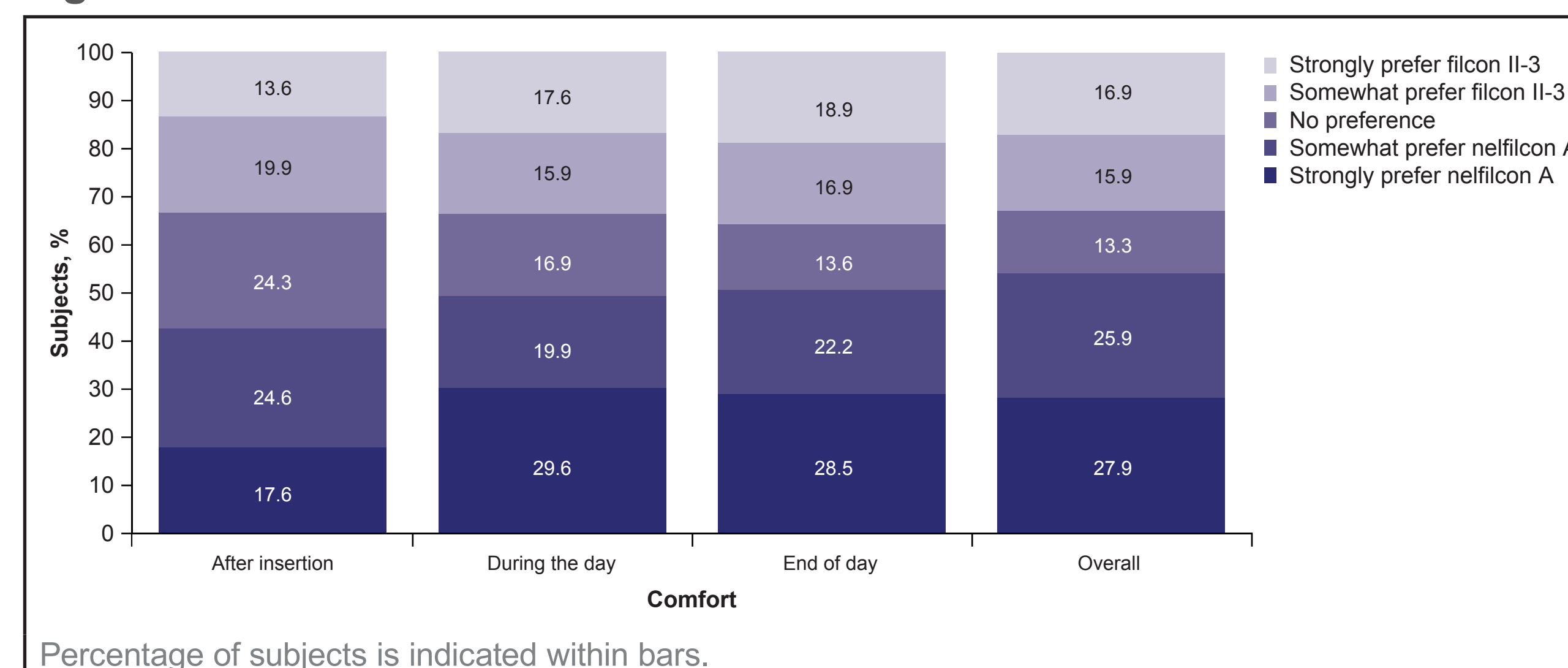
Figure 3. Subject-Reported Lens Satisfaction



### Preference and Purchase Intent

- ▶ Significantly more subjects preferred nelfilcon A lenses over filcon II-3 lenses with respect to comfort during the day, at the end of the day, and overall (Figure 4).
- A lens preference was reported by 75.7% to 86.7% of subjects across the 4 comfort variables; nelfilcon A lenses were preferred by significantly more subjects for comfort during the day (P=0.003), end of day comfort (P=0.006), and overall comfort (P<0.001).
- ▶ 66.1% of subjects reported an overall vision preference. Of these, significantly more reported an overall vision preference with nelfilcon A vs filcon II-3 lenses (68.3% vs 31.7%, P<0.001).

Figure 4. Preference for Comfort Variables



- ▶ No significant differences were reported for subjects' preference in terms of lens handling (Figure 5) or dryness symptoms (Figure 6).

Figure 5. Preference for Handling Variables

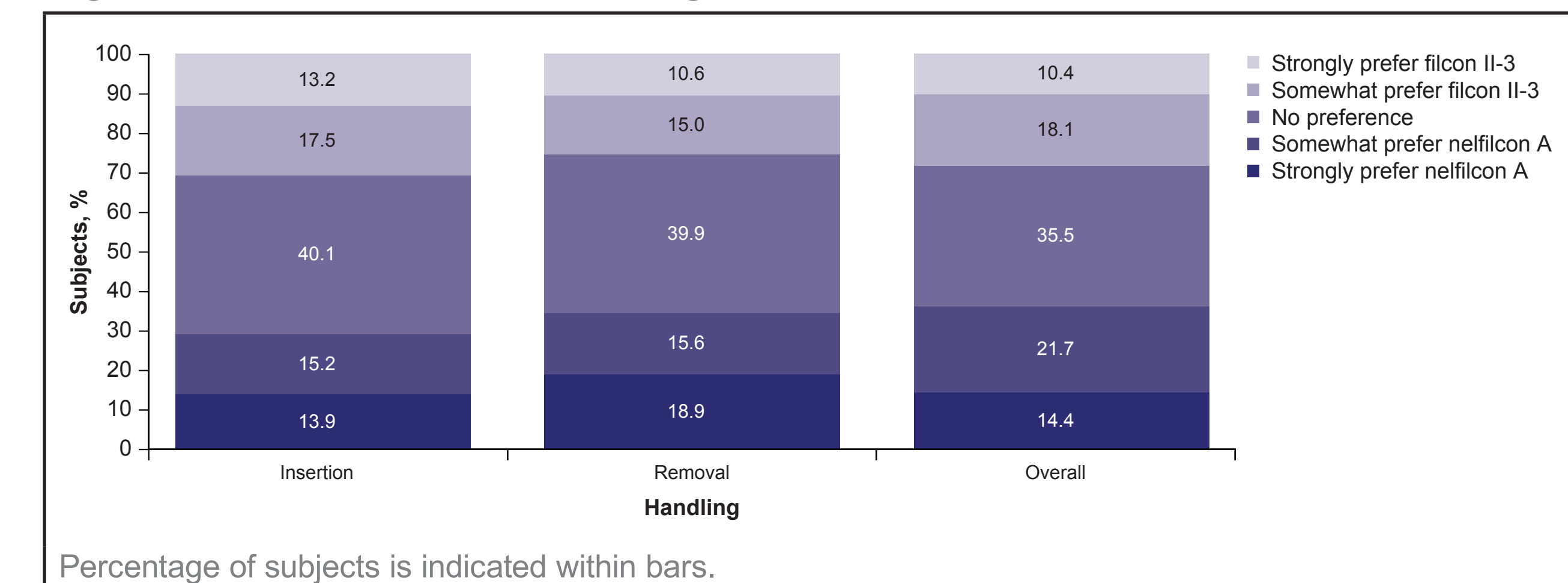
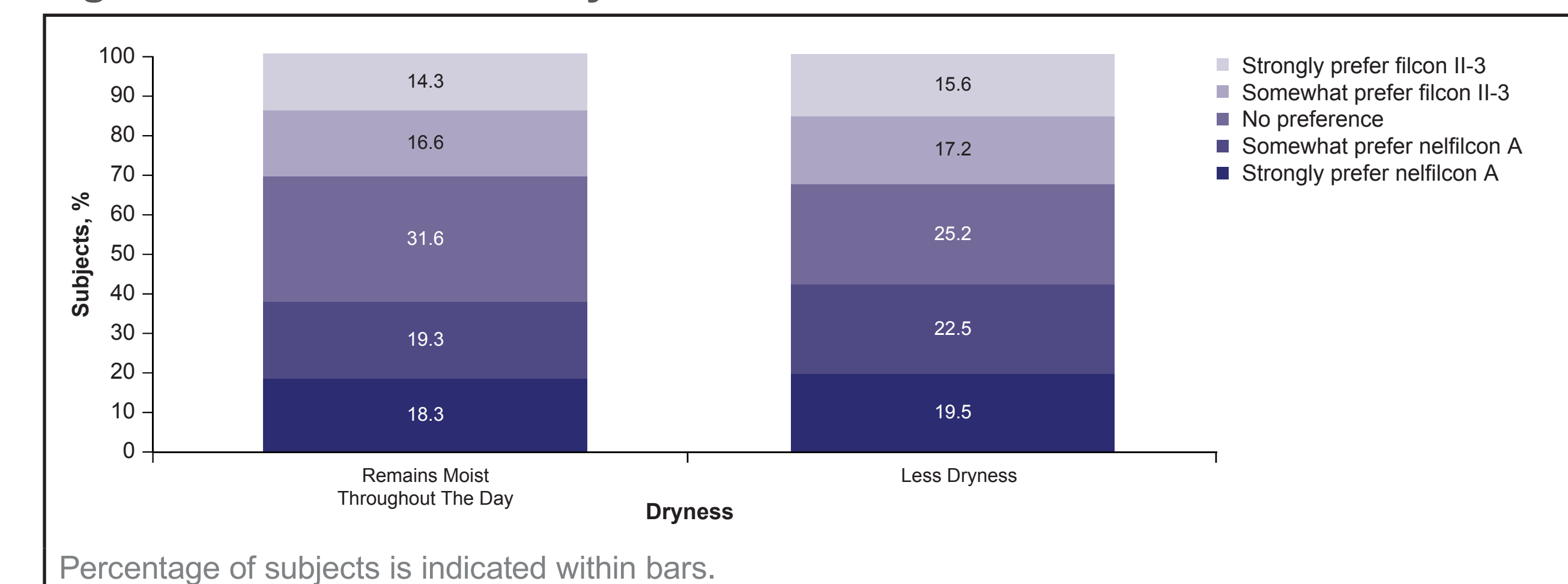


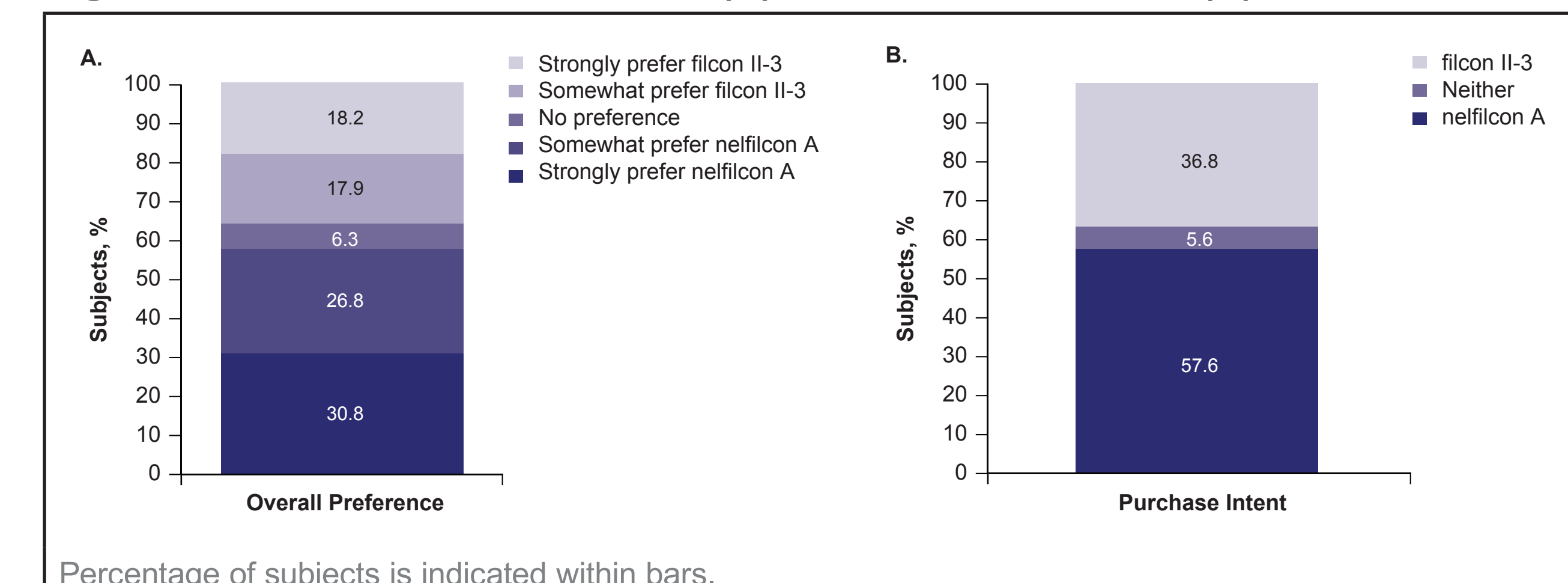
Figure 6. Preference For Dryness Variables



- ▶ Overall, significantly more subjects reported a preference for nelfilcon A lenses compared with filcon II-3 lenses (Figure 7A).

- Among the 93.7% of subjects who reported an overall lens preference, 61.5% preferred the nelfilcon A lenses over the filcon II-3 lenses (P<0.001).
- Of the 94.4% of subjects with a purchase intent, 57.6% and 36.8% reported a purchase intent for nelfilcon A and filcon II-3 lenses, respectively (P<0.001; Figure 7B).

Figure 7. Overall Lens Preference (A) and Purchase Intent (B)



## Conclusions

- ▶ Both DD lenses were well accepted. After 1 week of wear, nelfilcon A lenses showed superior daytime comfort, handling at removal, overall lens satisfaction, vision ratings, and less dryness throughout the day compared with the filcon II-3 lenses.
- ▶ The attributes of DAILIES® AquaComfort Plus® contact lenses with added wetting agents polyethylene glycol and hydroxypropyl methylcellulose and the slow release of polyvinyl alcohol (PVA) eluted from the lens help maintain lens wettability and support a stable tear film,<sup>1,2</sup> and are likely to have contributed to the excellent on-eye subjective ratings reported in this study.

## References

1. Winterton LC, et al. *J Biomed Mater Res B Appl Biomater.* 2007;80(2):424-432.
2. Wolffsohn JS, et al. *Cont Lens Anterior Eye.* 2010;33(2):88-92.

## Disclosures

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