A Single-center Retrospective Trial of a Blink-assisted Eyelid Device in Treating the Signs and Symptoms of Dry Eye

Thomas Chester, OD[1]*

SIGNIFICANCE: The clinical features of meibomian gland disease include altered tear film stability, damage to the ocular surface, symptoms of ocular surface irritation, and visual fluctuations. Finding an adequate treatment to alleviate a patient's signs and symptoms is vital to caring for those with dry eye disease resulting from meibomian gland disease.

PURPOSE: The purpose of this analysis was to determine whether the controlled heating of meibomian glands with the SmartLid devices (TearCare) combined with evacuation of the liquefied meibum using a handheld clearance assistant would improve a patient's dry eye symptoms (as measured by the Standardized Patient Evaluation of Eye Dryness [SPEED] questionnaire) and signs (as measured by meibomian gland expression [MGE] scores).

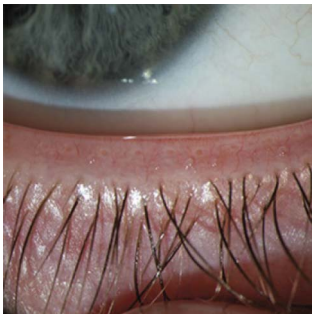
METHODS: This study involved a retrospective analysis of data gathered in a single-center ophthalmology/optometry practice. The symptom frequency and severity were assessed using the SPEED questionnaire, and the signs were assessed via MGE scores before and after (8 to 12 weeks) treatment. A further analysis evaluating efficacy in subgroups based on age, race, and sex was performed. A statistical analysis was performed with *t* tests for group comparisons.

RESULTS: A SPEED questionnaire was answered by 92 patients with dry eye disease. In addition, each patient's meibomian gland function was recorded as MGE scores for each eye (176 eyes). These procedures were completed before and approximately 8 weeks after a single bilateral TearCare treatment. The median total SPEED score was reduced from 16 to 9, and the total MGE scores improved from 5.0 to 9.0 in the right eye and 4.0 to 9.0 in the left eye after a single TearCare treatment.

CONCLUSIONS: A single TearCare treatment was effective in reducing both the signs and symptoms of dry eye in all subjects.

Optom Vis Sci 2021;98:605–612. doi:10.1097/OPX.0000000000001711

OPEN



Author Affiliations:
[1]Cleveland Eye Clinic, Brecksville, Ohio
*drchester@clevelandeyeclinic.com

The meibomian gland plays a critical role in the maintenance of a healthy tear film, which in turn functions in the protection and lubrication of the ocular surface.[1–3] The meibomian gland is a sebaceous gland located in the tarsal plates of the eyelids that secrete meibum, a substance comprising polar and nonpolar lipids.[1–3] Through the action of blinking, these lipids disperse onto the tear film and function to promote its stability and minimize evaporation.[2]

The International Workshop on Meibomian Gland Dysfunction describes the condition as a chronic duct obstruction and/or change in meibomian glandular secretion that can result in disruptions of the tear film, eye irritation symptoms, inflammation, and ocular surface disease.[2] Meibomian gland disease is often caused by terminal duct obstruction with thickened meibum containing keratinized cellular material.[2] The process leading to obstruction of the meibomian glands is affected by factors such as age, sex, hormonal fluctuations, and medications.[2] Obstruction of the meibomian gland may eventually lead to meibocyte atrophy, gland dropout, intraglandular cystic dilation, and low secretion.[2] The resultant decrease in meibum availability can cause increased instability, hyperosmolarity, and evaporation of the tear film; ocular surface inflammation; and evaporative dry eye.[2,4]

Meibomian gland disease is the most frequent cause of dry eye disease.[2] The prevalence of meibomian gland disease has been estimated at up to 86% of individuals with dry eye.[2,5] Even this high rate is potentially an underestimate because most individuals with meibomian gland disease seem to be asymptomatic.[6,7] Addressing meibomian gland disease is particularly important today because of modern lifestyles that frequently depend on spending extended amounts of time viewing electronic devices, where blinking rates are reduced.[8] For patients who are scheduled to undergo cataract surgery, the presence of dry eye and the resultant compromised ocular surface can adversely affect the chance for successful outcomes.[9]

The clinical features of meibomian gland disease include altered tear film stability, symptoms of ocular surface irritation, visual fluctuation, and damage to the ocular surface.[2] A reduced quantity and quality of meibum can result in decreases in the tear film lipid layer, tear hyperosmolarity, mechanical irritation, and the promotion of inflammation.[10] The dry eye disease that results from meibomian gland disease can ultimately lead to adverse effects on an individual's quality of life, both in everyday activities and in productivity in work.[11–13]

Finding an adequate treatment to alleviate patient signs and symptoms is vital to caring for those with dry eye disease. Optimal

treatment of meibomian gland disease typically requires evacuation of the meibomian gland contents.[14,15] Historically, this has been complemented by the adjunctive use of warm compresses.[14,16] This warming of the glands promotes their evacuation, resulting in increases in lipid concentrations in the tear film.[17,18] However, warm compresses are associated with several drawbacks.[19,20] They are often not sufficiently warm to melt the meibum lipids, and they tend to cool too quickly. Warm compresses have not been shown to achieve the requisite meibum melting temperature of 41°C at the inner eyelid. Other caveats include a lack of ergonomic fit for the patient and the fact that warm compresses do not allow for natural blinking because the eye is closed. Finally, compresses tend to be labor-intensive and time-consuming for the patient.

Other techniques are warranted to address these limitations and relieve obstructions of the meibomian gland. Patient eyelid massage has been used to treat obstructions of the meibomian gland.[19] Caveats of this method include a lack of meibum melting, long-term patient compliance, and a potential for the disruption of normal eyelid anatomy.[19]

Because of the recognition of dry eye disease as a public health concern, several new devices for treating meibomian gland obstruction have been introduced.[21] In-office vectored thermal pulsation (LipiFlow; Johnson & Johnson Vision, Santa Ana, CA) has gained favor in recent years.[14–16,22,23] Other warming devices include EyeExpress (Holbar Medical Products, Tyler, TX), a heated mask that warms the external eyelid to approximately 43°C.[24] The iLux (Tearfilm Innovations, Carlsbad, CA) instrument is a handheld device that treats meibomian gland disease using light-based heat and compression under direct visualization by the physician through a magnifying lens.[23] The Thermoflo device (MIBO Medical Group, Dallas, TX) comprises a control unit and handpiece that provides 42°C heat to the external surface of the eyelid through a silver eye pad.[24]

Recently, a wearable, software-controlled, therapeutic eyelid device, the TearCare system was designed to melt and clear obstructions of the meibomian glands within the eyelids (Fig. 1).[19] The TearCare system comprises four electrothermal single-use SmartLid devices that are affixed to the exterior surface of the eyelids above the tarsal plates. The devices are ergonomic and allow for natural blinking action. They deliver a regulated, targeted amount of thermal energy across the lids at a safe, consistent, and maximized therapeutic temperature to melt meibum. The SmartLid devices achieve and steadily maintain an external eyelid temperature of 45°C so that the requisite therapeutic, meibum-melting, inner-eyelid temperature of 41°C can be achieved within the meibomian glands.[17,25] After the therapeutic thermal cycle, manual and tailored meibomian gland evacuation is performed with the TearCare clearance assistant by an eye care provider.[19] The device uses two levels of expression, natural blinking and mechanical expression, under direct visualization by the provider using the clearance assistant.

Few studies have been conducted with the TearCare system thus far. In a prospective, single-center, randomized, parallel-group study of 24 patients with dry eye disease, Badawi[19] found the system to be an effective treatment option. Beneficial effects in terms of the signs and symptoms of dry eye disease persisted for at least 6 months after a single treatment.[19] In the 6-month extension study, the author reported a statistically significant improvement from baseline at 1 year in meibomian gland scores, corneal and conjunctival staining scores, and symptoms of dry eye disease after a second treatment at 6 months.[26] In a previous exploratory study (Cheetah), improvements in both dry eye disease signs (tear breakup time, meibomian gland secretion score, corneal and conjunctival staining) and symptoms (Ocular Surface Disease Index) were observed at both 1-week and 1-month time points for TearCare in comparison to placebo.[27] Hovanesian et al.[28] reported the effectiveness of TearCare comparable with LipiFlow for 135 patients with dry eye disease in terms of improvement in tear breakup time, meibomian gland scores, and

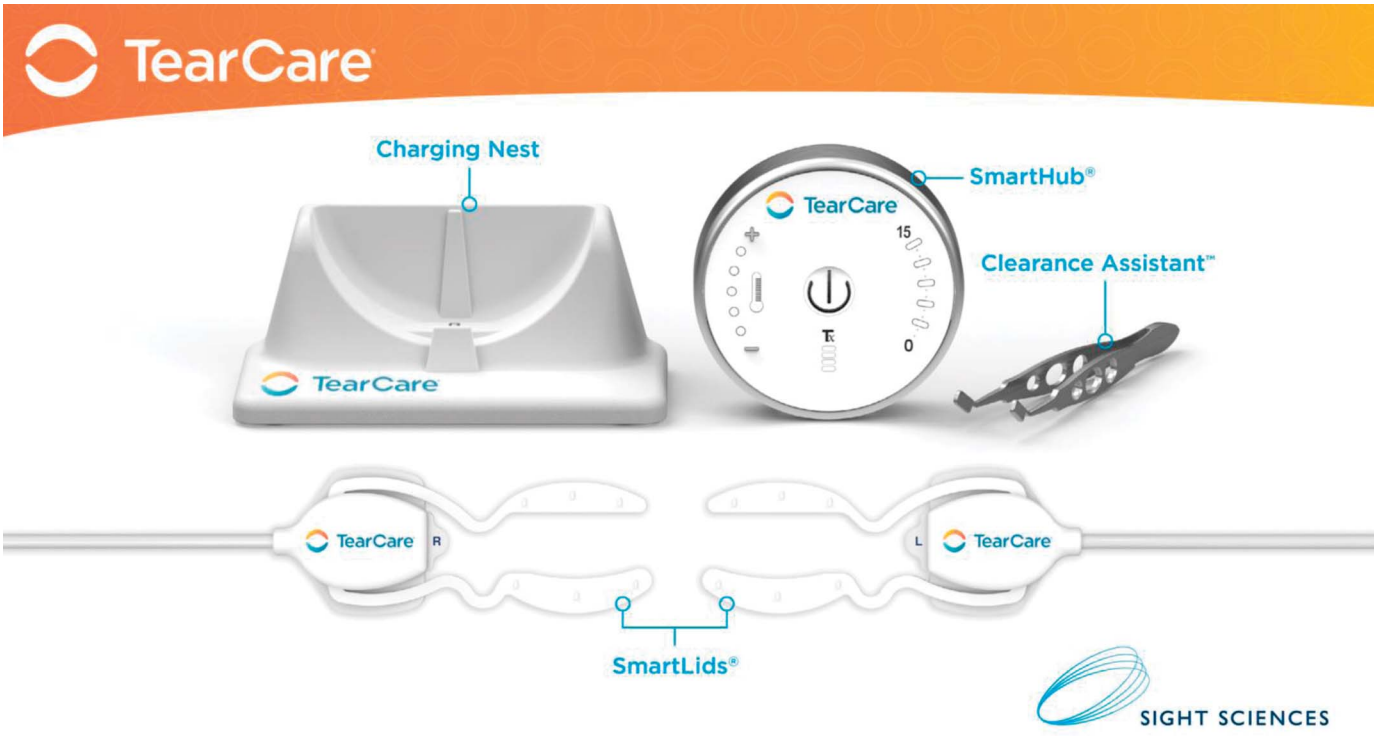


FIGURE 1. TearCare device showing the charging nest, SmartHub, clearance assistant, and SmartLid devices.

Ocular Surface Disease Index scores in their prospective, single-masked, controlled, randomized, multicenter pivotal study (OLYMPIA). The OLYMPIA trial reported superior symptom relief of TearCare compared with LipiFlow for patient-reported outcomes on the Ocular Surface Disease Index questionnaire ($P < .05$). The current study sought to evaluate the safety and efficacy of the TearCare procedure in treating the signs and symptoms of meibomian gland disease–associated dry eye disease for 3 months.

METHODS

This study involved a retrospective analysis of data gathered in a single-center ophthalmology/optometry practice. Waiver of consent and waiver of Health Insurance Portability and Accountability Act authorization were obtained, as this study meets the criteria of 45 Code of Federal Regulations 46.116(d) and 45 Code of Federal Regulations 164.512 (i.)(2)(ii).[29,30] The study included 92 patients who had a Standardized Patient Evaluation of Eye Dryness questionnaire score greater than 0, complete patient records, and a single treatment with the TearCare system. Patients who had active infection, inflammation, or a condition (ocular or systemic) that would have prohibited them from completing the treatment or who were lost to follow-up were excluded.

The objective of this study was to assess the efficacy of the TearCare system in treating meibomian gland function and patient dry eye symptoms. Assessments were made before and 8 to 12 weeks after treatment. We proposed that the specific therapeutic heating of the meibomian glands with the SmartLid devices followed with meibomian gland evacuation using a handheld clearance assistant would improve a patient's dry eye symptoms (as measured by the Standardized Patient Evaluation of Eye Dryness questionnaire) and dry eye signs (as measured by the meibomian gland expression score). It is noteworthy that no eligible patients had to be excluded from the study because of the inability of the SmartLids to appropriately fit on the eyelids because of condition, shape, size, contour of the eyelids, or the size of the palpebral fissure.

Data gathered included patient demographics, Standardized Patient Evaluation of Eye Dryness, and meibomian gland expressibility scores. Demographic data included age, sex, and race. The Standardized Patient Evaluation of Eye Dryness questionnaire provides a score from 0 to 28, which results from eight items that evaluate the frequency and severity of dry eye symptoms.[31] The symptoms assessed in the questionnaire included frequency and severity of burning or watering; dryness, grittiness, or scratchiness; eye fatigue; soreness or irritation; and total scores both before and after treatment.[32] The frequency scores were as follows: 0, never; 1, sometimes; 2, often; and 3, constant. The severity scores were as follows: 0, no problem; 1, tolerable; 2, uncomfortable; 3, bothersome; and 4, intolerable. The sensitivity and specificity of the Standardized Patient Evaluation of Eye Dryness instrument are relatively high, 0.90 and 0.80, respectively.[31]

Meibomian gland expression scores were obtained for temporal, medial, nasal, and total samples from each eye before and after treatment.[33–35] The meibomian gland expression scores approximate a count of the numbers of functioning glands at each location.

Statistical Analysis

Examination of the data began with calculation of summary statistics (median and interquartile range for nonnormally distributed, rank, and count data; frequencies and percentages for categorical data). Inferential statistics were based on data type and distributional assessments. A Spearman correlation was used to assess a potential relationship between age and Standardized Patient Evaluation of Eye Dryness percent change in total scores. The Wilcoxon rank sum test with exact option was used to assess for a potential difference in percent change in Standardized Patient Evaluation of Eye Dryness total scores by sex. The sign test was used to assess potential differences in pre-post measures of Standardized Patient Evaluation of Eye Dryness total scores, as well as the individual symptom frequency and severity scores (with Bonferroni adjustment to type I error rate of α level of significance to account for multiple comparisons). Generalized estimating equations using a log link and exchangeable correlation structure were used to assess for potential pre-post changes in meibomian gland expressibility count variables, by quadrant and by total. Race was not sufficiently heterogeneous to accommodate analysis.

RESULTS

There were 92 patients enrolled in the study, with a median (minimum, maximum) age of 62.3 (27.4, 94.3) years. Approximately two-thirds (78.3%) were female, and 21.7% were male (Table 1). Most patients were White (n = 88; 95.6%), whereas four (4.4%) were African American. The subjects completing 12 weeks of follow-up (n = 92) were included in this study.

The median (interquartile range) pre-treatment Standardized Patient Evaluation of Eye Dryness total score was 16.0 (11.0 to 20.0), which was significantly different from the post-treatment Standardized Patient Evaluation of Eye Dryness total score, which was 9.0 (5.5 to 15.0; $P < .001$). The median (interquartile range) percent change (decrease) in Standardized Patient Evaluation of Eye Dryness score was 33.3% (7.9 to 62.2%), with a maximum decrease of 100%. Change in the total Standardized Patient Evaluation of Eye Dryness score did not have a significant correlation with age, nor was it different by sex (both, $P > .50$).

Individual symptoms were evaluated at a significance level of $\alpha = 0.025$ (Bonferroni adjustment) to account for multiple comparisons. Individual symptom evaluation provides evidence of significant pre-post changes for dryness/soreness/burning/fatigue frequency, as well as dryness/soreness/fatigue severity ($P < .001$ for each). Burning severity also was significantly different between the pre- and post-treatment analyses ($P = .02$). For significant symptoms, the pre-treatment median was 2.0 to 3.0 and the post-treatment

TABLE 1. Summary statistics

Demographic variables	n	%	Median	IQR		Min	Max
Age (y)	92		62.3	53.9	73.1	27.4	94.3
Sex							
Female	72	78.3					
Male	20	21.7					
Race							
White	88	95.6					
African American	4	4.4					

IQR = interquartile range; Max = maximum; Min = minimum.

median was 1.0, with minor variation in interquartile ranges. See Table 2 and Fig. 2 for the full results.

Total meibomian gland expression scores in the right eye and left eye were significantly different from pre- to post-treatment ($P < .001$ for both; Table 3, Fig. 3). Median counts increased from 5.0 to 9.0 for the right eye and 4.0 to 9.0 for the left eye. Meibomian gland expression scores for individual quadrant (temporal right eye and left eye, medial right eye and left eye, nasal right eye and left eye) were all significantly different between pre- and post-treatment measurements ($P < .001$ for each when interpreted with a Bonferroni-adjusted α level of significance equal to 0.025 to account for multiple comparisons and to control type I error rate). Medians ranged from 1.0 to 2.0 pre-treatment, and the median was 3.0 for each measure post-treatment, with minor variations in interquartile ranges. See Table 3 and Fig. 3 for the full results.

DISCUSSION

This study was designed to evaluate the efficacy of the TearCare system in treating the signs and symptoms of meibomian gland disease–associated dry eye disease over an 8- to 12-week period. The study findings demonstrated statistically significant improvements in the frequency and severity of all Standardized Patient Evaluation of Eye Dryness symptom questionnaire variables after a single TearCare treatment. Significant improvements in meibomian gland scores also were observed after treatment. These results indicate that a single treatment with the TearCare device was effective in improving both the signs and symptoms of dry eye for at least 12 weeks.

Our patient cohort comprised older individuals and had a high proportion of women. This is not surprising given that advancing age and female sex are both risk factors for dry eye.[36–39] Our study did not find a significant correlation in total Standardized Patient Evaluation of Eye Dryness scores with age. This may have been due to the fact that most of the patients were elderly, and we did not have an adequate number of younger patients from which to make comparisons. The same was true for the effect of sex on Standardized Patient Evaluation of Eye Dryness scores. We may have been able to detect differences with a larger sample of male patients.

The Standardized Patient Evaluation of Eye Dryness scores showed clinically relevant improvements after a single TearCare treatment. Before treatment, most patients experienced dry eye symptoms such as dryness, soreness, burning, and fatigue "often" that, after a single TearCare treatment, changed for most patients to "some of the time."

Before treatment, the patients typically rated their soreness, burning, and fatigue as being uncomfortable and their dryness symptoms as bothersome. However, after treatment, the median severity of all these symptoms diminished to a level that was considered tolerable. The total Standardized Patient Evaluation of Eye Dryness scores were reduced after treatment (from 16 to 9), a substantial decrease. Total median Standardized Patient Evaluation of Eye Dryness scores were decreased by one-third (33.3%) after treatment. Taken together, these results suggest that a single TearCare treatment results in statistically and clinically significant dry eye symptom relief.

TABLE 2. SPEED ordinal symptom variables

	n	Median	IQR		Min	Max	Sign test, *P*
Pre-treatment							
Dry frequency	92	2.0	1.0	3.0	0.0	3.0	<.001
Soreness frequency	92	2.0	1.0	2.0	0.0	3.0	<.001
Burning frequency	92	2.0	1.0	2.0	0.0	4.0	<.001
Fatigue frequency	92	2.0	1.0	3.0	0.0	3.0	<.001
Dry severity	92	3.0	2.0	3.0	0.0	4.0	<.001
Soreness severity	92	2.0	1.0	3.0	0.0	4.0	<.001
Burning severity	92	2.0	1.0	3.0	0.0	4.0	.02
Fatigue severity	92	2.0	1.0	3.0	0.0	4.0	<.001
SPEED total score	92	16.0	11.0	20.0	2.0	28.0	<.001
Post-treatment							
Dry frequency	84	1.0	1.0	2.0	0.0	3.0	
Soreness frequency	84	1.0	0.0	2.0	0.0	3.0	
Burning frequency	84	1.0	1.0	2.0	0.0	3.0	
Fatigue frequency	84	1.0	1.0	2.0	0.0	3.0	
Dry severity	84	1.0	1.0	2.0	0.0	4.0	
Soreness severity	84	1.0	0.0	2.0	0.0	4.0	
Burning severity	84	1.0	1.0	2.0	0.0	4.0	
Fatigue severity	84	1.0	0.0	2.0	0.0	4.0	
SPEED total score	92	9.0	5.5	15.0	0.0	28.0	
SPEED total score percent change	92	–33.3	–62.2	–7.9	–100.0	300.0	

IQR = interquartile range; Max = maximum; Min = minimum; Sign = significance; SPEED = Standardized Patient Evaluation of Eye Dryness.

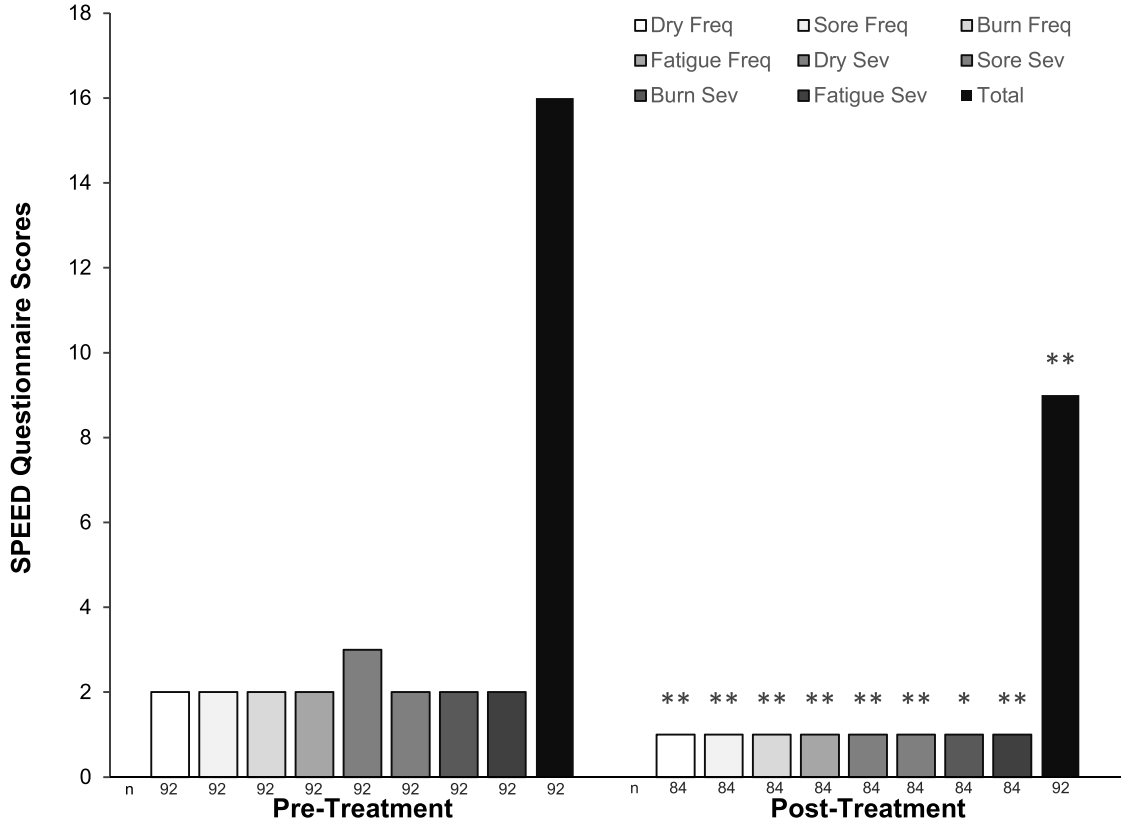


FIGURE 2. Median SPEED symptom scores before and after TearCare treatment. Burn = burning; Dry = dryness; Freq = frequency; Sev = severity; Sore = soreness; SPEED = Standardized Patient Evaluation of Eye Dryness. $^{**}P < .001$, compared with pre-treatment values.

The results of this study support those from Hovanesian et al.[28] in the OLYMPIA trial. Their single-masked, controlled, multicenter, randomized (1:1 TearCare and LipiFlow) study involved 135 patients with dry eye disease. Significant improvements ($P < .0001$) in meibomian gland secretion scores were observed, 11.2 ± 11.1, in the TearCare group. A significantly greater proportion of TearCare patients (22%) experienced significant symptomatic improvements by at least one Ocular Surface Disease Index category compared with LipiFlow patients.[28] The current study complemented these results by showing statistically significant and clinically meaningful improvements with TearCare in both Standardized Patient Evaluation of Eye Dryness questionnaire variables and meibomian gland expression scores.

Badawi[19] observed significant improvements in patient questionnaire scores for TearCare patients compared with those using warm compress therapy. These beneficial effects were observed for Standardized Patient Evaluation of Eye Dryness, Ocular Surface Disease Index, and Symptom Assessment iN Dry Eye scores for up to 6 months.[19] A 6-month extension of this study in which a subset of patients received a second treatment 7 months after the first saw significant improvements in symptoms.[26] Interestingly, the mean Symptom Assessment iN Dry Eye scores were reduced even further than they had been after the first treatment.[26]

Karpecki et al.[27] observed that, in a multicenter, prospective, exploratory trial of 58 eyes (29 subjects), a single TearCare procedure was safe and effective in treating signs/symptoms of dry eye disease. Significant improvements were seen in all subjects (100%) in all signs and symptoms of dry eye disease within 1 week

TABLE 3. Summary statistics for meibomian gland expression count variables and results of paired difference testing

	n	Median	IQR		Min	Max	GEE, *P*
Pre-treatment							
Temporal OD	88	2.0	1.0	3.0	0.0	4.0	<.001
Medial OD	88	1.0	1.0	2.0	0.0	4.0	<.001
Nasal OD	88	1.0	1.0	2.0	0.0	5.0	<.001
Temporal OS	88	1.5	1.0	2.0	0.0	4.0	<.001
Medial OS	88	1.0	1.0	2.0	0.0	4.0	<.001
Nasal OS	88	1.5	1.0	2.0	0.0	4.0	<.001
Pre-OD Total	88	5.0	2.5	6.0	1.0	10.0	<.001
Pre-OS Total	88	4.0	3.0	6.0	0.0	11.0	<.001
Post-treatment							
Temporal OD	88	3.0	2.0	4.0	1.0	6.0	
Medial OD	88	3.0	2.0	3.0	1.0	6.0	
Nasal OD	88	3.0	2.0	4.0	1.0	6.0	
Temporal OS	88	3.0	2.0	4.0	0.0	7.0	
Medial OS	88	3.0	2.0	3.0	1.0	6.0	
Nasal OS	88	3.0	2.0	4.0	0.0	6.0	
Post-OD total	88	9.0	7.0	11.0	4.0	16.0	
Post-OS total	88	9.0	7.0	10.0	3.0	16.0	

GEE = generalized estimating equations; IQR = interquartile range; Max = maximum; Min = minimum; OD = right eye; OS = left eye.

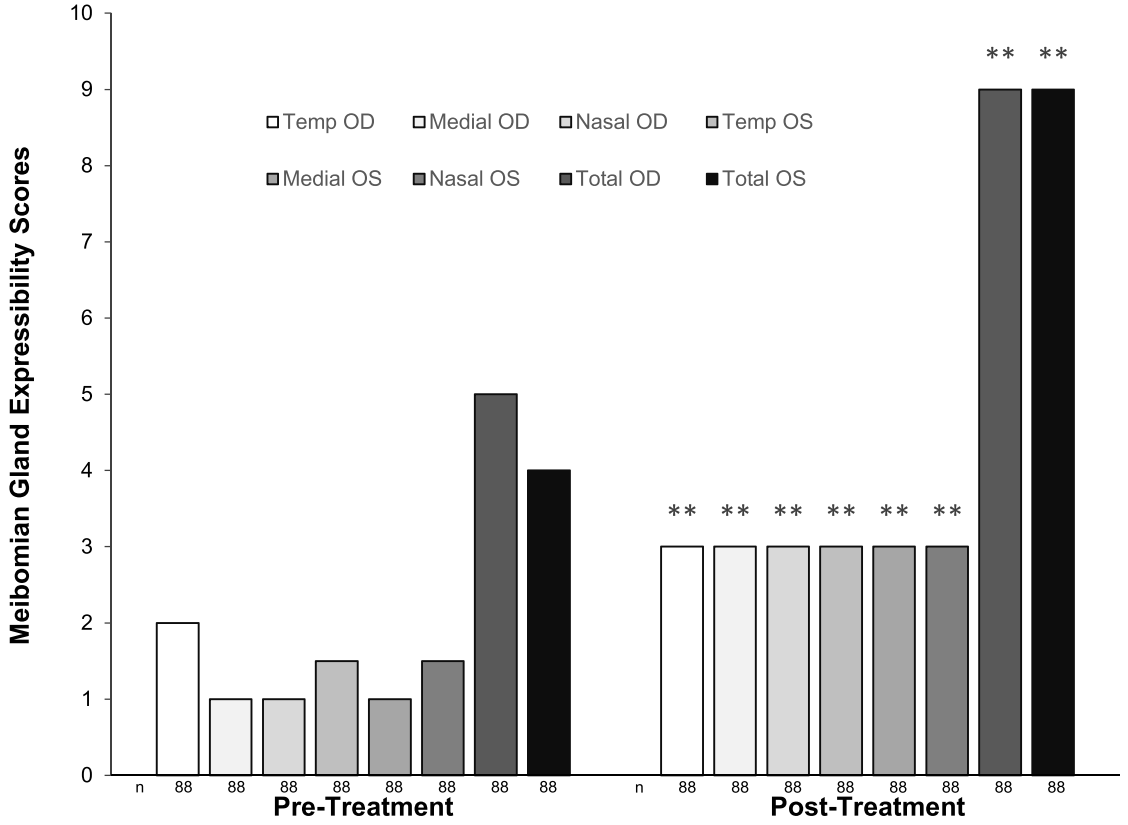


FIGURE 3. Median meibomian gland expression scores. OD = right eye; OS = left eye. $^{**}P < .001$, compared with pre-treatment values.

of treatment, and 83% of the subjects experienced clinically meaningful symptom relief measured by the Ocular Surface Disease Index. The pre-treatment tear breakup time of 3.7 ± 1.1 seconds was improved by 2.6 ± 1.6 seconds (70%) at 1 week and by 3.1 ± 2.2 seconds (84%) at 1 month ($P < .001$). A mean pre-treatment Ocular Surface Disease Index score of 54.9 ± 20.2 was improved by 17.9 ± 20.9 at 1 week and 25.8 ± 24.3 at 1 month ($P < .001$). Similar to this trial, the pre-treatment meibomian gland expression scores of 5.6 ± 4.0 improved by 9.3 ± 4.0 at 1 week and 8.8 ± 5.8 at 1 month ($P < .001$).

The patient responses to the Standardized Patient Evaluation of Eye Dryness questionnaire from the current study support the findings of others that dry eye symptoms such as dryness, discomfort, soreness, burning, and fatigue have been shown to affect a patient's quality of life.[11–13] In a cross-sectional study of 450 participants from the Women's Health Study and 240 from the Physicians' Health Study, Miljanovic et al.[12] found those with dry eye had difficulties with reading, carrying out their professional work, using a computer, watching television, and driving during the day or night. A study from China found dry eye symptoms were associated with an adverse effect on vision-related quality of life in non–clinic-based general population cohort.[11] This reduction in quality of life manifested as more ocular pain and discomfort, and impaired mental health.[11] Although there are several instruments that evaluate the effect of dry eye in a patient's quality of life, it is difficult to quantify the full impact of the disease.[13] Miljanovic et al.[12] concluded dry eye disease is an important public health concern, which deserves increased attention and resources.

Patients who received TearCare treatment in the current study experienced substantial improvements in meibomian gland function. Before treatment, the median meibomian gland expression score was 1 across all zones in both eyes. After treatment, the median meibomian gland expression score of all eyes progressed to a score of 3, suggesting an increase in the number of functional meibomian glands. In addition, the median total meibomian gland expression scores showed an improvement in the number of functioning meibomian glands. Qualitative and quantitative changes in meibomian gland secretions are the most prominent hallmarks of meibomian gland disease.[2]

The OLYMPIA study found TearCare patients achieved improvements in meibomian gland secretion scores and, as a result, required 22% fewer lubricant drops compared with those receiving LipiFlow treatment.[28] Badawi[19] observed greater improvements for patients with dry eye disease in the change from baseline in meibomian gland secretion scores in the TearCare patient group compared with the warm compress group from 2 weeks to 6 months. Mean tear breakup times improved compared with those taken at baseline beginning at day 1 until the last sampling at 6 months.[19] Interestingly, both mean meibomian gland secretion scores and tear breakup time were basically unchanged from baseline during the same 6-month period in patients who used warm compresses.[19] In the 6-month extension of this study, meibomian gland secretion scores and tear breakup time were further improved after a second treatment that occurred 7 months after the first one.[26]

Using the full functionality of the blinking eye, the proprietary SmartLid technology of the device is designed to conform to the

eyelid anatomy and achieve therapeutic meibum melting temperatures at the tarsal conjunctiva, thereby clearing meibomian gland obstructions while sparing the cornea. The TearCare system achieves and maintains an elevated eyelid temperature of 45°C, which in turn achieves a therapeutic, meibum-melting, inner eyelid temperature of 41°C for 15 minutes.[19] This 45°C external/41°C internal therapeutic temperature profile is specifically engineered to provide effective melting of abnormal meibum lipids[25] while being safe for the patient.[19,40] Blackie and colleagues[17] previously have demonstrated the safety and necessity of applying 45°C in the form of warm compresses for 30 minutes to achieve a sufficient inner eyelid meibum-melting temperature. The improvements in meibomian gland expression scores after treatment indicate the TearCare device is effective at providing a safe and optimal therapeutic temperature for melting meibum, confirming the findings of Badawi.[19]

Limitations to the current analysis include use of a convenience sample, the lack of an a priori sample size analysis, unknown underlying distributional shape or variance/covariance structure of the data, and potential presence of confounding factors that cannot be evaluated because of the retrospective nature of the study design. Because of the stated limitations, statistical power to detect effects may have been lower than the standard 80%. Therefore, these findings are to be considered preliminary in nature. That said, the similarity between the results of this study and the data published thus far suggests that these results can be generalized with more data collected from further studies.

The TearCare system was effective in improving both the signs and symptoms of dry eye. The device has been engineered to deliver a specific meibum-melting temperature at the inner eyelid and meibomian gland level that promotes the effective melting of hardened meibum. The data presented here and evidenced in previous trials (Badawi, Cheetah, and OLYMPIA) show repeatability of effectiveness. The combination of meibum liquefication and manual lid expression to clear hardened obstructions from the meibomian glands results in clinically significant improvements in the signs and symptoms of dry eye disease. Additional large-scale, prospective studies, including morphological evaluations, are needed to confirm these results.

ARTICLE INFORMATION

Submitted: August 24, 2020

Accepted: January 18, 2021

Funding/Support: Sight Sciences (TC).

Conflict of Interest Disclosure: TC has received honoraria and consulting fees from Sight Sciences, Shire (Novartis), Allergan, Sun, and Johnson & Johnson. This study was funded by a grant from Sight Sciences.

Author Contributions and Acknowledgments: Conceptualization: TC; Data Curation: TC; Funding Acquisition: TC; Investigation: TC; Methodology: TC; Project Administration: TC; Resources: TC; Supervision: TC; Writing – Review & Editing: TC.

The author would like to acknowledge Julie Crider, PhD, for medical writing/editing contributions, which were funded by a grant from Sight Sciences; Neil L. McNinch, MS, RN, PSTAT, with an affiliation to McNinch Biostats, LLC., Kent, OH, for performing the statistical analysis and writing/editing; and Jill Pullman, COT, for project administration and manuscript review.

REFERENCES

1. Foulks GN, Bron AJ. Meibomian Gland Dysfunction: A Clinical Scheme for Description, Diagnosis, Classification, and Grading. Ocul Surf 2003;1:107–26.

2. Nichols KK, Foulks GN, Bron AJ, et al. The International Workshop on Meibomian Gland Dysfunction: Executive Summary. Invest Ophthalmol Vis Sci 2011;52:1922–9.

3. Pflugfelder SC, Stern ME. Biological Functions of Tear Film. Exp Eye Res 2020;197:108115.

4. Braun RJ, King-Smith PE, Begley CG, et al. Dynamics and Function of the Tear Film in Relation to the Blink Cycle. Prog Retin Eye Res 2015;45:132–64.

5. Rabensteiner DF, Aminfar H, Boldin I, et al. The Prevalence of Meibomian Gland Dysfunction, Tear Film and Ocular Surface Parameters in an Austrian Dry Eye Clinic Population. Acta Ophthalmol 2018;96:e707–11.

6. Viso E, Rodriguez-Ares MT, Abelenda D, et al. Prevalence of Asymptomatic and Symptomatic Meibomian Gland Dysfunction in the General Population of Spain. Invest Ophthalmol Vis Sci 2012;53:2601–6.

7. Jie Y, Xu L, Wu YY, et al. Prevalence of Dry Eye among Adult Chinese in the Beijing Eye Study. Eye (Lond) 2009;23:688–93.

8. American Optometric Association (AOA). Computer vision syndrome; 2020. Available at: https://www.aoa.org/patients-and-public/caring-for-your-vision/protecting-your-vision/computer-vision-syndrome. Accessed July 15, 2020.

9. Trattler WB, Majmudar PA, Donnenfeld ED, et al. The Prospective Health Assessment of Cataract Patients' Ocular Surface (PHACO) Study: The Effect of Dry Eye. Clin Ophthalmol 2017;11:1423–30.

10. Chhadva P, Goldhardt R, Galor A. Meibomian Gland Disease: The Role of Gland Dysfunction in Dry Eye Disease. Ophthalmology 2017;124:S20–6.

11. Le Q, Zhou X, Ge L, et al. Impact of Dry Eye Syndrome on Vision-related Quality of Life in a Non–clinic-based General Population. BMC Ophthalmol 2012;12:22.

12. Miljanovic B, Dana R, Sullivan DA, et al. Impact of Dry Eye Syndrome on Vision-related Quality of Life. Am J Ophthalmol 2007;143:409–15.

13. Uchino M, Schaumberg DA. Dry Eye Disease: Impact on Quality of Life and Vision. Curr Ophthalmol Rep 2013;1:51–7.

14. Blackie CA, Coleman CA, Holland EJ. The Sustained Effect (12 Months) of a Single-dose Vectored Thermal Pulsation Procedure for Meibomian Gland Dysfunction and Evaporative Dry Eye. Clin Ophthalmol 2016;10:1385–96.

15. Lane SS, DuBiner HB, Epstein RJ, et al. A New System, the Lipiflow, for the Treatment of Meibomian Gland Dysfunction. Cornea 2012;31:396–404.

16. Blackie CA, Carlson AN, Korb DR. Treatment for Meibomian Gland Dysfunction and Dry Eye Symptoms with a Single-dose Vectored Thermal Pulsation: A Review. Curr Opin Ophthalmol 2015;26:306–13.

17. Blackie CA, Solomon JD, Greiner JV, et al. Inner Eyelid Surface Temperature as a Function of Warm Compress Methodology. Optom Vis Sci 2008;85:675–83.

18. Olson MC, Korb DR, Greiner JV. Increase in Tear Film Lipid Layer Thickness Following Treatment with Warm Compresses in Patients with Meibomian Gland Dysfunction. Eye Contact Lens 2003;29:96–9.

19. Badawi D. A Novel System, Tearcare®, for the Treatment of the Signs and Symptoms of Dry Eye Disease. Clin Ophthalmol 2018;12:683–94.

20. Lam AK, Lam CH. Effect of Warm Compress Therapy from Hard-boiled Eggs on Corneal Shape. Cornea 2007;26:163–7.

21. The Epidemiology of Dry Eye Disease: Report of the Epidemiology Subcommittee of the International Dry Eye Workshop (2007). Ocul Surf 2007;5:93–107.

22. Arita R, Fukuoka S. Non-pharmaceutical Treatment Options for Meibomian Gland Dysfunction. Clin Exp Optom 2020;103:742–55.

23. Tauber J, Owen J, Bloomenstein M, et al. Comparison of the Ilux and the Lipiflow for the Treatment of Meibomian Gland Dysfunction and Symptoms: A Randomized Clinical Trial. Clin Ophthalmol 2020;14:405–18.

24. Kent C. Devices for Treating the Meibomian Glands. Rev Ophthalmol 2018;25. Available at: https://www.reviewofophthalmology.com/article/devices-for-treating-the-meibomian-glands. Accessed December 11, 2020.

25. Bron AJ, Tiffany JM, Gouveia SM, et al. Functional Aspects of the Tear Film Lipid Layer. Exp Eye Res 2004;78:347–60.

26. Badawi D. Tearcare® System Extension Study: Evaluation of the Safety, Effectiveness, and Durability through 12 Months of a Second Tearcare® Treatment on Subjects with Dry Eye Disease. Clin Ophthalmol 2019;13:189–98.

27. Karpecki P, Wirta D, Osmanovic S, et al. A Prospective, Post-market, Multicenter Trial (Cheetah) Suggested Tearcare® System as a Safe and Effective Blink-assisted Eyelid Device for the Treatment of Dry Eye Disease. Clin Ophthalmol 2020;14:4551–9.

28. Hovanesian JA, Holland EJ, Karpecki P, et al. A Novel, Targeted, Blink-assisted, Thermal Eyelid Therapy and MG Clearance in the Treatment of MGD: A Prospective, Single-masked, Multicenter RCT (OLYMPIA). American Association of Ophthalmology. Virtual Meeting; November 13–15, 2020.

29. Electronic Code of Federal Regulations. In: General Requirements for Informed Consent: 45 CFR 46.116.

Available at: https://www.ecfr.gov/cgi-bin/text-idx?m=07&d=19&y=2020&cd=20200714&submit=go&sid=&node=pt45.1.46&pd=20180719. Accessed July 16, 2020.

30. Disclosures for Public Health Activities. 45 CFR 164.512(b); April 3, 2003. Available at: https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/publichealth/publichealth.pdf. Accessed July 16, 2020.

31. Ngo W, Situ P, Keir N, et al. Psychometric Properties and Validation of the Standard Patient Evaluation of Eye Dryness Questionnaire. Cornea 2013;32:1204–10.

32. Asiedu K. Rasch Analysis of the Standard Patient Evaluation of Eye Dryness Questionnaire. Eye Contact Lens 2017;43:394–8.

33. Fu J, Chou Y, Hao R, et al. Evaluation of Ocular Surface Impairment in Meibomian Gland Dysfunction of Varying Severity Using a Comprehensive Grading Scale. Medicine (Baltimore) 2019;98:e16547.

34. Tomlinson A, Bron AJ, Korb DR, et al. The International Workshop on Meibomian Gland Dysfunction: Report of the Diagnosis Subcommittee. Invest Ophthalmol Vis Sci 2011;52:2006–49.

35. Wu H, Lin Z, Yang F, et al. Meibomian Gland Dysfunction Correlates to the Tear Film Instability and Ocular Discomfort in Patients with Pterygium. Sci Rep 2017;7:45115.

36. Schaumberg DA, Sullivan DA, Buring JE, et al. Prevalence of Dry Eye Syndrome among US Women. Am J Ophthalmol 2003;136:318–26.

37. Shujaat S, Jawed M, Memon S, et al. Determination of Risk Factors and Treatment of Dry Eye Disease in Type 1 Diabetes Before Corneal Complications at Sindh Institute of Ophthalmology and Visual Sciences. Open Ophthalmol J 2017;11:355–61.

38. de Paiva CS. Effects of Aging in Dry Eye. Int Ophthalmol Clin 2017;57:47–64.

39. 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.

40. Despa F, Orgill DP, Neuwalder J, et al. The Relative Thermal Stability of Tissue Macromolecules and Cellular Structure in Burn Injury. Burns 2005;31:568–77.