The Relief of Dry Eye Signs and Symptoms Using a Combination of Lubricants, Lid Hygiene, and Ocular Nutraceuticals

Sruthi Srinivasan, William Ngo, Lyndon Jones

Centre for Contact Lens Research, School of Optometry and Vision Science, University of Waterloo, Canada

Introduction

The working definition of dry eye, as defined by the Dry Eye Workshop 2007 is:[1]

"Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface"

Some common management strategies include artificial tears, warm compresses, lid hygiene, and nutritional supplements (omega 3 fatty acids).[2,3] While these individual treatments provide temporary relief, a combination therapy may be more beneficial.

Purpose

To determine the combined effect of TheraTears® Lubricant Eye Drops, TheraTears® TheraLid® Cleanser, and TheraTears® Nutrition on dry eye signs and symptoms.

Methods

This was a prospective, 3:1 randomized, controlled, single-blind study that enrolled 33 dry eye (OSDI > 23) participants, who used artificial tears at least three times a week.

Participants were screened at baseline and randomized into either the treatment or control groups.

Participants in the treatment group were instructed to use the following products as per label:

- TheraTears® Multidose Lubricant Eye Drops 1-2x (and prn) a day
- TheraTears® TheraLid®** Cleanser 1-2x (and prn) a day
- TheraTears® Nutrition 3 gel capsules 1x a day
- TheraTears® Preservative-free single-use containers 1-2x (and prn) a day

**TheraLid is the Canadian label for SteriLid

Participants in the control group were not provided products and were instructed to maintain their routine dry eye management regimen.

Ocular measurements were obtained at baseline, 2 weeks, 1 month, and 3 months. An outline of the study design is displayed in Figure 1.

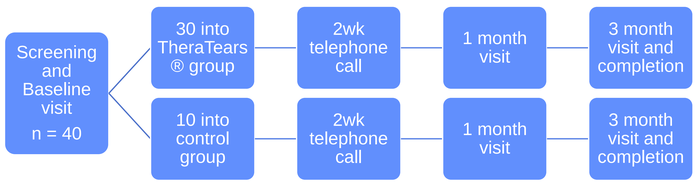

Figure 1: Overview of study outline

Methods (cont'd)

The primary ocular measurements obtained were:

- Ocular Surface Disease Index (OSDI)
- Symptom Assessment iN Dry Eye (SANDE) visual analogue scale
- Osmolarity
- Non-invasive tear breakup time (NIBUT)
- Corneal staining

Some additional exploratory variables were also studied:

- Lid wiper epitheliopathy
- LipiView® Interferometric Color Unit (ICU)

Results

Twenty five participants completed the study. Twenty were randomized into the treatment group, and 5 were randomized into the control group. Statistical analysis was conducted with GraphPad Prism 6.05. Normality fit testing was conducted with the Shapiro-Wilk test, at a threshold of $\alpha = 0.05$. Repeated measures ANOVA was conducted on data sets that passed the normality test, and Friedman ANOVA was conducted on data sets that did not. Participant compliance rates are outlined in Table 1, and graphs for some primary outcomes are displayed in Figures 2 – 5. All other outcome measures for the treatment group are displayed in Table 2. There were no significant differences detected in any of the outcome measures for the control group.

Table 1: Compliance rate for study products

	Multidose Lubricant Eye Drops	TheraLid Cleanser	Nutrition	Preservative-free single-use containers
Compliance	2.4 times per day	1.1 times per day	3.0 capsules, 1.0 times per day	- 25% used them regularly (1-4 times daily) - 75% used them infrequently (e.g. twice a week), or none at all

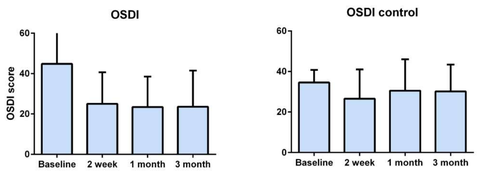

Figure 2: Summary of OSDI score changes over time. For the treatment group (left), there was a significant decrease in OSDI score (-19.8) after the initial visit. This reduction was maintained at OSDI ≈ 25.0 for the rest of the study visits. The control group (right) showed no significant changes over time.

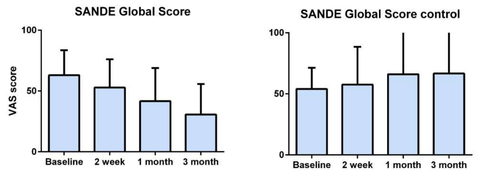

Figure 3: Summary of SANDE visual analogue score changes throughout the duration of the study. The scores in the treatment group (left) declined significantly after each visit (total net change of -32.9). The control group (right) showed an increase in scores, however this increase was not statistically significant.

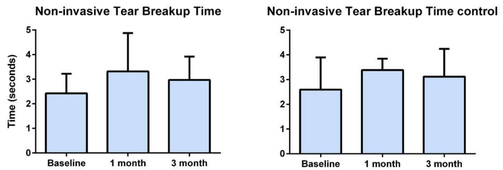

Figure 4: Summary of NIBUT changes throughout the duration of the study. There was a statistically significant increase (net change of +0.54s) in NIBUT for the treatment group (left), but not for the control group (right) (net change of +0.79s). While the control group appeared to have a larger net change in TBUT, it may not be for certain due to the limited sample size.

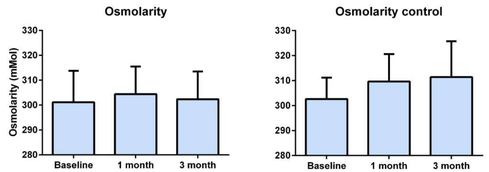

Figure 5: There was no statistically significant difference in osmolarity for both groups between all visits.

Results (cont'd)

Table 2: Treatment group outcome measures

Ocular Measurement	Baseline	2 weeks	1 month	3 month	p-value
OSDI	44.8 ± 17.0	25.0 ± 15.6	23.4 ± 15.1	23.6 ± 17.9	<0.01
SANDE	63.0 ± 20.6	52.8 ± 23.2	41.6 ± 27.3	30.1 ± 25.1	<0.01
NIBUT†	2.43 ± 0.79	N/A	3.31 ± 1.54	2.97 ± 0.95	0.02
Osmolarity	301.2 ± 12.6	N/A	304.4 ± 11.1	302.4 ± 11.1	0.35
Vascularity†	2.0 ± 1.1	N/A	1.8 ± 0.8	1.6 ± 0.8	0.13
Lash Loss†	1.0 ± 0.7	N/A	0.7 ± 0.7	0.8 ± 0.8	0.12
Lid Edema†	0.6 ± 0.5	N/A	0.5 ± 0.5	0.4 ± 0.5	0.049
Telangiectasia†	2.4 ± 1.4	N/A	2.5 ± 1.4	2.2 ± 1.3	0.04
Tear film debris†	0.6 ± 0.5	N/A	0.4 ± 0.5	0.3 ± 0.5	0.046
Meibum quality†	2.4 ± 0.7	N/A	2.0 ± 0.6	1.6 ± 0.7	<0.01
Number of glands blocked†	5.6 ± 2.3	N/A	4.2 ± 2.6	2.6 ± 2.2	<0.01
Expressibility†	2.3 ± 0.7	N/A	1.8 ± 0.8	1.7 ± 0.8	<0.01
Schirmer's test†	10.9 ± 8.4	N/A	9.8 ± 7.8	14.2 ± 10.7	0.41
LipiView ICU	82.2 ± 15.4	N/A	76.6 ± 15.9	79.5 ± 16.7	0.21
Meniscus Height†	0.24 ± 0.17	N/A	0.25 ± 0.17	0.24 ± 0.16	0.78
Lid Wiper Epitheliopathy†	0.3 ± 0.7	N/A	0.4 ± 0.7	0.4 ± 0.8	0.29
Corneal Staining†	61.5 ± 48.4	N/A	70.2 ± 73.1	52.2 ± 96.1	0.36
Conjunctival Staining†	1.2 ± 1.0	N/A	0.9 ± 0.7	0.8 ± 1.0	0.08
Meibography†	2.4 ± 2.0	N/A	2.4 ± 2.1	2.4 ± 2.0	0.66

† indicates Friedman ANOVA
Red indicates p<0.05

Conclusion

Dry eye signs and symptoms could be relieved by using a combination of lubricant eye drops, lid hygiene and nutritional supplements.

References

1. Lemp MA, Baudouin C, Baum J, Dogru M, Foulks G, Kinoshita S, Laibson P, McCulley JP, Murube J, Pflugfelder SC, Rolando M, Toda I. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf 2007;5:75-92.
2. Pflugfelder SC, Geerling G, Kinoshita S, Lemp MA, McCulley JP, Nelson D, Novack G, Shimazaki J, Wilson C. Management and therapy of dry eye disease: report of the Management and Therapy Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf 2007;5:163-78.
3. Yavuz B, Bozdag Pehlivan S, Unlu N. An overview on dry eye treatment: approaches for cyclosporin a delivery. Scientific World Journal 2012;2012:194848.

This study was funded by Advanced Vision Research Inc.

Email contact for correspondence: wngo@uwaterloo.ca

QR code links to PDF