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 (ficon 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

Eligible subjects were currently wearing any spherical DD lens except study lenses or private-labeled equivalent lenses and wore lenses ≥8 hours/day and were wearing hydrogel lenses in the majority of cases, with only 11% wearing silicone hydrogel lenses in the majority of cases, with only 11% wearing silicone hydrogel lenses in the majority of cases.

The study consisted of a baseline visit and 2 follow-up visits conducted 1 week after use of each lens.

Key exclusion criteria: eye injury or surgery ≤12 weeks before enrolment; 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.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Subjects (n=316)</th>
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<tbody>
<tr>
<td>Mean ± SD age, years</td>
<td>33.9±11.1</td>
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<tr>
<td>Sex, n (%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>197 (62.3)</td>
</tr>
<tr>
<td>Male</td>
<td>119 (37.7)</td>
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<tr>
<td>Habitual lens brand, n (%)</td>
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<tr>
<td>Alcon (Focus Dailies All Day Comfort, Sehenswert One Day, Focal Dailies Basic)</td>
<td>91 (28.8)</td>
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<tr>
<td>Johnson &amp; Johnson (1-Day Acuvue Moist, 1-Day Acuvue Truey, 1-Day Acuvue)</td>
<td>90 (28.5)</td>
</tr>
<tr>
<td>Cooper (Proclear 1 Day, Biomedics 1 Day)</td>
<td>81 (25.6)</td>
</tr>
<tr>
<td>Bausch &amp; Lomb (SoftLens Daily Disposable, Softens One Day, Intellers One Day, Optocon Daily)</td>
<td>52 (16.4)</td>
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<tr>
<td>Sauflon (Bioclear One Day)</td>
<td>2 (0.6)</td>
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Lens Wearing Time

Mean ± SD subject-reported wear time was similar for both study lenses (nelfilcon A, 12.7±2.4 hours; ficon II-3, 12.4±2.6 hours).

Subjective Lens Ratings

Subjective comfort ratings after 1 week of wear (Figure 1) were noninferior for nelfilcon A vs ficon 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).

Preference and Purchase Intent

Significantly more subjects preferred nelfilcon A lenses over ficon 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 ficon II-3 lenses (68.3% vs 31.7%, P<0.001).

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 ficon 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 1,2 and are likely to have contributed to the excellent on-eye subjective ratings reported in this study.

References


Disclosures

This study was sponsored by Alcon Research, Ltd. (Fort Worth, TX), Drs. Fahmy, Kern, and Maissa are Alcon employees. Medical writing assistance was provided by Heather D. Starkey, PhD, of Complete Healthcare Communications, Inc. (Chadds Ford, PA) and was funded by Alcon.