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ORIGINAL ARTICLE

A Comparison of an Eyelid-Warming Device to Traditional Compress Therapy

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ABSTRACT

Purpose. To assess the warming and humidifying effect and ocular safety of the Blephasteam® eyelid-warming device vs. warm and moist compresses in healthy volunteers.

Methods. Twenty subjects (8 females, 12 males; mean age 39.2 years) were included in the study. Temperature and relative humidity were measured over a period of 10 min at the lower eyelid margin of one randomly selected eye during application of the Blephasteam device and, 1 h later, during application of warm compresses (in a randomized order). Ocular signs and visual acuity were assessed before and after each application.

Results. The mean duration of warming (temperature ≥38°C) was significantly longer with Blephasteam than with compresses (7.5 vs. 1.0 min; $p < 0.01$). There was no significant difference between treatments in the duration of 100% relative humidity. Compared with pretreatment values, visual acuity significantly improved after Blephasteam treatment ($p < 0.05$) but significantly decreased after treatment with compresses ($p < 0.05$). Limbal redness, eyelid redness, and corneal staining scores all improved significantly after Blephasteam treatment ($p < 0.05$ for all). Ocular signs did not change after compress treatment except conjunctival redness, which was significantly increased ($p = 0.01$ vs. pretreatment).

Conclusions. The Blephasteam eyelid-warming device appeared to provide more effective warming than warm and moist compresses in a group of healthy volunteers. Visual acuity, limbal redness, and eyelid redness were improved after Blephasteam use but not after treatment with compresses.

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Key Words: dry eye syndromes, meibomian gland dysfunction, meibomian gland therapy, temperature, warm compress

Many patients report dry eye symptoms, such as stinging, burning, itching, light sensitivity, and blurry vision,[1–4] which limit quality of life and occupational productivity.[5,6] The lipid layer of the tear film maintains tear film stability,[7] and any change in quantity and/or quality of the lipid layer consequently results in evaporative dry eye.[8,9] Meibomian gland dysfunction (MGD) is one of the most common abnormalities in ophthalmic practice and is the major cause of abnormalities in the lipid layer of the tear film[10] and therefore of evaporative dry eye.[8] This dysfunction induces an obstruction of meibomian gland orifices leading to a decrease in meibum secretion which is essential for the lipid layer of the tear film; consequently, MGD causes a number of eye disorders including dry eye syndrome.[8] Conventional treatment options for MGD include topical lubricants and corticosteroids, topical and oral antibiotics, and eyelid warming and massage.[8,9,11] Historically, the application of warm compresses to the eyelids has been the standard treatment for MGD.[12–14] Studies have shown that treatment with warm compresses leads to improvements in tear film lipid layer thickness and tear film stability in patients with MGD.[12,15] However, the efficacy of warm compresses is variable, and long-term treatment is required to achieve adequate improvement of symptoms; therefore, patients frequently discontinue treatment.[16] To improve patient compliance, eyelid-warming devices have been developed to be more convenient to use than conventional warm compresses therapy.[16–18] Studies in patients with MGD have demonstrated that these devices lead to improvements in tear evaporation, tear film stability, and lipid layer thickness.[16,19–21] The novel

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Blephasteam® eyelid-warming device (Laboratoires Thea, Clermont Ferrand, France) has also been shown to improve tear film lipid layer thickness and ocular comfort in normal subjects and in patients with dry eye syndrome.[22–25]

The aim of this study was to investigate the warming and humidifying effect and ocular safety of the Blephasteam eyelid-warming device in healthy volunteers compared with warm and moist compresses.

MATERIALS AND METHODS

Inclusion and Exclusion Criteria

Subjects were randomly selected from the patient pool of the Horst Riede GmbH, Weinheim, Germany, for participation. Subjects were allowed to participate in the study if they would have fulfilled the inclusion criteria, which included written informed consent, at least 18 years old, healthy with regard to eyelid disease, and with normal ocular examination: best corrected visual acuity ≥6/6, normal tears non-invasive break-up time ≥10 s, and normal corneo-conjunctival surface with lissamine green. Exclusion criteria included pregnancy on self-report; breast feeding; any ocular or systemic pathology known to affect the tear film or ocular surface; abnormal ocular findings on initial examination; a history of ocular trauma, infection, or inflammation within the previous 3 months; a history of a recent acute illness with a recovery period within the 2 weeks before the inclusion visit (day 0); any ocular pathology such as keratitis, blepharitis, conjunctivitis, uveitis, and/or one of the following abnormalities or pathologies detected during slit-lamp examination (using Efron grading scale)[26]: conjunctival hyperaemia (score ≥2); limbal hyperaemia (score ≥2); upper lid redness (score ≥2); lower lid redness (score ≥2); corneal staining (score ≥2); MGD (score ≥1); blepharitis (score ≥1). Subjects did not have a previous experience of receiving warm compresses.

The non-invasive tear break-up time was measured at baseline using a Tearscope® (Keeler, Windsor, UK) applying a fine grid. The median of three consecutive measurements was noted.

No eye make-up was allowed to be worn on the day of the study or during the study. All procedures were conducted in accordance with the Declaration of Helsinki (1983), and approval for the study was granted by the Cardiff School of Optometry and Vision Sciences Ethics Committee.

Application of the Treatment

Blephasteam (Laboratoires Thea) consists of a pair of goggles (Fig. 1) with eyepieces that create a wet chamber combining heat and moisture. The moist heat released by Blephasteam melts the meibum and encourages its release from the glands.

The Blephasteam is an alternating current-supplied device having a specified heat-up period—colored lights indicate when the device was ready for use. In the study, the user inserted two disposable rings, which were moistened with sterile saline, inside each eyepiece to produce humidity. The subject's eyes did not come into contact with these rings. The device was worn for 10 min; this period is timed by the device.

Terry cloths (100% cotton, white, 530 g/m^2, Möve AG, Bietigheim, Germany) were used as warm compresses, folded three times. Warm compresses were warmed up in heated distilled water to achieve a maximum temperature of 41°C when being placed over the subjects' eyes. The temperature of the compresses was measured before they were applied. The subjects' eyes were closed while the compresses were applied during 10 min. Each subject

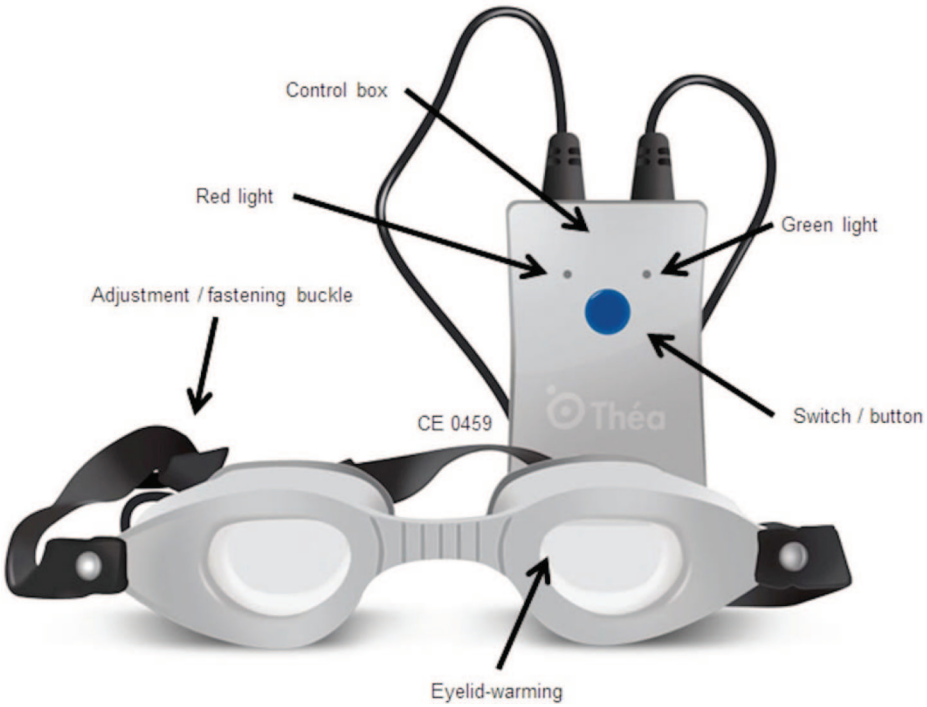

FIGURE 1. The Blephasteam eyelid-warming device. Reproduced with permission from Laboratories Thea. A color version of this figure is available online at www.optvissci.com.

used a new device and compresses; the distilled water was not reused.

Ambient room temperature and humidity were controlled by air condition to be stable over the complete study.

Efficacy Parameter

Measurement of Temperature and Humidity between Eyelid and Blephasteam or Compresses

A small thermo/humidity sensor (Driesen + Kern GmbH, Germany) was positioned in front of lower eyelid margin to measure humidity and temperature at that area provided by the warm compresses and the Blephasteam device. The sensor was connected via a multiplexer box to a computer to maintain continuous readings using the EK-H4 Viewer 1.0 (Sensirion AG, Staefa, Switzerland). Temperature and humidity were recorded every minute in 10 consecutive measurements over a period of 10 min in the lower eyelid margin area of one randomly selected eye during application of the Blephasteam device (A) and, 1 h later,[25,27] during application of warm and moist compresses (B). To exclude any order effect, order of treatment was randomized A-B or B-A (Fig. 2). The duration of warming and the duration of relative humidity of 100% were recorded for each subject. Duration of warming was defined to be the time in minutes when measured temperature was ≥38°C; duration of relative humidity was defined to be the time in minutes when measured humidity was 100%. Warming rate was calculated after collection of temperature and humidity data [(Max − Min)/time]. Blephasteam as well as compresses were not removed during the measurements.

Wellness After Treatment

An optional question about comfort was added to the protocol by the investigator. Subjects were asked to score their comfort immediately after treatment using a "wellness" scale from 0 to 10—a score of 0 represented "no wellness effect" and 10 represented "maximal wellness effect". Psychologically, subjects may feel Blephasteam to be more user friendly than the traditional warm compresses. To exclude such an effect, Blephasteam and warm compresses were applied to the subject by an assistant and order of application was randomized.

Safety Parameters

Ocular Surface Integrity (Slitlamp Examination)

Conjunctival and limbal hyperaemia, upper and lower lid redness, corneal staining (fluorescein and lissamine green), MGD, and blepharitis were assessed before and directly after application of the Blephasteam device or compresses, using a slitlamp microscope and classified using the Efron grading scale,[26] with increments of 0.1 of a unit.

Visual Acuity

Visual acuity was measured before and 5 min[28] after application of the Blephasteam device or compresses using logMAR eye charts at high contrast and low contrast. Visual acuity should be a marker of efficacy and safety.

Masking

All measurements were masked against the observer. Investigators conducting the pre- and post-treatment ophthalmic examinations were blind to study treatment because staff members at the clinic, not the study investigators, applied the Blephasteam device and compresses to the study subjects. Care was taken to avoid any signs on the face after application of the treatment—which would have unmasked the observer—by waiting 5 min before investigation. Subjects were instructed not to disclose device information to other staff members or any investigators. Subjects were masked against examinations.

Statistical Analyses

After the data were analyzed for normality, differences in ocular signs before and after treatment and differences in duration of warming and humidity between treatments were assessed using the paired t-test (or the non-parametric equivalent: Wilcoxon signed-rank test). Differences between the consecutive measurements during one treatment application were analyzed using the analysis of variance (or the non-parametric equivalent: Friedman's test).

RESULTS

Subjects

Twenty healthy volunteers (8 females and 12 males; mean age 39.2 ± 12.59 years and age range 22 to 60 years) were included in the study. As no significant differences in visual acuity and ocular signs were found between the right and left eyes at the initial examination ($p > 0.090$ for all; Table 1), only data from the right eyes were analyzed.

Temperature

The mean ± standard deviation (SD) temperature increased from 30.66 ± 1.956°C to 38.32 ± 1.189°C within the first 2

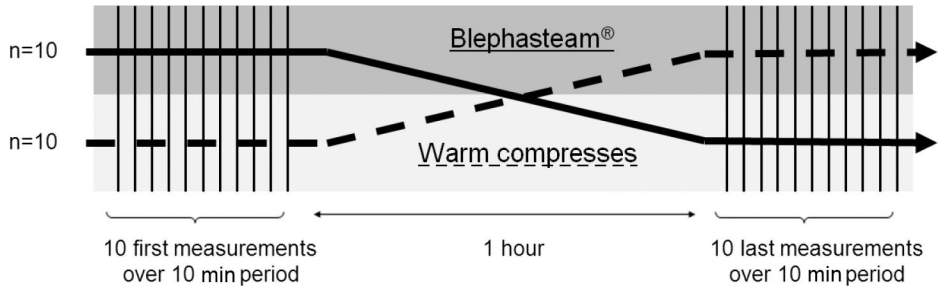

FIGURE 2. Illustration of randomized order of application and timing of application of the Blephasteam device and warm compresses (figure is not drawn to scale).

min during Blephasteam treatment (Fig. 3). Subsequently, the temperature increased slightly to reach a mean of 40.55 ± 0.982°C ($p < 0.001$ vs. baseline), resulting in a warming rate of about +0.28°C/min. The mean temperature increased from 30.58 ± 1.923°C to 38.16 ± 1.507°C during the first minute of warm compress treatment (Fig. 3). Subsequently, the mean temperature decreased rapidly to reach 34.73 ± 1.411°C ($p < 0.001$ vs. baseline), resulting in a cooling rate of about −0.44°C/min.

The mean eyelid temperature was not significantly different between the Blephasteam device and the compresses at 0 and 2 min ($p = 0.550$ and $p = 0.218$, respectively) but was significantly lower with the Blephasteam device at 1 min ($p = 0.030$) and was significantly higher with the Blephasteam device ($p < 0.001$) from 3 min onward (Fig. 3).

TABLE 1.
Visual acuity, ocular signs, and tear film stability in right (OD) and left (OS) eyes of 20 healthy volunteers at enrolment

	OD		OS	
	Mean	SD	Mean	SD
Visual acuity—high contrast	−0.02	0.093	−0.01	0.096
Visual acuity—low contrast	0.37	0.147	0.37	0.155
Conjunctival redness[a]	1.04	0.483	0.98	0.479
Limbal redness[a]	0.79	0.553	0.82	0.535
Upper lid redness[a]	0.89	0.559	0.92	0.530
Lower lid redness[a]	0.83	0.491	0.93	0.572
Corneal staining[a]	0.19	0.311	0.15	0.270
Meibomian gland dysfunction[a]	0.37	0.334	0.33	0.340
Blepharitis[a]	0.25	0.315	0.24	0.314
Lissamine green staining	0.15	0.366	0.20	0.410
Non-invasive tear break-up time	15.14	3.956	15.81	4.341

[a]EFRON grading scheme.

Humidity

Relative humidity measurements are shown in Fig. 4. There were significant differences in relative humidity between consecutive measurements at 0, 1, and 2 min for Blephasteam and at 0 and 1 min for the compresses ($p < 0.001$ for all comparisons), but there were no significant differences in relative humidity between subsequent measurements with either treatment.

Relative humidity was significantly higher with compresses at 1 min than with Blephasteam ($p = 0.017$), but there were no significant differences between treatments at all other time points ($p > 0.204$ for all comparisons; Fig. 4).

Duration of Warming and Humidifying

The mean ambient room temperature was 25.21 ± 0.70°C and the mean relative humidity was 33.38 ± 3.63%. The mean duration of warming was significantly longer with Blephasteam treatment than with compresses (7.50 ± 1.987 min vs. 1.00 ± 1.124 min; $p < 0.001$). The mean duration of a relative humidity of 100% was similar with Blephasteam and compresses (8.00 ± 1.214 min vs. 7.90 ± 2.245 min; $p = 0.551$).

Visual Acuity and Ocular Signs

Visual acuity significantly improved after Blephasteam treatment but significantly decreased after treatment with compresses ($p < 0.049$ vs. pretreatment values for both treatments; Table 2). Limbal redness, lid redness, and corneal staining scores all improved significantly from pretreatment values after treatment with Blephasteam ($p < 0.043$ for all; Table 2). No significant changes in ocular signs were observed after treatment with compresses except in the conjunctival redness score, which significantly increased ($p = 0.010$ vs. pretreatment) after application (Table 2).

Wellness Factor

The wellness factor was significantly higher after treatment with the Blephasteam device compared with the compresses ($p < 0.001$; Table 2).

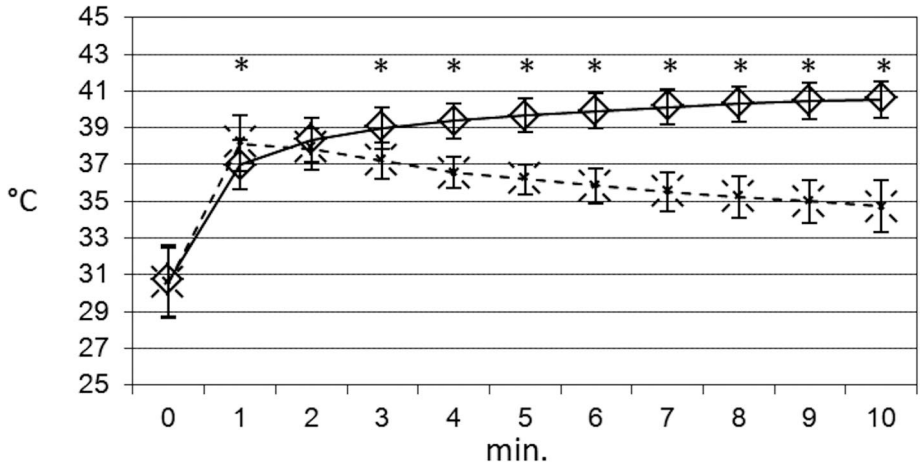

FIGURE 3. Eyelid mean temperature (°C) during treatment with the Blephasteam device and warm compresses. Solid line = Blephasteam, dashed line = compresses. Asterisks indicate significant differences in temperature between Blephasteam and compresses.

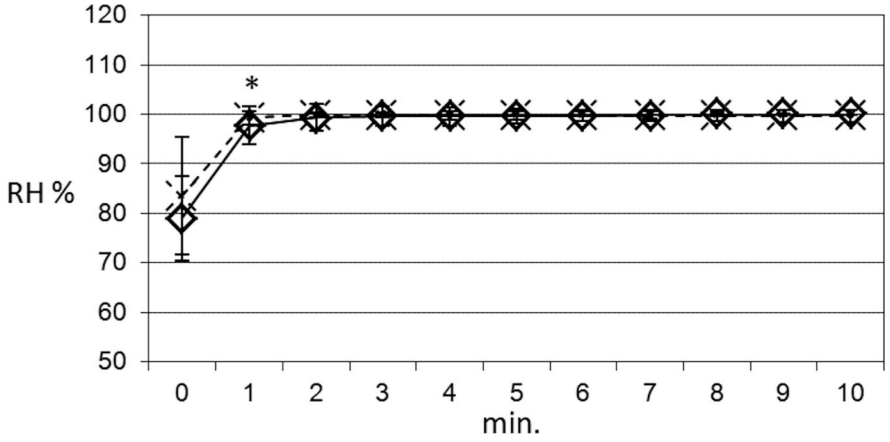

FIGURE 4. Eyelid mean relative humidity (RH; %) during treatment with the Blephasteam device and warm compresses. Solid line = Blephasteam, dashed line = compresses. Asterisks indicate significant differences in relative humidity between Blephasteam and compresses.

TABLE 2.
Visual acuity (logMAR) and ocular signs before and after treatment and wellness factor after treatment with the Blephasteam device and warm compresses

	Blephasteam device					Warm compresses				
	Before		After			Before		After		
	Mean	SD	Mean	SD	p	Mean	SD	Mean	SD	p
Visual acuity—high contrast	−0.01	0.089	−0.04	0.089	**0.049**[a]	−0.02	0.093	0.00	0.095	**0.016**[a]
Visual acuity—low contrast	0.36	0.148	0.30	0.188	**0.015**[a]	0.37	0.147	0.40	0.152	**0.040**[a]
Conjunctival redness[b]	1.02	0.376	0.90	0.688	0.319[a]	0.88	0.580	1.15	0.635	**0.010**[a]
Limbal redness[b]	0.76	0.422	0.57	0.442	**0.042**[a]	0.67	0.540	0.83	0.603	0.143[a]
Upper lid redness[b]	0.80	0.432	0.62	0.497	**0.016**[a]	0.80	0.620	0.93	0.731	0.160[a]
Lower lid redness[b]	0.77	0.411	0.59	0.484	**0.014**[a]	0.84	0.610	0.90	0.706	0.486[a]
Corneal staining[b]	0.15	0.295	0.09	0.207	**0.043**[c]	0.16	0.239	0.13	0.224	0.068[c]
Meibomian gland dysfunction[b]	0.22	0.297	0.28	0.322	0.419[c]	0.26	0.282	0.45	0.465	0.109[c]
Blepharitis[b]	0.24	0.373	0.18	0.300	0.110[c]	0.22	0.317	0.39	0.475	0.114[c]
Lissamine green staining	0.15	0.366	0.00	0.000	0.109[c]	0.05	0.224	0.10	0.308	0.317[c]
Wellness factor			7.60	1.698				3.90	2.693	<**0.001**[d]

Bold numbers indicate $p < 0.05$.
[a]Analyzed by paired t-test.
[b]EFRON grading scale.
[c]Analyzed by Wilcoxon signed-rank test.
[d]Comparison between Blephasteam device and warm compresses; analyzed by paired t-test.

DISCUSSION

The humidifying effect of the Blephasteam device and the warm compresses was generally similar and continued over the total period of application. However, the warming effect of the Blephasteam device was significantly better than the compresses. The Blephasteam offers constant warming over the application period, whereas the warm compresses are heated once and then cool off quickly. In patients with MGD, the melting point of meibum oil is increased; meibum from normal subjects melts at 32°C, whereas the melting point is >35°C in patients with MGD.[29,30] A constant warming of the meibomian glands to ≥38°C is vital to liquefy the meibum oil before eyelid massage.[30] The melting of meibum oil after warming is expected to lead to increased secretion of meibum oil[14] and consequently to have positive effects on the tear film lipid layer. At least 4 min of treatment with warm compresses is required to achieve an eyelid temperature of 40°C.[31] In our study, the Blephasteam device had a warming duration of 7.5 min, whereas the warming effect of the compresses was much shorter (1 min) and might be insufficient. When using warm compresses, patients may replace the compresses too often, start with compresses that are too hot, or stop the application too early. In these situations, the recommended mild eyelid massage will either be insufficient, as the meibum oil is still too viscous, or too forceful. Compresses that are too warm and massage too forcefully can harm the ocular surface.[32]

The significant improvement of the high- and low-contrast visual acuity after application of Blephasteam in this study might provide further, albeit indirect, evidence for a positive effect of Blephasteam. This effect, which was probably minimized due to the measuring of visual acuity 5 min after Blephasteam or compress removal, might be due to changes of the lipid layer[7] and/or changes

of the cornea integrity.[28] This positive effect was not found after treatment with compresses, probably because of the short warming effect. Moreover, warm compresses can induce visual degradation.[28] The lipid layer has an important effect on visual function by stabilizing the tear film[7] and providing a smooth optical surface.[29] Patients with dry eye syndrome commonly report visual complaints such as blurry vision[3] and have impaired visual acuity.[33] It was not evaluated in this study whether the lipid layer was improved after Blephasteam. However, since warming and humidity do have effects on lipid layer,[21,34] this explanation is plausible. The insufficient effect in lid warming of warm compresses was also reported by Lane et al.[17] comparing LipiFlow with warm compresses in the treatment of MGD. LipiFlow is an "in-office" treatment system combining lid warming and automatically lid massage, while Blephasteam can easily be applied by patients themselves at home.

The positive effect on visual acuity of Blephasteam might also be considered as a safety criterion.[28] It can be speculated that the potential ability of the Blephasteam device to improve visual acuity in patients with MGD would be of interesting clinical significance.

Ocular signs improved after treatment with Blephasteam even in these normal patients but either showed no significant change or worsened after treatment with compresses. Although these changes have limited clinical significance, these results suggest that the Blephasteam device is a well-tolerated treatment method.

Previous studies in patients with MGD have demonstrated that warm compresses improve tear stability[15] and tear film lipid layer thickness.[12] Similarly, various types of devices, including a disposable eyelid-warming device,[20] an infrared warm compression device,[16] and a warm moist air device,[21] have been shown to improve tear stability, dry eye symptoms, ocular comfort, and thickness of the tear film lipid layer in patients with MGD. As stated above, the Blephasteam device appears to also have these positive effects.

Compliance with eyelid warming and massage is often discussed by clinicians. Interestingly, in our study, subject-rated comfort was nearly twice as high after Blephasteam treatment as after treatment with compresses. This could be because the compresses are awkward to handle. During treatment with Blephasteam, the patient is also able to blink, which promotes meibomian oil release, allowing tear film restoration.[35] Even if the patient did not proceed with accurate eyelid massage and hygiene immediately after Blephasteam application, re-production of the meibomian oil in the glands is expected to be more effective than with compresses.[32]

A possible limitation of this study is that the application of the warm compresses may not have allowed optimal warming. This could partly explain the difference in the warming effect between the Blephasteam device and the compresses. To achieve maximum efficacy for the treatment of MGD, warm compresses should be heated to about 45°C and frequently changed to maintain the temperature.[31] In our study, the compresses were heated to a maximum of 41°C and were not changed.

CONCLUSIONS

The Blephasteam eyelid-warming device has a significantly greater warming effect than warm and moist compresses in healthy volunteers. Although Blephasteam and the compresses have a similar humidifying effect, the very short warming effect with the compresses may be insufficient for adequate treatment of MGD. Furthermore, application of Blephasteam significantly improves ocular signs and visual acuity, suggesting that this is a safe treatment method. A longitudinal study investigating habitual use of Blephasteam and compresses in patients with MGD would be useful to confirm the findings of this study.

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