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ORIGINAL ARTICLE

Tear Film with "Orgahexa EyeMasks" in Patients with Meibomian Gland Dysfunction

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ABSTRACT

Purpose. To evaluate the efficacy of a new Orgahexa eye warmer mask for patients with simple meibomian gland dysfunction (MGD) in a prospective comparative study.

Methods. Twenty right eyes of 20 patients with simple MGD, and 22 right eyes of 22 healthy controls were studied. Subjects were allocated to Orgahexa or conventional eye mask wear for 10 min (short-term study), and for 2 weeks (long-term study). Eyelid temperature measurements, slit lamp examination, tear film break-up time, Schirmer test, vital staining, tear film lipid layer interferometry, and dry eye symptomatology scoring with visual analog scales were performed.

Results. The Orgahexa eye warmer improved both tear function and ocular surface status, and decreased symptoms significantly without any complications.

Conclusions. The Orgahexa eye warmer is a simple, safe, and convenient method, which seems to improve the ocular surface status and tear functions in patients with simple MGD.
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Key Words: meibomian gland dysfunction, tear stability, tear lipid layer, eye warming

Meibomian gland dysfunction (MGD), associated with inflammation, obstruction, or abnormal secretion of the meibomian glands, is extremely common and yet often overlooked in ophthalmic practices.[1] The prevalence of MGD is regarded to be 33% in subjects younger than 30 years and 71.1% in those 60 years or older.[2] MGD has been reported to induce increased tear evaporation and decreased tear stability.[3] Current treatment options available for MGD include thermal and mechanical techniques designed to express inspissated meibomian secretions, topical antibiotics, and steroid eyedrops and ointments as well as systemic antibiotics and hormonal (androgen) therapies.[1,3]

Eyelid warming is one of the fundamental treatments for MGD. Previously, we reported the efficacy of various devices to warm the eyelids of patients with MGD.[4–6] In this study, we evaluated the efficacy of a newly developed eye mask, Orgahexa eye warmer, on tear functions and ocular surface status of patients with simple MGD.

METHODS

Subjects and Examinations

Twenty right eyes of 20 patients (8 males, 12 females; mean age 54.5 years) with simple MGD and 22 right eyes of 22 healthy control subjects (9 males, 13 females; 48.6 years) were enrolled in this prospective unmasked non-randomized study. Ten patients with MGD were allocated to eye warming with Orgahexa eye warmer masks and 10 patients were allocated to conventional eye masks. Likewise, 11 control subjects underwent eye warming with Orgahexa eye warmer masks and 11 healthy controls received eye warming with conventional eye masks. Masks were applied in patients and the control subjects for 10 min to study the effects on eyelid temperature and tear functions in a short-term study and overnight during sleep for 2 weeks in a long-term study. The patients in the current study received the mask wear protocol without any other topical medication. The change in tear function and ocular surface status as well as changes in symptomatology with eye warming were evaluated by slit lamp examination, tear film break-up time (BUT) measurements, Schirmer test, fluorescein and rose bengal staining scores, and visual analog scale (VAS) scores both in short- and long-term studies. None of the patients or controls had a history of Stevens-Johnson syndrome, chemical, thermal, or radiation injury, nor other systemic disorder, nor had undergone any ocular surgery or procedure that would create an ocular surface problem. Subjects in this study also did not have a history of any prescription or over-the-counter topical and/or systemic drug use or contact lens wear that could alter the ocular surface and tear function status. At ocular examination, particular attention was paid to the lid margins, tarsal and bulbar conjunctiva, and corneas. MGD was assessed by careful slit lamp examination of the gland orifices, mucocutaneous junction changes, and by digital expression of meibomian lipids. The same physician (YM) pressed gently on the upper and lower eyelids to express the meibomian lipids. Meibum viscosity was graded as described by Shimazaki et al.[7] Briefly, the degree of expression was evaluated semi-quantitatively as follows: grade 0, clear non-viscous meibum expressed easily; grade 1, cloudy slightly viscous meibum expressed with mild pressure; grade 2, cloudy viscous meibum expressed with more than moderate pressure; and grade 3, meibum cannot be expressed even with intense pressure. Only patients with simple MGD were included in this study. The criteria for the diagnosis of simple MGD[3] were described as follows: (1) occluded meibomian gland orifices, (2) cloudy or inspissated glandular secretion with lack of clear meibum secretion after the application of moderate digital pressure on the tarsus of the upper and lower eye lid, (3) presence of keratinization or displacement of the mucocutaneous junction, (4) absence of inflammatory lid disease such as blepharitis, as well as inflammatory skin disorders such as atopic dermatitis, seborrhea sicca, and acne rosacea, (5) absence of history and clinical findings of cicatricial eyelid and conjunctival diseases such as trachoma, erythema multiforme, ocular cicatricial pemphigoid, chemical, thermal, or radiation injury, and (6) absence of excessive meibomian lipid secretion (seborrheic MGD). Temperature and humidity of the examination room were maintained at a range from 20 to 24°C (68 to 75°F) and 30 to 50%, respectively during the short- and long-term trials. All patients were recruited in this study with written informed consent. The examination procedures were also ethic board reviewed and approved.

Measurement of Eyelid Temperatures

The temperature of the eyelids was measured with a contact digital record thermometer (TNA 120, Tasco Co, Tokyo, Japan) which was kept in direct contact with the medial canthal eyelid skin for 3 min before and after eye warming in the short- and long-term studies. The device could measure temperatures between −100°C (148°F) and 1200°C (2192°F) with a resolution sensitivity of 0.1°C (0.2°F). The measurement response time was <1.5 s, i.e., the thermometer digital display response time (as described by the manufacturer) was <1.5 s with the readings showing a gradual increase over 1 min with eventual stabilization. Considering the cooling effect after the mask removal, we continued measuring the eyelid temperature for an additional 2 min after stabilization of the eyelid temperature. The subjects were instructed to measure their own eyelid temperatures and bring the print-outs of the thermometer digital displays with them. In the long-term study, temperature measurements were performed after the last night of wear immediately upon mask removal. All subjects had scheduled appointments on the morning of the last night of mask wear for further ocular surface and tear function examinations. No two patients had appointments on the same day.

DR-1 Tear Film Lipid Layer Interferometry

DR-1 interferometry (Kowa, Tokyo, Japan) observes the specular reflected light from the tear surface. Light from a white light source is reflected by a half mirror, focused by a lens, and then used to illuminate the tear surface. The specular reflected light from the tear surface returns through the half mirror to a charge coupled device camera that produces the image on the device monitor. Two polarizers and a quarter-wave plate help eliminate unnecessary reflected light from the lens and detect only the specular reflected light from the tear fluid. The camera is focused on a 2.2 mm × 3.0 mm area of the central cornea such that a circular area 2 mm in diameter is observable. Lipid layer interference images were recorded soon after a complete blink. The classification of tear lipid layer patterns have been described previously elsewhere.[8] The change of the interference pattern from uniform gray color to many colors of non-uniform distribution indicates expression of lipids into the tear film in DR-1 lipid layer interferometry.[8]

Tear Function Examinations

The standard tear film BUT measurement was performed after instillation of 2 μl of 1% fluorescein preservative free solution in the conjunctival sac with a micropipette. The subjects were then instructed to blink several times for a few seconds to ensure adequate mixing of the dye. The interval between the last complete blink and the appearance of the first corneal black spot in the stained tear film was measured three times and the mean value of the measurements was calculated. A tear film BUT value of <5 s was considered abnormal.

For further evaluation of tears, the standard Schirmer test without topical anesthesia was performed. The sterilized strips of filter paper (Alcon Laboratories, TX) were placed in the lateral canthus away from the cornea and left in place for 5 min. Readings were recorded in millimeters of wetting for 5 min.

Ocular Surface Evaluation

Fluorescein and rose bengal stain scoring of the ocular surface was also performed by the double vital staining method. The rose bengal and fluorescein staining scores of the ocular surface ranged between 0 and 9 points. The van Bijsterveld scoring system was used for rose bengal staining. Briefly, the ocular surface was divided into three zones: nasal conjunctival, corneal, and temporal conjunctival areas. A staining score between 0 and 3 points was employed in each zone with the minimum and maximum total staining scores ranging between 0 and 9 points. Presence of scarce punctate staining received 1 point. Presence of denser staining not covering the entire zone received 2 points. Presence of rose bengal staining over the entire zone received 3 points. In fluorescein staining, the cornea was divided into three equal upper, middle, and lower zones. Each zone had a staining score ranging between 0 and 3 points with the minimum and maximum total staining scores ranging between 0 and 9 points. Likewise, the presence of scarce staining in one zone was scored as 1 point whereas punctate staining covering the entire zone was scored as 3 points.

Evaluation of Ocular Symptoms

Dry eye and ocular fatigue symptomatology was evaluated with the VAS. The questionnaire included symptomatology such as tiredness, dryness sensation, and ocular discomfort. Absence of any symptom constituted a 0 point score on the VAS whereas intense unbearable symptoms constituted a full score of 100 points. Briefly, the VAS was prepared as 10-cm lines and the patients were asked to check a point on the line corresponding to their degree of symptom. Participants completed the VAS sheets before and after mask application.[9] Higher scores on the VAS referred to a more severe degree of symptomatology in this study.

Statistical Analysis

Age and gender differences between the groups were tested by t-test and χ^2 tests. A Kruskal Wallis test was employed to test the changes in VAS score, Schirmer test, vital staining scores, tear film BUT, DR-1 tear film lipid layer interferometry, and lid temperatures with eye mask application. The type of eye warmer used was masked to the statistician (MK) performing the analyses. The differences were considered statistically significant if the p-values were below 0.05.

The Orgahexa Eye Warmer Mask

The Orgahexa fiber material is produced by burning 100% cotton at high temperatures to obtain pure coal, and the resultant carbon fibers are then woven into a fiber mesh cloth holes the diameter of a pore. The Orgahexa eye warmer, made of natural carbon fiber (Orgahexa fiber), releases far-infrared radiation indefinitely when exposed to body heat, which then warms the mask.

Although the Orgahexa fiber material and sheets are commercially available, the Orgahexa eye warmer masks used in this study were only for preliminary research purposes (Therath Medico, Tokyo, Japan). The diameter of carbon fibers used for weaving is 8 μm and the diameter of the pores in the woven material is between 12 and 25 Å. Organic carbon fiber materials are being used as medical devices such as operating table warmer sheets and warming knee supporters. Fig. 1A, B shows the application of organic carbon fiber (Orgahexa) eye warmer mask and a conventional eye mask in a representative subject. The outer surface and the straps of Orgahexa fiber masks are made of 100% polyester, where the middle layer and the inner surface attached to the inner meshwork applied to the eyelid surface contains 100% Orgahexa fiber material. Elemental analysis of the material as provided by the research laboratory showed that the material contains 48.3% carbon, 6.15% hydrogen, approximately 0.07% nitrogen and 46.3% oxygen. The lower section of Orgahexa eye warmer masks did not have any cloth covering the nose area (Fig. 1C). The outer and inner surfaces of the conventional masks were made of cotton and nylon with additional cloth to cover the nose area (Fig. 1D). The middle layer under the inner surface contained a thin cardboard sheet and cotton blackout fabric within the body of the mask. The straps are

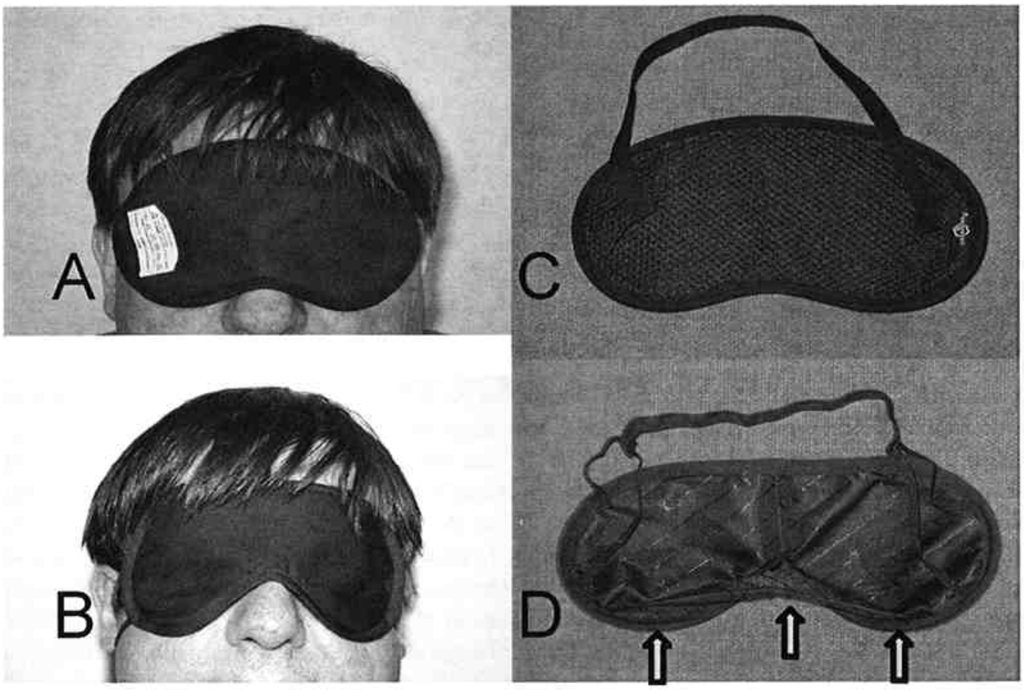

FIGURE 1.

A and B, Application of organic carbon fiber (Orgahexa) eye warmer mask and a conventional eye mask in a consenting subject, respectively. Masks were worn for 10 min and overnight during sleeping in short-term and long-term studies. C, The outer surface and the straps of Orgahexa fiber masks are made of 100% polyester where the middle layer and the inner surface attached to the inner meshwork applied to eyelid surface contains 100% Orgahexa fiber material. Note the absence of material to cover the nose area at the lower end of the Orgahexa eye warmer masks, resulting in a tight fit around the eyes. D, The outer and inner surfaces of the conventional masks were made of cotton and nylon with additional cloth inferiorly to cover the nose area (arrows). A color version of this figure is available online at www.optvissci.com.

TABLE 1.
The changes in mean VAS symptom scores in MGD patients before and after treatment who underwent both short- and long-term studies

Total symptom scores	Time of examination		
	Before	After 10 min	After 2 weeks
Orgahexa eye warmer mask group	50.6 ± 30.1	41.9 ± 21.3[a]	18.8 ± 17.5[a,b]
Conventional mask group	52.3 ± 25.7	48.5 ± 10.3	48.1 ± 20.6

Mean ± standard deviation.
[a] $p < 0.05$ compared with the value before the treatment.
[b] $p < 0.05$ compared with the value between 10 min. and 2 weeks treatment.

made of nylon and thin elastic. Masks were worn for 10 min in the short-term study and overnight during sleep in the long-term study. Patients did not know which type of mask they were using in this study.

RESULTS

There were no significant age and gender differences between patients with MGD and control subjects in this study.

VAS Symptom Scores

VAS scores showed significant improvement in both short-term (pre-Orgahexa mask wear mean VAS score: 50.6 ± 30.1; post-Orgahexa mask wear mean VAS score: 41.9 ± 21.3) and long-term studies (post-Orgahexa mask wear mean VAS score: 18.8 ± 17.5) in patients with MGD after eye warming with Orgahexa eye warmer masks whereas no significant differences could be observed with conventional eye masks (Table 1).

Eyelid Temperatures

Temperature measurements of the eyelids revealed that 10 min of Orgahexa eye warmer application provided an average increase of 0.8 ± 0.4°C (1.6 ± 0.8°F) in patients with MGD ($p < 0.001$) and an increase of 0.8 ± 0.7°C (1.6 ± 1.4°F) in normal subjects ($p < 0.001$). Two weeks' wear was associated with a mean lid temperature increase of 1.2 ± 0.2°C (2.4 ± 0.4°F) in patients with MGD and a mean increase of 0.72 ± 0.4°C (1.44 ± 0.8°F) in normal subjects. Eyelid temperature alterations with Orgahexa and conventional eye masks are shown in Fig. 2. The temperature increases from baseline at 10 min and 2 weeks in Orgahexa eye warmer mask wearers in the right eyes of each individual MGD patient and control subject is shown in Table 2. The temperature increase from baseline was more consistent with little variation at 2 weeks in the eyes of patients with MGD and although a warming effect was present, the extent was lesser and more variable in healthy controls at 2 weeks.

Meibum Viscosity Grade

The mean meibum viscosity grades (MVGs) before, 10 min and 2 weeks after Orgahexa eye warmer mask application in patients with MGD were 2.8 ± 0.6, 2.52 ± 0.4 and 1.9 ± 0.6, respectively. The decrease in viscosity grade at 2 weeks was statistically significant when compared to the baseline value before the trial and the mean grade after 10 min of eye warming ($p < 0.05$). There were no significant differences between the MVGs with conventional mask applications in patients with MGD (mean MVG before Orgahexa mask application: 2.75 ± 0.2, MVG at 10 min: 2.6 ± 0.2, MVG at 2 weeks: 2.8 ± 0.4). Likewise, the mean MVGs in normal subjects before the short- and long-term eye warming trials with conventional masks were 1.0 ± 0.5, and no significant differences could be observed with conventional masks at 10 min or 2 weeks (data not shown).

Tear Function and Ocular Surface Vital Staining Findings

The mean baseline (pre-Orgahexa mask wear) tear film BUT, fluorescein, rose bengal staining scores, and DR-1 grades were 3.0 ± 1.6 s, 2.9 ± 1.1 points, 3.2 ± 0.8 points, and 3.5 ± 0.5 in MGD patients (Table 3), respectively. Although not shown in a different figure or table, all these values were statistically worse compared to the baseline values in the healthy control subjects (tear film BUT: 9.9 ± 3.2 s, mean fluorescein score: 0.8 ± 0.8 points, mean rose bengal score: 0.1 ± 0.2 points, mean DR-1 grade: 2.0 ± 1.0) ($p < 0.05$). The mean tear film BUT was significantly prolonged from the baseline value of 3.0 ± 1.6 s to 10.5 ± 4.6 s in the long-term study patients with MGD who wore Orgahexa eye warmer masks ($p < 0.05$). The mean fluorescein and rose bengal staining scores improved significantly from the baseline values (mean fluorescein staining score: 2.9 ± 1.1 points, mean rose bengal staining score: 3.2 ± 0.8 points) at the end of the 2 weeks of Orgahexa eye warmer mask wear, respectively (mean fluorescein staining score: 1.0 ± 0.2 points, mean rose bengal staining score: 1.4 ± 0.5 points). Likewise, the mean lipid layer interferometry grades also improved significantly over 2 weeks in patients with MGD who wore the Orgahexa eye warmer masks (prewear mean DR-1 grade: 3.5 ± 0.5; postwear mean DR-1 grade: 2.0 ± 0.5) ($p < 0.05$). Although not shown in a different table or figure, there were no significant differences between the mean tear film BUT, mean fluorescein staining scores, Schirmer test values, and DR-1 grades after 2 weeks of eyelid warming with the Orgahexa eye warmer masks in MGD patients when compared to the baseline values (before Orgahexa eye mask wear) in the healthy control subjects. The only exception was the mean rose bengal score which was significantly higher after the long-term study in MGD patients (1.4 ± 0.5) compared to the baseline rose bengal score in healthy control subjects (0.1 ± 0.2). There were no significant differences in relation to tear functions and vital staining scores in control subjects who wore the Orgahexa eye warmer masks in both short- and long-term studies ($p > 0.05$). Likewise, no significant differences in relation to tear functions and vital staining scores could be observed in short- and long-term trials both in MGD patients and control subjects who wore the conventional masks as shown in Table 3. All subjects completed both

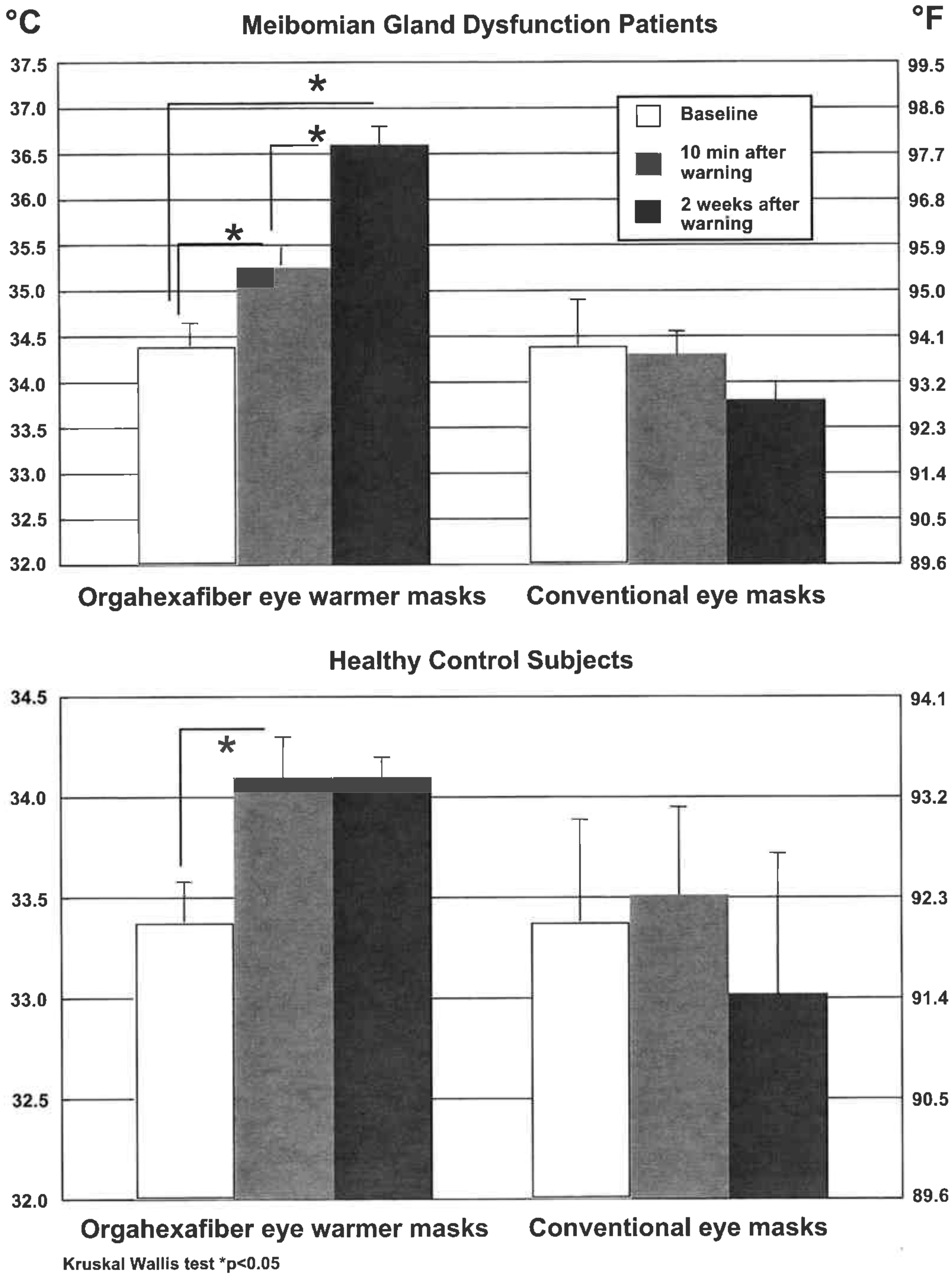

FIGURE 2.
Eyelid temperature alterations with Orgahexa and conventional eye masks in short- and long-term studies in MGD patients and healthy control subjects.

short- and long-term studies, and no side effects related to mask wear were observed.

DISCUSSION

MGD has been reported to result in alteration and/or reduction of lipid secretions leading to increased tear evaporation, decreased tear stability, loss of lubrication, and damage to the ocular surface epithelium, resulting in dry eye symptomatology. The conventional treatment of MGD consists of lid hygiene, warm compresses, topical and systemic antibiotics, topical steroids, artificial tears, and castor oil eyedrops as well as systemic androgen therapies.[1,10,11]

Among the aforementioned treatment modalities, warm compress therapy has become a standard treatment for MGD. Warm towel compresses applied to the skin of the closed eyelids for 5 min have been reported to increase the tear film lipid layer thickness by more than 80% in obstructive MGD patients with an additional 20% increase after 15 min of treatment.[12] The increase in tear film lipid layer thickness in that study was found to be significantly related to reduction of symptom scores. Goto et al. reported in-

TABLE 2.
Eyelid temperature increases (°C/°F) from baseline at 10 min and 2 weeks in Orgahexa eye warmer mask wearers in the right eyes of each MGD patient and control subject

	MGD patients		Controls	
	10 min	2 weeks	10 min	2 weeks
Case 1	1.0 (2.0)	1.2 (2.4)	0.1 (0.2)	0.3 (0.6)
Case 2	1.8 (3.6)	2.0 (4.0)	1.4 (2.8)	1.0 (2.0)
Case 3	0.5 (1.0)	1.2 (2.4)	0.2 (0.4)	0.5 (1.0)
Case 4	0.6 (1.2)	1.2 (2.4)	1.4 (2.8)	0.6 (1.2)
Case 5	0.8 (1.6)	1.2 (2.4)	0.2 (0.4)	0.4 (0.8)
Case 6	0.5 (1.0)	1.2 (2.4)	1.8 (3.6)	1.5 (3.0)
Case 7	0.8 (1.6)	1.2 (2.4)	0.3 (0.6)	0.4 (0.8)
Case 8	0.8 (1.6)	1.2 (2.4)	1.5 (3.0)	1.2 (3.0)
Case 9	0.4 (0.8)	1.2 (2.4)	0.1 (0.2)	0.4 (0.8)
Case 10	1.0 (2.0)	1.2 (2.4)	1.5 (3.0)	1.1 (2.2)
Case 11	—	—	0.3 (0.6)	0.6 (1.2)
Mean ± SD	0.8 ± 0.4 (1.6 ± 0.8)	1.2 ± 0.2 (2.4 ± 0.4)	0.8 ± 0.7 (1.6 ± 1.4)	0.72 ± 0.40 (1.44 ± 0.8)

TABLE 3.
The changes of tear functions and ocular surface status in MGD patients and controls with Orgahexa eye warmer and conventional eye masks in short- and long-term studies

	Orgahexa eye warmer masks			Conventional eye masks		
	Before	10 min	2 weeks	Before	10 min	2 weeks
MGD patients						
BUT (s)	3.0 ± 1.6	3.4 ± 1.2	$10.5 \pm 4.6^{a,b}$	3.5 ± 0.5	3.0 ± 1.5	2.8 ± 1.2
FS (pts)	2.9 ± 1.1	2.8 ± 1.2	$1.0 \pm 0.2^{a,b}$	3.1 ± 1.4	3.2 ± 1.4	3.0 ± 1.0
RB (pts)	3.2 ± 0.8	3.0 ± 0.5	$1.4 \pm 0.5^{a,b}$	3.5 ± 1.6	3.4 ± 1.0	4.0 ± 1.5
Schirmer (mm)	7.0 ± 1.5	8.1 ± 1.5	9.0 ± 1.0	8.0 ± 1.0	8.5 ± 2.5	9.0 ± 2.0
DR-1 grade	3.5 ± 0.5	4.0 ± 0.5	$2.0 \pm 0.5^{a,b}$	4.0 ± 1.0	4.0 ± 1.0	3.75 ± 1.0
Controls						
BUT (sec)	9.9 ± 3.2	10 ± 1.2	8.5 ± 3.5	8.8 ± 3.5	7.9 ± 1.1	9.2 ± 1.5
FS (pts)	0.8 ± 0.8	0.8 ± 0.8	0.5 ± 0.2	3.1 ± 1.4	3.2 ± 1.4	3.0 ± 1.0
RB (pts)	0.1 ± 0.2	0.1 ± 0.2	0.2 ± 0.1	0 ± 0	0 ± 0	0 ± 0
Schirmer (mm)	17.9 ± 2.9	18.1 ± 2.5	19.0 ± 1.5	22 ± 10	20 ± 5	21.5 ± 11.5
DR-1 grade	2.0 ± 1.0	2.5 ± 1.0	2.0 ± 0.5	2.0 ± 1.0	2.0 ± 1.0	2.5 ± 0.5

Kruskal Wallis test $^{a}p < 0.05$ compared with the value before treatment.
$^{b}p < 0.05$ comparison between the values at 10 min and 2 weeks.
BUT, break-up time; FS, fluorescein staining; RB, rose bengal staining.

creased tear stability and decreased dry eye symptomatology after 2 weeks of treatment with an infrared warmer device applied to the eyelids 5 min twice a day in obstructive MGD patients.[5]

Recently, Matsumoto et al. evaluated the safety and short-term effects of an original warm moist air device on tear function and ocular surface of patients with simple MGD by measuring the tear film BUT, Schirmer test, tear film lipid layer thickness, vital staining scores, and assessing the VAS scores before and 10 min after application while also comparing the outcome measures with those of healthy control subjects. In that study, warm moist air application was observed to be associated with significant improvement of tear stability and symptom scores in MGD patients in the short-term and also over 2 weeks.[6] The therapeutic efficacy of different eye warming treatment modalities, however, may be limited by patient compliance. Eye warming in MGD usually requires continuous compliance over a long period of time to achieve satisfactory results and patients may discontinue treatment. Therefore, there is a need for more convenient methods of performing warm compression. In this study, we evaluated the Orgahexa fiber eye warmer mask made of coal fibers obtained from cotton burnt at high temperatures and woven into a mesh material from which the masks were made. Orgahexa fiber materials are used in medicine as sheets to cover operating tables in hospitals, and as warming knee supports releasing far-infrared radiation when exposed to body temperature.

It has been reported that MGD is associated with decreased meibum secretions.[13,14] Shine and McCulley suggested that meibomian secretions with ester fractions of different composition can have different melting points and that MGD can cause a shift toward lipids with higher melting points producing a stagnant and less dynamic tear film.[15,16] Indeed, meibomian secretions from normal subjects have been shown to begin to melt at 32°C (90°F) and at 35°C (95°F) in patients with obstructive MGD.[1] The maximum eyelid temperature after 2 weeks of warming by the Orgahexa warmer eye masks was 36.8°C (98.2°F) which we believe could melt the meibomian lipids. The mean eyelid temperature increases from baseline attained with Orgahexa eye warmer masks in MGD patients after 10 min and 2 weeks of warming were 0.8 ± 0.4°C and 1.2 ± 0.2°C, respectively. The mean eyelid temperature increase with the Orgahexa eye warmer masks for the current short-term study is lower than the range of eyelid warming described for infrared heater after a warming period of 10 min (1.9 ± 3.6°C/3.8 ± 7.2°F) .[4,5] The mean eyelid temperature increase after 2 weeks of eyelid warming by the Orgahexa masks was comparable to the increase of 1°C described for the warm moist air device by Matsumoto et al.[6]

In this study, we showed that the Orgahexa eye warmer provided warming of the eyelids, better expressibility of meibomian lipids with eventual attainment of better lipid layer interferometry grades, concomitant increase of tear stability, and decrease of dry eye symptoms in patients with simple MGD without use of other medications. We attribute these findings to warming of the eyelids, which melts the meibomian lipids to ease the release into the tear film, and decreased tear evaporation (although not measured in the current study) with an overall improvement in the ocular surface health. Indeed, the tear function and ocular surface vital staining scores and DR-1 grades were significantly worse in MGD patients when compared to control subjects before Orgahexa eye warmer mask applications. After 2 weeks of eye warming with the Orgahexa masks, we did not observe any significant differences between the aforementioned parameters in MGD patients and the baseline values in the healthy controls suggesting improvement of the ocular surface health except the rose bengal score. Absence of the aforementioned improvements in patients and controls using conventional eye masks also strengthen our belief on the favorable effects of Orgahexa eye warmer treatment on the ocular surface. When eyelid temperature change from the baseline value with Orgahexa eye warmer mask use was studied in the right eyes of each MGD patient and control subject, it was observed that the temperature increase from baseline was more consistent with little variation at 2 weeks in eyes of patients with MGD, and although a warming effect was present, the extent was less and more variable in healthy controls at 2 weeks. These findings may be explained by the possible differences of eyelid thickness and vascularity between the two groups, differences of absorption of the amount of heat radiated by the masks by the altered meibum composition, differences of exposure/contact areas between the masks and eyelid surfaces, all of which should be investigated in future trials.

We did not observe significant changes in tear functions, especially in the lipid layer of control subjects using Orgahexa eye warmer masks, and attributed this finding to differences of lipid expression in the control subjects compared to patients with MGD in addition to aforementioned differences. The current study could not be carried out with a double-blind randomized protocol because the Orgahexa fiber eye warmer and conventional masks had obvious design and appearance differences, the authors were not supplied with conventional eye masks of exactly the same shape and size as the Orgahexa eye warmer masks by the research facility, and because the conventional masks arrived later than the trial initiation date (Therath Medico, Tokyo, Japan). Thus, it should be noted that the absence of masking and a randomized design might have been associated with biases on the results of the current study. Yet, the study provided objective evidence of good efficacy of Orgahexa eye warmer masks in warming the eyelids and in improving the ocular surface health status in MGD patients when compared to conventional masks. A possible explanation for the favorable effects on the tear functions and ocular surface epithelium in MGD patients may be a better warming effect by the Orgahexa material (which needs to be confirmed in future prospective trials employing thermography) and compression of the eyelids by the mask expressing the lipids into the tear film over 2 weeks. We observed that most commercially available conventional masks, including all conventional masks used in this study, had extra cloth covering the nose leading to a loose fit around the eyes, which may very well decrease the contact between the mask and the eyelids and may even decrease the warming effects of such masks. Future prospective trials testing the effect of Orgahexa eye warmer mask applications on a larger number of subjects in double-blind trials and comparing the clinical outcomes with other treatment modalities would provide essential and interesting information. Although we do not expect long-term maintenance of the favorable effects on the ocular surface with cessation of Orgahexa fiber eye warmer mask wear, future studies with a cross-over design looking into the alterations of tear functions and ocular surface status with termination of Orgahexa eye warmer mask application might reveal invaluable information about the duration or persistence of favorable mask effects on the ocular surface health.

In summary, Orgahexa mask wear during sleep seemed to be an effective mode of treatment for MGD. All patients completed both short- and long-term trials wearing the masks successfully during sleep. The simplicity of application, significant amelioration of tear and ocular surface health, and minimization of patient discomfort may make Orgahexa eye warmers a safe and recommendable treatment option for MGD.

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