Comparison of Pre-Lens Tear Film Stability of Nelfincon A with Different Optical Designs Using Placido Ring Projection

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Introduction

Contact lens wear is known to be one of the causes of tear film (TF) instability, increased evaporation rate, and dry eye symptoms, leading to decreased ocular comfort towards the end of the day and reduced wearing time.

In cases in which the TF is unable to fully wet the contact lens surface, there is a decrease in TF optical quality, hence visual impairment, an increase in deposition, and reduced comfort.

Further, aging has been associated with significant changes in the tear lipid layer and a significantly higher TF evaporation specifically in patients older than 45 years. This reduction in TF stability and eye comfort is associated with higher incidence of tear-related problems in an aging population.

Although several techniques are available, there are no established methods for an objective assessment of the pre-lens TF stability.

Moreover, confocal topography has been used to assess the pre-lens noninvasive tear breakup time (NLTBUT), enabling the observation of a much larger zone, covering more than the optical zone of a contact lens.

Circular areas are projected onto the corneal surface, the reflection on the TF is observed, and the first TF (NLTBUT) is recorded at the first observation of an area division.

Although the time to first TF break is often used as the clinical marker of contact lenses on eye wearability, recent findings have shown that this measurement alone is insufficient to fully characterize on-eye contact lens wearability.

The Keratograph 5M (Oculus; OCULUS Optikwerk GmbH, Wetzlar, Germany) device can project placido ring images onto the lens surface and capture a video of the reflected image via snapshots taken every 5 seconds for 25 seconds (Figure 1). New-developed software shows simultaneous visualization of areas and times of destabilization after the blink.

The primary objective of this study was to evaluate the pre-lens TF characteristics of nelfincon A daily disposable contact lenses with different optical design compared with those with a spherical design over 12 hours of wear.

The secondary objective was to evaluate the day-to-day and inter-subject variability of TF characteristics assessed using the Oculus K5 imaging system.

Methods

Prospective randomized balanced crossover study in presbyopes and astigmatics aged ≥18 years adopted to soft contact lenses

Figure 2.

Presbyopes were assigned to multifocal plus (DACP) multifocal lenses, followed by DACP sphero lenses or vice versa.

Astigmatics were assigned to DACP toric lenses, followed by DACP spherophoric lenses or vice versa.

After a washout period, all subjects wore DACP sphero lenses for retaining.

Each lens was worn for 12 hours; during each period, videos of the ring system pigeons projected onto the ocular surfaces using the KS Oculus-fitting Live Mode and NKBUT Mode were recorded for 3 consecutive time points for 25 seconds post-blink.

Before contact lens insertion: pre-placement period (PPT).

5 min, 8 h, and 12 h after contact lens insertion: post-implant period (PIT).

Videos assessed subjectively using the TF-Scan software.

Surface wettability grading:

Grade 0 = full wettability

Grade 1 = mild distortion and fading

Grade 2 = clearly visible ring distortions ≤50% of the assessed area

Grade 3 = clearly visible ring distortions >50% of the assessed area

TF parameters analyzed on the KS Oculus-fitting video included:

- Time to first break (NKBUT) (first disturbance)
- Maximum % distortion over 25 seconds post-blink
- Area under the curve (AUC) (distortion over 25 seconds post-blink)
- The percent distortion at 5 and 10 seconds

Results

Table 1. Baseline demographic characteristics

<table>
<thead>
<tr>
<th>Age, yr</th>
<th>Presbyopes (N=22)</th>
<th>Astigmatics (N=21)</th>
<th>Overall (N=43)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>51.1 ± 13.1</td>
<td>52.8 ± 8.5</td>
<td>51.4 ± 13.9</td>
</tr>
<tr>
<td>Range</td>
<td>21 to 80</td>
<td>21 to 83</td>
<td>21 to 80</td>
</tr>
</tbody>
</table>

Habitual lens characteristics at baseline

- Fourteen presbyopes (83.3%) used reusable lenses and 8 (37.3%) used daily lenses.
- Lens material was silicone hydrogel in 14 (83.3%) and non-silicone hydrogel in 6 (37.3%).
- Twelve astigmatics (57.1%) used reusable lenses and 5 (23.8%) used daily lenses.
- Lens material was silicone hydrogel in 13 (91.9%) and non-silicone hydrogel in 2 (13.8%).

Table 2. Inter-subject variability for DACP sphero lenses

<table>
<thead>
<tr>
<th>Period</th>
<th>Presbyopes</th>
<th>Astigmatics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to first disturbance (sec)</td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>PPT</td>
<td>3.6 ± 0.7</td>
<td>4</td>
</tr>
<tr>
<td>PIT1</td>
<td>2.3 ± 0.6</td>
<td>3</td>
</tr>
<tr>
<td>PIT2</td>
<td>1.8 ± 0.6</td>
<td>2</td>
</tr>
<tr>
<td>PIT3</td>
<td>1.6 ± 0.5</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 3. Mean (±SD) differences for DACP sphero lenses between Period 3 and Periods 1 & 2 for time to first disturbance, AUC % distortion, and maximum % distortion

<table>
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<td>2</td>
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<td>PIT3</td>
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Conclusion

The surface wettability of DACP multifocal and toric daily disposable contact lenses was at least as good as that of the spherical design after 12 hours of lens wear.

Wettability was not affected by the optical design of the lens.

This method was successful in determining the intra- and inter-subject variability in TF characteristics measurements over 35 seconds post-blink.

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