

A Surface Treatment Solution for Scleral Lens Wearers with Dry Eye

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Acculens

Alden Optical

Art Optical

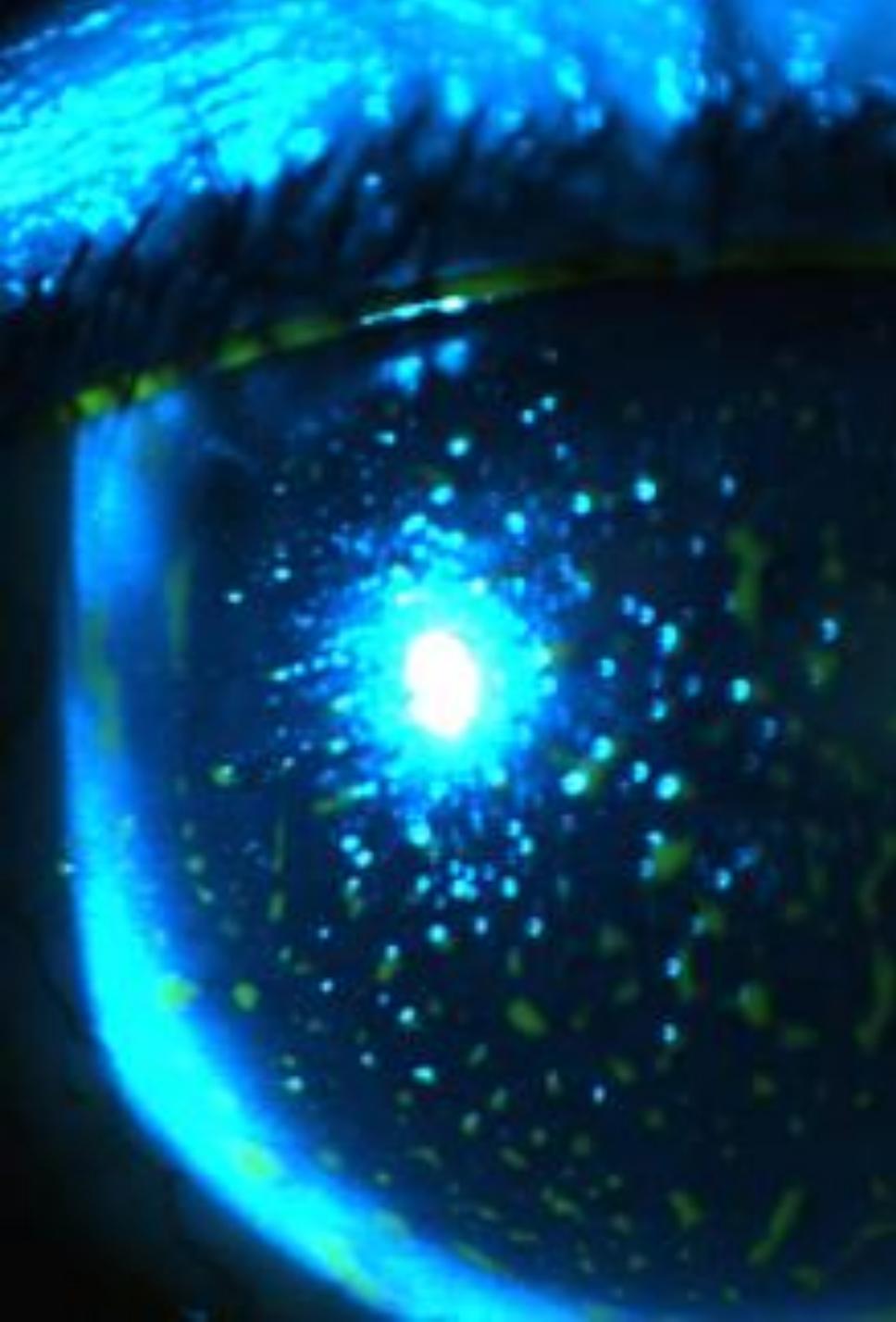
Blanchard Contact Lenses

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?**

1. Caroline, P. et al. Hydra-PEG: A solution to contact lens discomfort? Global Specialty Lens Symposium 2015

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

3. Walker M, Redfern R. Scleral Lens surface coating improves vision and comfort. 8th Annual International Conference of TFOS 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**

Inclusion

Age ≥ 18

DE & CLD
Score > 12 on the OSDI
Score > 13 on the CLDEQ-8
Reduced TBUT <10, a sign of DE and CLD

Habitual SL wear
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

Scleral Lens
No older than 1 year
Diameters between 15.0 mm to 19.0 mm inclusive

VA
BCVA better than 20/30 in either eye

Exclusion

Corneal surgery within 3 months of the study
Ocular pathology other than dry eye that could have a significant impact on visual function
Anatomic variations of the conjunctiva other than pinguecula that can impair proper scleral lens fitting

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

Statistical Analysis

Results

Sample Characteristics

19 participants

16 women and 3 men

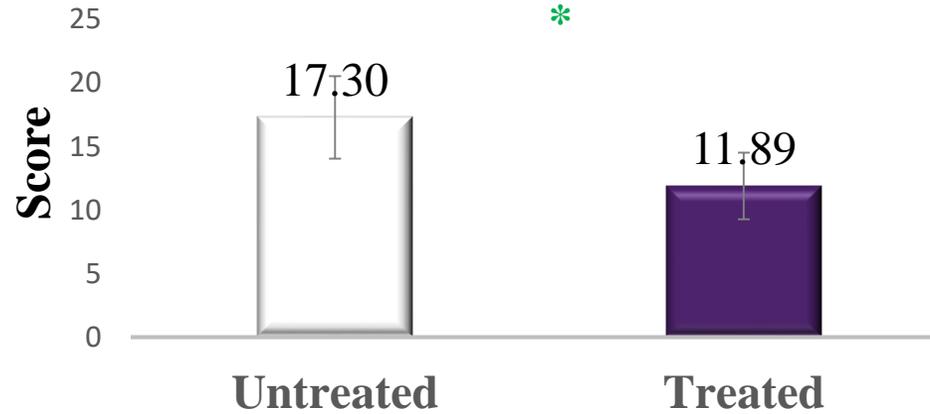
Mean age: 51.8 ± 8 years

Range: 25-73 years

Moderate to severe symptomatic DE at baseline

Symptom Comparisons Between Untreated and Treated SL Wear

CLDEQ-8

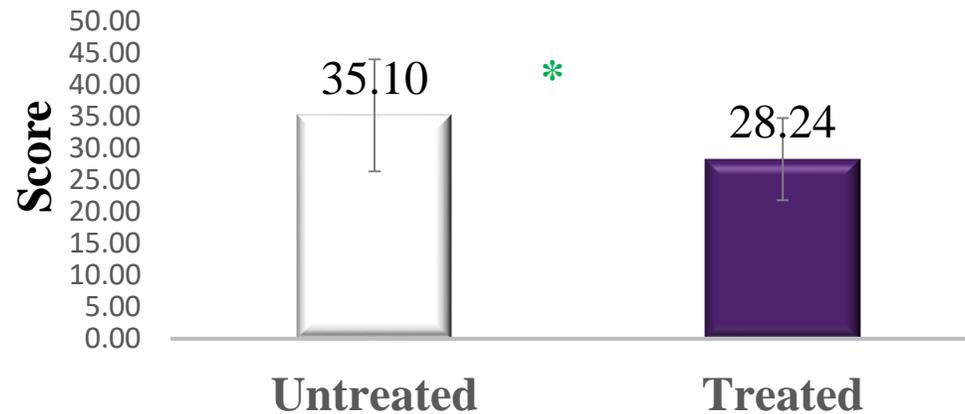


Lens comfort

***p<0.01**

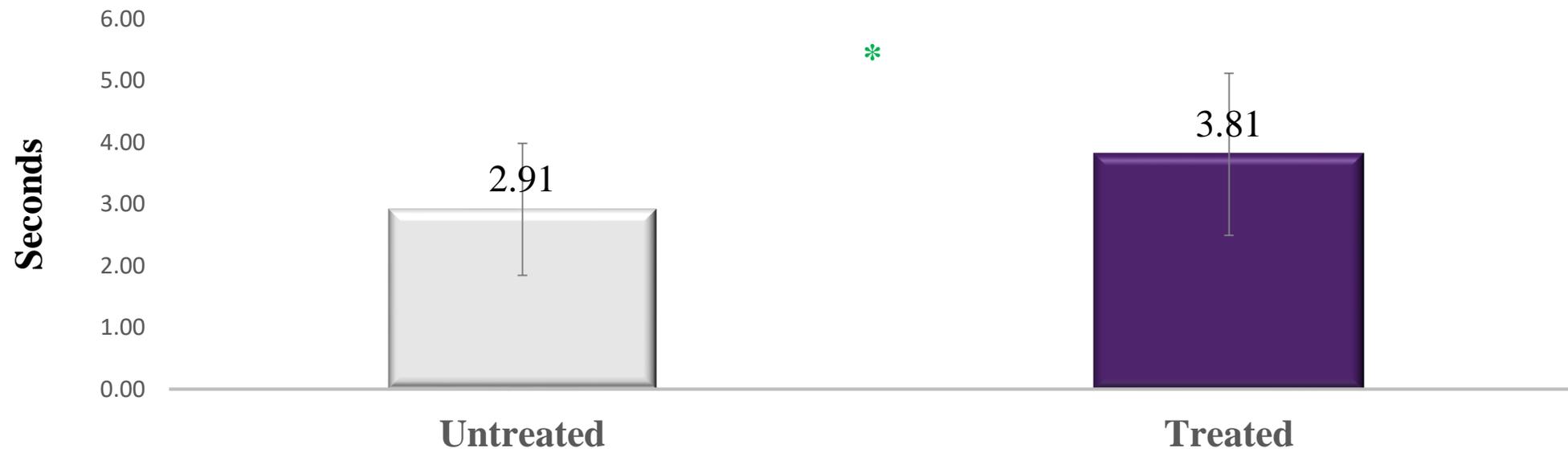
One sided p value
Lower scores are better
Wilcoxon signed rank comparisons

OSDI



DE symptoms

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

Untreated		Treated		p value
Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	
1.00 (1.00)	1.40 (1.05)	1.00 (1.50)	0.92 (0.79)	p<0.05*

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

**Ocular Surface Staining Comparisons Between
Untreated and Treated SL wear**

Conjunctival Lissamine Green Staining

Temporal

Untreated		Treated		p value
Median (IQR)	Mean(SD)	Median (IQR)	Mean (SD)	
1.00 (1.00)	1.23 (1.03)	1.00 (1.00)	0.95 (0.79)	p<0.05*

Nasal

Untreated		Treated		p value
Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	
1.00 (1.13)	1.03 (0.98)	1.00 (0.50)	0.79 (0.71)	p>0.05

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

**Ocular Surface Staining Comparisons Between
Untreated and Treated SL wear**

Lid Wiper Epitheliopathy

Conjunctival Papillae

Untreated		Treated		p value	Untreated		Treated		p value
Median (IQR)	Mean (SD)	Median(IQR)	Mean(SD)		Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	
1.50 (0.81)	1.41 (0.62)	1.00 (1.00)	0.89 (0.76)	p<0.01*	1.00 (1.00)	1.45 (0.51)	1.00 (0.50)	0.89 (0.66)	p<0.01*

One sided p values

Lower scores are better, Wilcoxon signed ranked comparisons

Lens related Ocular Surface Changes Between Untreated and Treated SL Wear

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

Untreated Mean (SD)	Treated Mean (SD)	^a p value
1.63(0.90)	0.68 (0.58)	0.002*

Lower scores reflect longer wear times
Paired t-test of lens wearing time scores
^a One sided p value *p<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

Untreated Mean (SD)	Treated Mean (SD)	^a p value
2.06 (1.43)	1.17 (1.15)	0.002*

Lower scores reflect less frequent foggy vision
Paired t-test comparison of frequency of foggy vision scores
^a 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.

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References

1. Caroline, P. et al. Hydra-PEG: A solution to contact lens discomfort? Poster presented at the Global Specialty Lens Symposium 2015.
2. Sindt C. Evaluation polyethylene glycol surface coating on gas permeable lenses to improve wearability and wettability. Poster presented at Annual Meeting of the Association for Research in Vision and Ophthalmology 2016.
3. Walker M, Redfern R. Scleral Lens surface coating improves vision and comfort. Poster presented at the 8th Annual International Conference of the Tear Film and Ocular Surface Society 2016.