The Eye Doctor Premium® Heated Eye Compress (PHEC) Plus The Eye Doctor Tea Tree Oil Wipes (TTOW) Trial

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Later day contact lens discomfort is a frequent complaint amongst contact lens wearers. Historically treatments have been approached from the direction of lens design changes, often frequently and almost as often with little or no success. This trial used the CLDEQ-8 to query the frequency and intensity of 5 symptoms associated with contact lens discomfort, subjective scores, and clinical measures to assess the response to the planned treatments.

Objective

The primary objective of this trial was to determine if statistically significant differences (SSDs) could be measured using (1) the 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8), (2) the subjective vision score, (3) the subjective comfort score, (4) the pre-lens non-invasive tear breakup time (PLNITBUT), and (5) the meiboscore among subjects who had mild or moderate late day contact lens discomfort when treated with a warm heat application (The Eye Doctor Premium® Heated Eye Compress) plus Tea Tree Oil Wipes (The Eye Doctor Tea Tree Lid Wipes) regimen.

Methods

This was a prospective, open-label, single group trial. Subjects were not masked to Sponsor or treatment. Eleven (11) subjects were enrolled. One (1) subject withdrew, and 10 subjects completed the trial.
Potential patients were consented and screened with the CLDEQ-8 and a clinical exam. Those who met the inclusion/exclusion criteria were enrolled, treated, and scheduled for follow-up and exited after 21 ± 2 days.

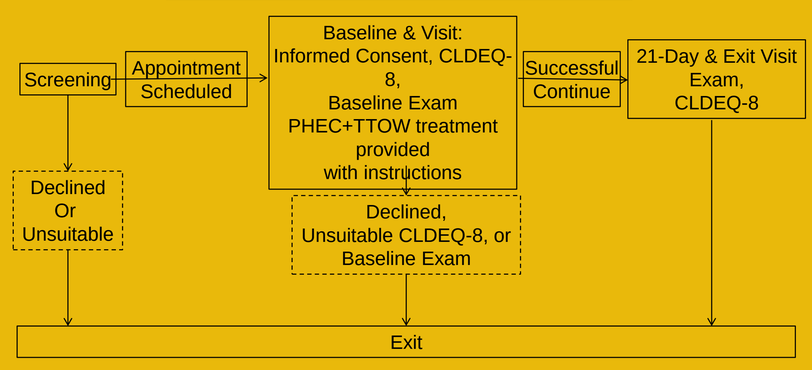
Inclusion Criteria

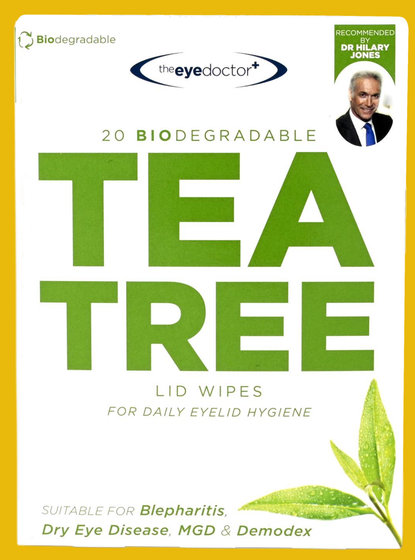
- CLDEQ-8 score indicating mild to moderate later day contact lens discomfort.
- Complaint of or documented contact lens discomfort for at least 3 months.
- Agreement to the trial protocol.
- Agreement to the trial visit schedule..

Exclusion Criteria

- Ocular surgery within 6 months or enrollment that contraindicates PHEC+TTOW treatment.
- Existing heat application and/or lid cleaning
- A clinical need for a lens design or Rx change.

Flow Chart





Results

Subject Profile

Completing Subjects: Sex & Age	Sex	%	Age
female	8	80%	62.9 ± 7.1 (52 - 71)
male	2	20%	69.3 ± 1.9 (68 - 71)
total	10	100%	64.2 ± 6.9 (52 - 71)

Completing Subject: CL Wear	Baseline	21-Day	21-Day-Baseline
days/week	6.6 ± 0.7 (5 - 7), n=10	6.7 ± 0.7 (5 - 7), n=10	0.1 ± 0.3 (0 - 1), n=10
hours/day	10.6 ± 3.0 (6 - 14), n=10	11.1 ± 2.3 (8 - 15), n=10	0.5 ± 2.5 (-2 - 6), n=10
Eyes wearing	both, 9; only 1 eye, 1	both, 9; only 1 eye, 1	

CLDEQ-8

Statistically significant differences indicating improvements in total frequency and total intensity of symptoms for completing subjects were found between Baseline and 21-Day.

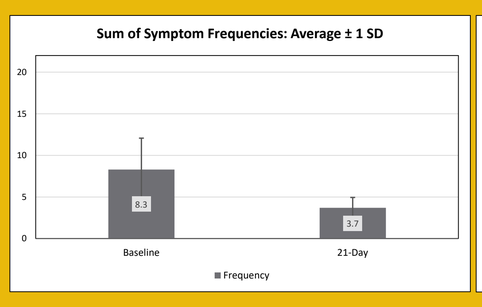
Statistically significant differences for completing subjects were found between Baseline and 21-Day for frequency of eye discomfort, eye dryness, changeable/blurry vision, and closing eyes during the day and for intensity of eye discomfort and eye dryness.

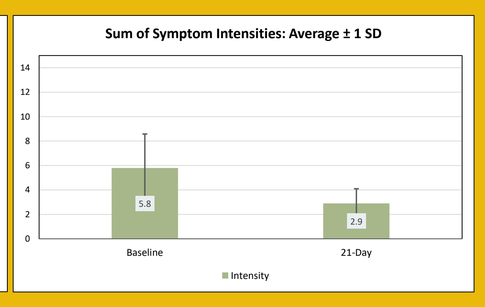
Frequency and intensity of all symptoms were improved with frequency and intensity of eye dryness at or above the level that indicates clinical significance.[1, 2]

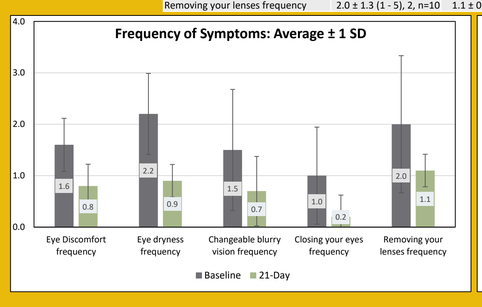
CLDEQ-8 Symptom Sums: Completing Subjects	Average ± SD (min - max), median, n			
	Baseline	21-Day	21-Day-Baseline	Wilcoxon P
Frequency	8.3 ± 3.8 (3 - 15), 9, n=10	3.7 ± 1.3 (2 - 6), 3, n=10	-4.6 ± 3.0 (-10 - 0), -5, n=10	0.0068
Intensity	5.8 ± 2.8 (2 - 12), 6, n=10	2.9 ± 1.2 (1 - 5), 3, n=10	-2.9 ± 2.4 (-8 - 0), -3, n=10	0.0067

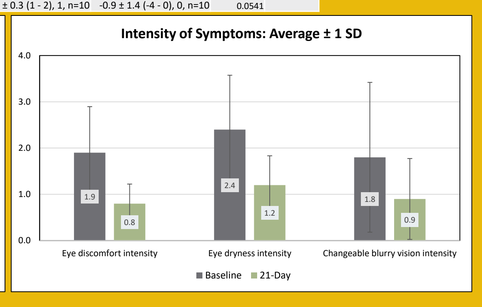
*Values less than or equal to 0.05 indicate statistically significant difference.

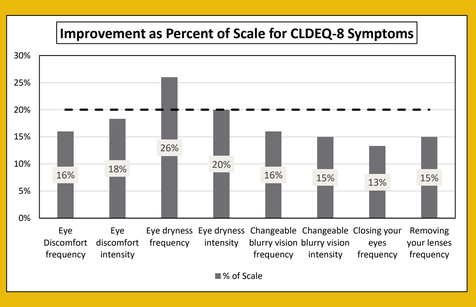
Subjective Scoring: Completing Subjects	Average ± SD (min - max), median, n				
	Baseline	21-Day	Differences	Wilcoxon P	Count SSD
Eye Discomfort frequency	1.6 ± 0.5 (1 - 2), 2, n=10	0.8 ± 0.4 (0 - 1), 1, n=10	-0.8 ± 0.6 (-2 - 0), -1, n=10	0.0107	6 of 8
Eye discomfort intensity	1.9 ± 1.0 (1 - 4), 2, n=10	0.8 ± 0.4 (0 - 1), 1, n=10	-1.1 ± 1.0 (-3 - 0), -1, n=10	0.0120	
Eye dryness frequency	2.2 ± 0.8 (1 - 3), 2, n=10	0.9 ± 0.3 (0 - 1), 1, n=10	-1.3 ± 0.7 (-2 - 0), -1, n=10	0.0058	
Eye dryness intensity	2.4 ± 1.2 (1 - 5), 2, n=10	1.2 ± 0.6 (0 - 2), 1, n=10	-1.2 ± 1.3 (-4 - 0), -1, n=10	0.0191	
Changeable blurry vision frequency	1.5 ± 1.2 (0 - 3), 2, n=10	0.7 ± 0.7 (0 - 2), 1, n=10	-0.8 ± 0.8 (-2 - 0), -1, n=10	0.0186	
Changeable blurry vision intensity	1.8 ± 1.6 (0 - 4), 2, n=10	0.9 ± 0.9 (0 - 2), 1, n=10	-0.9 ± 1.4 (-4 - 0), 0, n=10	0.0541	
Closing your eyes frequency	1.0 ± 0.9 (0 - 2), 1, n=10	0.2 ± 0.4 (0 - 1), 0, n=10	-0.8 ± 0.8 (-2 - 0), -1, n=10	0.0186	
Removing your lenses frequency	2.0 ± 1.3 (1 - 5), 2, n=10	1.1 ± 0.3 (1 - 2), 1, n=10	-0.9 ± 1.4 (-4 - 0), 0, n=10	0.0541	







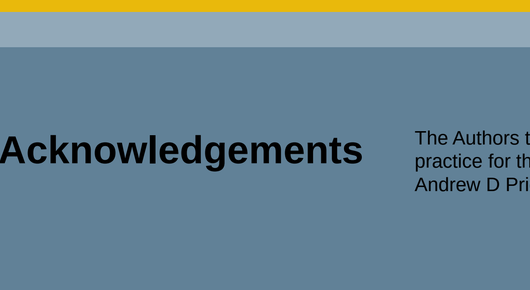




Subjective Vision & Comfort

Subjective Scoring: Completing Subjects	Average ± SD (min - max), median, n			
	Baseline	21-Day	Differences	Wilcoxon P
Subjective Distance Vision	7.8 ± 0.9 (6 - 9), 8, n=10	8.4 ± 1.0 (7 - 10), 9, n=10	0.6 ± 0.8 (-1 - 2), 1, n=10	0.0627
Subjective Near Vision	5.8 ± 1.6 (3 - 8), 6, n=10	7.2 ± 1.7 (3 - 9), 7, n=10	1.4 ± 1.6 (0 - 5), 1, n=10	0.0121
Subjective Overall Lens Comfort	7.6 ± 0.8 (6 - 9), 8, n=10	8.5 ± 1.1 (6 - 10), 9, n=10	0.9 ± 1.1 (-2 - 2), 1, n=10	0.0560

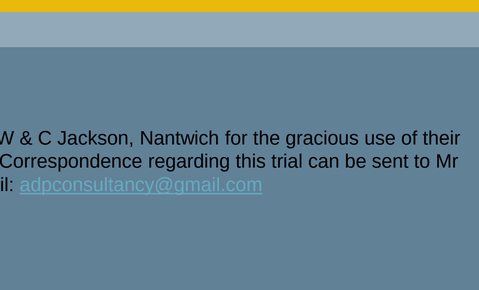
*Values less than or equal to 0.05 indicate statistically significant difference.



Meiboscore

Meiboscore: Completing Subjects	Average ± SD (min - max), median, n	
	OD	OS
Baseline	57.5% ± 25.9% (12% - 88%), 62.5%, n=10	50.0% ± 23.7% (12% - 88%), 50.0%, n=10
21-Day	56.2% ± 24.6% (12% - 88%), 62.5%, n=10	48.7% ± 24.0% (12% - 88%), 43.8%, n=10
Wilcoxon P	0.3681	0.3681

*Values less than or equal to 0.05 indicate statistically significant difference.



Snellen Visual Acuity Transformed to Visual Analog Scale (VAS)

No statistically significant differences were found between Baseline and 21-Day for distance or near visual acuity with either habitual correction or best corrected power.

Biomicroscopy

Biomicroscopy signs for completing subjects showed slight improvement from Baseline to 21-Days. Inferential statistical comparisons were not made for biomicroscopy signs.

Slit Lamp: Completing Subjects	Average ± SD (min - max), median, n			
	Baseline		21-Day	
	OD	OS	OD	OS
Conjunctival hyperaemia	0.3 ± 0.5 (0 - 1), 0.0, n=10	0.2 ± 0.4 (0 - 1), 0.0, n=10	0.0 ± 0.0 (0 - 0), 0.0, n=10	0.0 ± 0.0 (0 - 0), 0.0, n=10
Limbal hyperaemia	0.3 ± 0.5 (0 - 1), 0.0, n=10	0.5 ± 0.7 (0 - 2), 0.0, n=10	0.1 ± 0.3 (0 - 1), 0.0, n=10	0.0 ± 0.0 (0 - 0), 0.0, n=10
Corneal NaFl staining	0.1 ± 0.3 (0 - 1), 0.0, n=10	0.0 ± 0.0 (0 - 0), 0.0, n=10	0.1 ± 0.3 (0 - 1), 0.0, n=10	0.0 ± 0.0 (0 - 0), 0.0, n=10

Pre-Lens Non-Invasive Tear Break-Up Time (PLNITBUT)

No statistically significant differences were found for either the 1st or average PLNITBUT

1st PLNITBUT by Visit	Average ± SD (min - max), median, n	
	OD	OS
Baseline	6.7 ± 3.9 (2 - 16), 6.1, n=10	7.9 ± 5.8 (2 - 17), 6.3, n=10
21-Day	7.2 ± 4.6 (2 - 17), 6.4, n=10	6.6 ± 4.2 (3 - 17), 5.5, n=10
21-Day - BL	0.6 ± 4.8 (-7 - 9), 1.3, n=10	-1.2 ± 5.0 (-10 - 7), 0.1, n=10
Wilcoxon P	0.7211	0.8783

*Values less than or equal to 0.05 indicate statistically significant difference.

Average PLNITBUT by Visit	Average ± SD (min - max), median, n	
	OD	OS
Baseline	10.0 ± 2.4 (8 - 16), 9.5, n=10	10.7 ± 4.4 (2 - 17), 10.4, n=10
21-Day	10.1 ± 4.0 (4 - 17), 10.6, n=10	11.3 ± 3.5 (6 - 17), 11.5, n=10
21-Day - BL	0.1 ± 4.1 (-5 - 9), -0.1, n=10	0.7 ± 4.9 (-5 - 13), 0.5, n=10
Wilcoxon P	0.7211	0.9593

*Values less than or equal to 0.05 indicate statistically significant difference.

Likeliness to Recommend & Net Promoter

Likeliness to recommend the treatment among completing subjects averaged greater than 8 with 75% being promoters. These indicate that the treatment is likely to be well-recommended by 50% of those who receive it.[3]

Likeliness to Recommend: Completing Subjects	Average ± SD (min - max), median, n
	21-Day
Likeliness to Recommend	8.4 ± 1.8 (5 - 10), 9, n=10

Net Promoter: Completing Subjects	Count	%
Promoters: ≥9	6	75%
Detractors: ≤6	2	25%
Net Promoter	6	50%

Subject Comments

Comments from 7 subjects who completed the trial were reported.

Subject comments
1. contact lenses feel better 2. likes even better 3. eyes whiter.
very relaxing
Better than normal
Had to heat mask longer. Had initial blurriness. Like Tea Tree Wipes. Good to feel oils in eyes.
treatment soothing, wipes lovely
More moisture in eyes. Not as gritty.
Relaxing. Soothing

Conclusion

These results indicate that treatment with The Eye Doctor Premium® Heated Eye Compress Plus The Eye Doctor Tea Tree Oil Wipes produces statistically significant improvements in many contact lens symptoms among soft contact lens wearers that may not be reflected in a categorical clinical test and that the treatment may be enthusiastically recommended by patients. These results indicate that The Eye Doctor Premium® Heated Eye Compress Plus The Eye Doctor Tea Tree Oil Wipes is a promising treatment for soft contact lens wearers who have complaints, enabling them to wear lenses longer, with fewer problems and so may improve patient retention and reduce drop-out.

Declarations

This trial was funded for The Body Doctor Ltd, Unit 7, Denby Dale Industrial Estate, Wakefield Road, Denby Dale, Huddersfield, United Kingdom, HD8 8QH.
Mr Andrew D Price provides consultancy work for The Body Doctor.

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References

1. Farrar, J., et al: Defining the clinically important difference in pain outcome measures. Pain, 2000. 88(3): p. 287-294.
2. Farrar, J., J. Berlin, B. Strom: Clinically important changes in acute pain outcome measures: A validation study. J Pain Symptom Mgmt, 2003. 25(5): p. 406-411.
3. Reicheld, FF: The One Number You Need To Know. Harvard Business Review, December, 2003: p 46-54.