Treatment of Contact Lens Symptoms With Punctal Occlusion Treatment

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There have been many complaints of ocular discomfort among SCL wearers with all types of SCLs. Chief among the complaints has been dry eye. Several manufacturers have responded with products designed to improve SCL comfort. Punctal plugs have recently seen renewed interest in the management of dry eye. This trial used the CLDEQ 8 and the InflammaDry test to evaluate the response of adapted SCL wearers to punctal occlusion treatment (POT). The CLDEQ 8 and InflammaDry have been reported in several peer-reviewed journals as specific and sensitive instruments for dry eye diagnosis. [1,2,3,4,5,6.]

Objective

The primary objective of this trial was to determine if a statistically significant change could be measured using (1) the CLDEQ 8 and (2) the InflammaDry test among adapted SCL wearers who have mild or moderate symptoms when wearing SCLs after treatment with POT.

Methods

This was a prospective, open-label, single group trial. Subjects were not masked to Sponsor or treatment. Ten (10) subjects were enrolled and completed the trial.

Potential patients were consented and screened with the CLDEQ-8 and InflammaDry test. Those with mild or moderate symptoms and negative ID tests who met the inclusion/exclusion criteria received POT in both eyes and returned after 21 ± 2 days to complete the CLDEQ-8 and InflammaDry test and exit the trial.

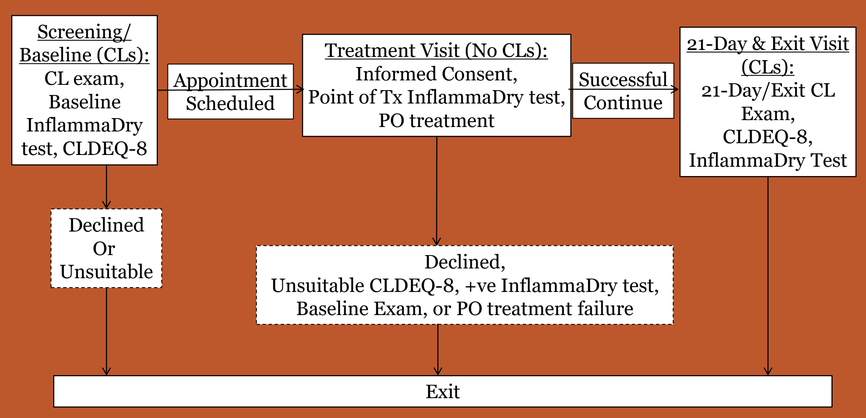
Inclusion Criteria

- Must be aged 18 years or more.
- At least 6 months' experience wearing their current brand of SCLs in both eyes at least 5 days/week for at least 8 hours/day.
- Mild to moderate symptoms when wearing SCLs.
- Negative InflammaDry test at point of treatment.
- Agreement to the trial protocol.
- Agreement to the trial visit schedule.

Exclusion Criteria

- Ocular surgery or disease that contraindicates using the BVI PPO.
- Potential subjects who do not wear their habitual SCLs in both eyes at least 5 days/week for at least 8 hours/day.
- Potential Subjects who require or will accept treatment in only 1 eye.
- Point of treatment positive InflammaDry test.

Flow Chart



RPS InflammaDry Test

BVI Parasol Punctal Occluder

Results

Subject Profile

	n (%)
female	7 (70%)
male	3 (30%)
Grand Total	10 (100%)

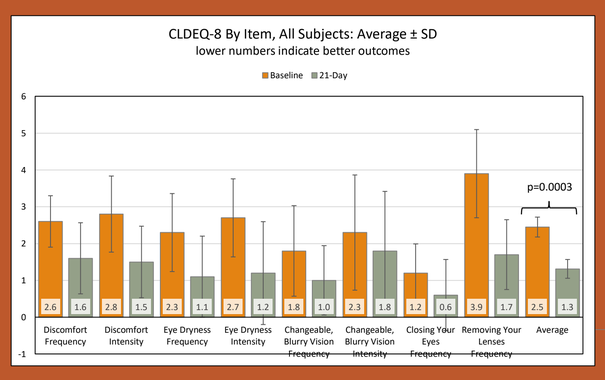
	Average ± SD (min-max), n
Age	47.9 ± 11.9 (30 - 68), n = 10
Habitual Brand Experience (months)	18.5 ± 19.3 (3 - 60), n = 10
Days/week worn	5.8 ± 0.8 (5 - 7), n = 10
Hours/day worn	9.8 ± 1.4 (8 - 12), n = 10

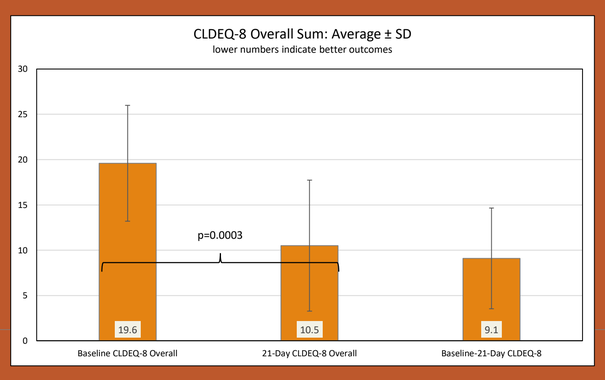
CLDEQ-8

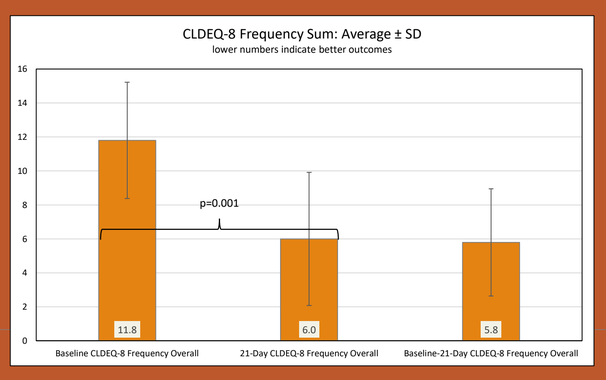
The frequency and intensity for every CLDEQ-8 symptom showed statistically significant improvement from the baseline by item overall average of 2.5±0.3 to 1.3±0.3 at 21 days (p=0.0003, paired t-test, 1-sided).

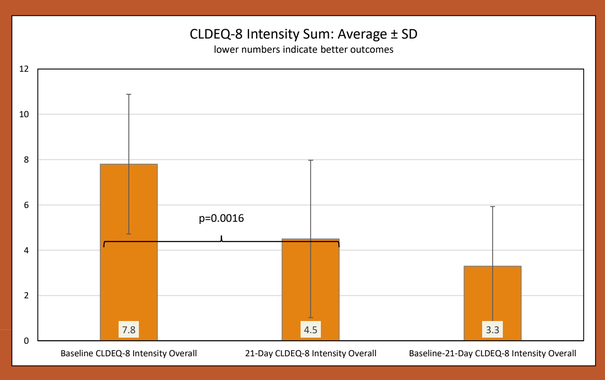
The average sum of CLDEQ-8 scores showed statistically significant improvement from 19.6±6.4 at baseline to 10.5±7.2 at 21 days (p=0.0003, paired t-test, 1-sided).

The average sum for CLDEQ-8 symptom frequency showed statistically significant improvement from 11.8±3.4 to 6.0±3.9 days (p=0.0001, paired t-test, 1-sided) and for intensity from 7.8 ± 3.1 to 4.5 ± 3.5 days (p=0.0016, paired t-test, 1-sided).









InflammaDry Test

	InflammaDry Test Results			
Count	Subject	Baseline	21-Day	Baseline to 21 Result
1	001	positive	positive	no change
2	002	positive	negative	+ to -
3	003	positive	positive	no change
4	004	positive	negative	+ to -
5	005	negative	negative	no change
6	006	positive	positive	no change
7	007	positive	negative	+ to -
8	008	positive	negative	+ to -
9	009	negative	negative	no change
10	010	positive	negative	+ to -
positive		8	3	p=0.6547
negative		2	7	

The ID test showed no statistically significant difference between baseline and 21 days with 5 subjects who had positive ID tests turning negative, 3 who were positive remained positive, and 2 who were negative remained negative at (p=0.0522, McNemar test).

Additional Analyses

Schirmer Test: The Schirmer Test improved an average of 5.4 ± 5.4 (5 to 13) millimeters (mm) in the right (OD) eye and 4.6 ± 7.6 (10 to 19) mm in the left (OS) eye from before treatment after 21 days of PO threatment.

Drops Use: Drops use/day improved from an average of 2.1 ± 1.7 (0 to 5) times/day at screening to 0.6 ± 0.7 (0 to 2) times/day after 21-days of PO treatment.

Subjective Vision Scores: Subjective distance vision average score was 0.5 ± 1.1 (-1 to 3) points better (0 to 10 scale) after 21 days of PO treatment. Subject near vision average score very slightly improved by 0.1 ± 0.6 (-1 to 1).

logMAR VA: Distance logMAR was unchanged after 21 days of PO treatment. However NV logMar mirrored the subjective near vision score being slightly improved OD, OS and OU.

Schirmer Test	Average ± SD (min - max, n
21-Day Schirmer Test Before Removing PPO OD	23.8 ± 6.2 (15 - 30 n = 10
Screening Schirmer Test OD	18.4 ± 7.3 (10 - 35 n = 10
21-Day-Screening OD	5.4 ± 5.4 (-5 - 13 n = 10
21-Day Schirmer Test Before Removing PPO OS	23.2 ± 6.3 (12 - 33 n = 10
Screening Schirmer Test OS	18.6 ± 8.4 (7 - 35 n = 10
21-Day-Screening OS	4.6 ± 7.6 (-10 - 19 n = 10

Drops Use/Day	Average ± SD (min – max), n
Screening Drops Use/Day	2.1 ± 1.7 (0 - 5) n = 10
21-Day Drops Use/Day	0.6 ± 0.7 (0 - 2) n = 10
Screening-21-Day Drops Use/Day	1.5 ± 1.6 (0 - 5) n = 10

Subjective Vision Grades	Average ± SD (min - max, n
21-Day Subjective Distance Vision Grade for Habitual SCLs	8.3 ± 1.4 (6 - 10) n = 10
Screening Subjective Distance Vision Grade for Habitual SCLs	7.8 ± 1.3 (5 - 10) n = 10
21-Day-Screening Subjective Distance Vision Grade for Habitual SCLs	0.5 ± 1.1 (-1 - 3) n = 10
21-Day Subjective Near Vision Grade for Habitual SCLs	7.2 ± 2.8 (2 - 10) n = 10
Screening Subjective Near Vision Grade for Habitual SCLs	7.1 ± 2.9 (2 - 10) n = 10
21-Day-Screening Subjective Near Vision Grade for Habitual SCLs	0.1 ± 0.6 (-1 - 1) n = 10

logMAR VA (Transformed)	Screening w/SCLs	Exit
Distance logMAR VA OD	0.06 ± 0.11 (-0.06 - 0.20) n = 10	-0.01 ± 0.07 (-0.18 - 0.06) n = 10
Distance logMAR VA OS	0.01 ± 0.07 (-0.10 - 0.10) n = 10	0.01 ± 0.06 (-0.06 - 0.10) n = 10
Distance logMAR VA OU	-0.04 ± 0.06 (-0.10 - 0.04) n = 10	-0.04 ± 0.06 (-0.10 - 0.04) n = 10
Near logMAR VA OD	0.41 ± 0.16 (0.20 - 0.70) n = 10	0.38 ± 0.16 (0.20 - 0.70) n = 10
Near logMAR VA OS	0.43 ± 0.17 (0.20 - 0.70) n = 10	0.37 ± 0.17 (0.20 - 0.70) n = 10
Near logMAR VA OU	0.38 ± 0.16 (0.20 - 0.60) n = 10	0.31 ± 0.16 (0.10 - 0.60) n = 10

Conclusion

These results indicate that POT can produce statistically significant improvements in the frequency, severity, and overall sum of subjective symptoms associated with dryness among SCL wearers while the categorical ID test showed improvement although no statistically significant change was found. These results indicate that POT is a promising treatment for SCL wearers who have dryness complaints. It is interesting to speculate that if the ID test could distinguish grades of inflammation then a movement from more positive to less positive may have been detected,

Declarations

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