A Surface Treatment Solution for Scleral Lens Wearers with Dry Eye

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ScleralFil™ was donated by Bausch + Lomb.

The scleral lenses were donated by the following lens manufacturers:

- Acculens
- Alden Optical
- Art Optical
- Blanchard Contact Lenses
- Metro Optics
- Valley Contax
- Visionary Optics
- Xcel Specialty Contacts
Background

- **Tangible Hydra-PEG™** is a novel coating technology designed to improve:
  - lens wettability
  - TBUT
  - deposit resistance
  - ultimately enhancing lens comfort

- Hydra-PEG can improve lens comfort and vision in CL wearers.¹⁻³

- Do these benefits extend to scleral lens (SL) wearers with **dry eye**?

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2. Sindt C. Evaluation polyethylene glycol surface coating on gas permeable lenses to improve wearability and wettability. ARVO 2016
Purpose

To compare lens comfort and dry eye (DE) symptoms of DE SL wearers fit with Tangible Hydra-PEG treated and untreated SL lenses.

DE signs, comfortable lens wearing time, vision quality, and lens related ocular surfaces changes were also assessed.
Methods
Participants

Subjects exhibiting contact lens discomfort (CLD) and DE symptoms were recruited for a **double-masked cross-over study**

<table>
<thead>
<tr>
<th><strong>Inclusion</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>≥18</td>
</tr>
<tr>
<td>DE &amp; CLD</td>
<td>Score &gt; 12 on the OSDI</td>
</tr>
<tr>
<td></td>
<td>Score &gt; 13 on the CLDEQ-8</td>
</tr>
<tr>
<td></td>
<td>Reduced TBUT &lt;10, a sign of DE and CLD</td>
</tr>
<tr>
<td>Habitual SL wear</td>
<td>Wear a SL for at least 8 hours a day, 5 days a week for at least 3 months prior to enrollment in the study</td>
</tr>
<tr>
<td>Scleral Lens</td>
<td>No older than 1 year</td>
</tr>
<tr>
<td></td>
<td>Diameters between 15.0 mm to 19.0 mm inclusive</td>
</tr>
<tr>
<td>VA</td>
<td>BCVA better than 20/30 in either eye</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Exclusion</strong></th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Corneal surgery within 3 months of the study</td>
</tr>
<tr>
<td></td>
<td>Ocular pathology other than dry eye that could have a significant impact on visual function</td>
</tr>
<tr>
<td></td>
<td>Anatomic variations of the conjunctiva other than pinguecula that can impair proper scleral lens fitting</td>
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</tbody>
</table>

Ocular Surface Disease Index (OSDI)  
Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)
Experimental Design

Subjects were randomized to wear either their habitual untreated SL or Hydra-PEG treated SL of the same parameters first for 30 days.

One week wash out periods of no SL wear were placed before and between the two 30-day test phases.

Subjects used ScleralFil™ (B+L) for lens application and Clear Care® (Alcon) for disinfection during the test phases.
Experimental Design

The study was double-masked.

Lens pairs were supplied in identical cases.

Lens cases differed only by code mark unknown to the testers and subjects.
Outcome Measures

- Lens comfort
- Dry eye symptoms
- A battery of ocular surface tests
- Comfortable Lens Wearing Time
- Foggy Vision

The above outcomes were measured at baseline, after the first test period, and after the cross-over. Lens comfort and DE symptoms were assessed with the CLDEQ-8 and the OSDI respectively.
Paired comparison t-tests were performed for data exhibiting a normal distribution. Non-normal distributions were compared using the Wilcoxon signed rank test.

SPSS software
Results
19 participants
16 women and 3 men
Mean age: 51.8 ± 8 years
Range: 25–73 years
Moderate to severe symptomatic DE at baseline
Symptom Comparisons Between Untreated and Treated SL Wear

### CLDEQ-8

- **Untreated**: 17.30
- **Treated**: 11.89

*One sided p value*

**Lens comfort**

*\( p < 0.01 \)*

Lower scores are better

Wilcoxon signed rank comparisons

### OSDI

- **Untreated**: 35.10
- **Treated**: 28.24

*One sided p value*

**DE symptoms**

*\( p < 0.01 \)*

Lower scores are better

Wilcoxon signed rank comparisons
TBUT Comparison Between Untreated and Treated SL wear

* $p < 0.01$

One sided p value

Higher scores are better, Paired-t test comparison
## Corneal Fluorescein Staining

<table>
<thead>
<tr>
<th></th>
<th>Untreated</th>
<th>Treated</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (IQR)</td>
<td>Mean (SD)</td>
<td>Median (IQR)</td>
</tr>
<tr>
<td></td>
<td>1.00 (1.00)</td>
<td>1.40 (1.05)</td>
<td>1.00 (1.50)</td>
</tr>
</tbody>
</table>

One sided p values
Lower scores are better, Wilcoxon signed rank comparisons

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## Ocular Surface Staining Comparisons Between Untreated and Treated SL wear
Conjunctival Lissamine Green Staining

<table>
<thead>
<tr>
<th></th>
<th>Untreated</th>
<th>Treated</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temporal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Untreated Median (IQR) Mean (SD)</td>
<td>1.00 (1.00)</td>
<td>1.00 (1.00)</td>
<td>1.23 (1.03)</td>
</tr>
<tr>
<td>Treated Median (IQR) Mean (SD)</td>
<td>1.00 (1.00)</td>
<td>1.00 (1.00)</td>
<td>0.95 (0.79)</td>
</tr>
<tr>
<td><strong>Nasal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Untreated Median (IQR) Mean (SD)</td>
<td>1.00 (1.00)</td>
<td>1.00 (1.00)</td>
<td>1.03 (0.98)</td>
</tr>
<tr>
<td>Treated Median (IQR) Mean (SD)</td>
<td>1.00 (1.00)</td>
<td>1.00 (1.00)</td>
<td>0.79 (0.71)</td>
</tr>
</tbody>
</table>

One sided p values
Lower scores are better, Wilcoxon signed rank comparisons

Ocular Surface Staining Comparisons Between Untreated and Treated SL wear
### Lens related Ocular Surface Changes Between Untreated and Treated SL Wear

<table>
<thead>
<tr>
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<th>Untreated Median (IQR) Mean (SD)</th>
<th>Treated Median (IQR) Mean (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lid Wiper Epitheliopathy</strong></td>
<td>1.50 (0.81) 1.41 (0.62)</td>
<td>1.00 (1.00) 0.89 (0.76)</td>
<td>p&lt;0.01*</td>
</tr>
<tr>
<td><strong>Conjunctival Papillae</strong></td>
<td>1.00 (1.00) 1.45 (0.51)</td>
<td>1.00 (0.50) 0.89 (0.66)</td>
<td>p&lt;0.01*</td>
</tr>
</tbody>
</table>

One sided p values
Lower scores are better, Wilcoxon signed ranked comparisons
Comfortable Lens Wearing Time

How many hours could you COMFORTABLY wear the scleral lenses?

0 > Twelve hours
1 Eight to Twelve hours
2 Four to Seven hours
3 One to Three hours
4 < One hour

<table>
<thead>
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<th>Untreated Mean (SD)</th>
<th>Treated Mean (SD)</th>
<th>*p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.63 (0.90)</td>
<td>0.68 (0.58)</td>
<td>0.002*</td>
</tr>
</tbody>
</table>

Lower scores reflect longer wear times
Paired t-test of lens wearing time scores
* One sided p value *<0.005
Frequency of Foggy Vision

Do you experience foggy vision with the lenses?

0 No
1 Once a day
2 Two times a day
3 Three times a day
4 > Three times a day

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<th>Untreated Mean (SD)</th>
<th>Treated Mean (SD)</th>
<th>(^*p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.06 (1.43)</td>
<td>1.17 (1.15)</td>
<td>0.002*</td>
</tr>
</tbody>
</table>

Lower scores reflect less frequent foggy vision
Paired t-test comparison of frequency of foggy vision scores
\(^*\)One sided \(p\) value \(^*\)\(p<0.005\)
Conclusions

Treated scleral lenses provided superior comfort and improved DE symptoms compared to the untreated lenses.

Lens-related ocular surface changes and frequency of foggy vision were reduced with treated lens wear.

Tangible Hydra-PEG is an effective technology which may improve outcomes for DE scleral lens wearers.
Acknowledgements

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References

