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.
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, Badawi19 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 expressibility 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 α = 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 $\alpha$ 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. 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 | $<.001$        |
| Soreness frequency   | 92 | 2.0    | 1.0 | 2.0 | 0.0 | $<.001$        |
| Burning frequency    | 92 | 2.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Fatigue frequency    | 92 | 2.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Dry severity         | 92 | 3.0    | 2.0 | 3.0 | 0.0 | $<.001$        |
| Soreness severity    | 92 | 2.0    | 0.0 | 3.0 | 0.0 | $<.001$        |
| Burning severity     | 92 | 2.0    | 0.0 | 3.0 | 0.0 | $<.001$        |
| Fatigue severity     | 92 | 2.0    | 0.0 | 3.0 | 0.0 | $<.001$        |
| SPEED total score    | 92 | 16.0   | 11.0| 20.0| 2.0 | $<.001$        |

|                      | n  | Median | IQR | Min | Max | Sign test, $P$ |
|----------------------|----|--------|-----|-----|-----|----------------|
| **Post-treatment**   |    |        |     |     |     |                |
| Dry frequency        | 84 | 1.0    | 1.0 | 3.0 | 0.0 | $<.001$        |
| Soreness frequency   | 84 | 1.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Burning frequency    | 84 | 1.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Fatigue frequency    | 84 | 1.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Dry severity         | 84 | 1.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Soreness severity    | 84 | 1.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Burning severity     | 84 | 1.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| Fatigue severity     | 84 | 1.0    | 0.0 | 2.0 | 0.0 | $<.001$        |
| SPEED total score    | 92 | 9.0    | 5.5 | 15.0| 0.0 | $<.001$        |
| 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.
The results of this study support those from Hovanesian et al. 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, $11.2 \pm 11.1$, 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. 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 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. 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. Interestingly, the mean Symptom Assessment in Dry Eye scores were reduced even further than they had been after the first treatment.

Karpecki et al. 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.

**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.**

| 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.
of treatment, and 83% of the subjects experienced clinically meaning-ful 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 me-dian 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 Badawi19 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. This 45°C external/41°C internal therapeutic temperature profile is specifically engineered to provide effective melting of abnormal meibum lipids while being safe for the patient. Blackie and colleagues 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. Limitations to the current analysis include use of a convenience sample, the lack of an a priori sample size analysis, unknown unconditional nature of the study, and consulting fees from Sight Sciences, Shire (Novartis), Allergan, Sun, and Johnson & Johnson. This study was funded by a grant from Sight Sciences.

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.

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