

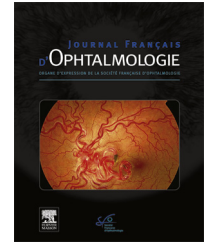


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ORIGINAL ARTICLE

Evaluation of an eyelid warming device (Blephasteam[®]) for the management of ocular surface diseases in France: The ESPOIR study

Évaluation de Blephasteam[®], lunettes chauffantes à chaleur humide, dans la prise en charge des pathologies de la surface oculaire en France

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KEYWORDS

Meibomian gland dysfunction;
Eyelid hygiene

Summary

Introduction. — Eyelid hygiene, including massage and warm compresses, is an important part of the treatment and prevention of Meibomian gland dysfunction (MGD). Although effective, it requires active participation of the patient and lacks standardisation. Blephasteam® is a medical device designed to warm and humidify the eyelid with heating glasses, in order to liquify meibum, thus relieving symptoms and preventing relapse.

Materials and methods. — The ESPOIR study (Evaluation of the Satisfaction of Patients with Management of Ocular Surface Diseases) presented herein was designed to evaluate the safety and efficacy of this medical device in patients with MGD. A total of 28 French centers participated in the study. One hundred and two patients presenting with symptomatic dysfunction or Meibomian-related dry eye underwent two sessions per day with the eyelid warming device and recorded diary entries on a number of parameters every 2 days for the first week and then weekly for the remaining 2 weeks. Patients were assessed on days 0 and 21.

Results. — Symptomatology, as recorded on a visual analogue scale (VAS) by the investigator (the primary efficacy variable) was significantly ($P < 0.001$) improved at the end of the study (59.97, 95% CI 55.64–64.30 vs. 39.71, 95% CI 34.78–44.65 on Days 0 and 21 respectively), as was the mean symptoms score (mean decrease of 19.93 ± 22.15 VAS units; $P < 0.001$), hyperemia score (-1.57 ± 1.96 and -1.45 ± 1.85 ; $P < 0.001$, in the worse and contralateral eye respectively), and quality of meibum (mean -4.03 ± 3.08 ; $P < 0.001$ and -3.32 ± 3.20 ; $P < 0.01$, in the worse and contralateral eye respectively). More than twice as many reported their symptoms had improved or disappeared compared with those whose symptoms had not changed or had worsened. Global symptomatology, as assessed by the patients, declined throughout the study, and a large majority of patients were satisfied or very satisfied with the treatment. Clear vision and blinking were not impaired during use of the eyelid warming device, which insures proper spreading of the tear film, and patients were able to continue daily activities such as reading and watching television. No adverse events were reported, and there were no changes in intraocular pressure or visual acuity. Safety was rated as satisfactory or very satisfactory by more than 95% of the investigators.

Conclusion. — The study suggests that the eyelid warming device is safe and effective in reducing ocular discomfort and symptoms in MGD.

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MOTS CLÉS

Dysfonctions des glandes de Meibomius ;
Hygiène des paupières

Résumé

Introduction. — L'hygiène des paupières incluant le massage et l'apport de chaleur par compresses chaudes, est un élément important de la prévention et du traitement des dysfonctions des glandes de Meibomius. Bien qu'efficace cette technique implique une participation active du patient et souffre de manque de standardisation. Blephasteam® est un dispositif médical ; les lunettes chauffantes, délivrent une chaleur humide constante sur les paupières afin de liquéfier le meibum et permettre un soulagement des symptômes et la prévention des rechutes.

Matériel et méthodes. — L'étude ESPOIR (Évaluation de la satisfaction des patients vis-à-vis de la prise en charge des pathologies de surface oculaire) présentée, ici, avait pour objectif d'évaluer l'efficacité et la tolérance de ce dispositif médical chez les patients souffrant de dysfonctionnement des glandes de Meibomius (MGD). Un total de 28 centres français ont participé à l'étude. Cent deux patients présentant un dysfonctionnement symptomatique ou une sécheresse oculaire liée aux glandes de Meibomius ont été inclus. Les patients ont bénéficié de deux sessions quotidiennes de dispositif médical et ont recueilli sur un agenda personnel, un ensemble de paramètres, tous les deux jours la première semaine et ensuite de façon hebdomadaire pour les deux semaines restantes.

Résultats. — La symptomatologie évaluée à l'aide d'une échelle visuelle analogique (EVA) par l'investigateur (critère principal) s'est montrée significativement ($p < 0,001$) améliorée en fin d'étude (59,97, 95 % CI 55,64–64,30 vs. 39,71, 95 % CI 34,78–44,65 à j0 et j21 respectivement), en parallèle avec le score moyen de symptômes (diminution moyenne de $19,93 \pm 22,15$ mm sur l'EVA ; $p < 0,001$), le score d'hyperémie ($-1,57 \pm 1,96$ et $-1,45 \pm 1,85$; $p < 0,001$ pour respectivement, l'œil le plus atteint et l'œil controlatéral), et la qualité du meibum (diminution moyenne de $-4,03 \pm 3,08$; $p < 0,001$ et $-3,32 \pm 3,20$; $p < 0,01$, pour respectivement, l'œil le plus atteint et l'œil controlatéral). Plus du double de patients ont rapporté que leurs symptômes s'étaient améliorés ou avaient disparu par rapport à ceux dont les symptômes étaient soit



inchangés, soit aggravés. La symptomatologie globale évaluée par les patients a diminué tout au long de l'étude et une large majorité de patients ont été satisfaits ou très satisfaits du traitement. Avec les lunettes, la vision n'est pas réduite et le clignement des paupières est maintenu, ce qui favorise l'étalement du film lacrymal. Les patients ont pu continuer leurs activités quotidiennes comme la lecture ou le fait de regarder la télévision. Aucun effet indésirable n'a été rapporté et il n'y a pas eu de modifications de la pression intra-oculaire ou de l'acuité visuelle. La tolérance a été jugée satisfaisante ou très satisfaisante par plus de 95 % des investigateurs.

Conclusion. – Cette étude suggère que le dispositif médical est efficace et bien toléré dans l'amélioration du confort oculaire et des symptômes liés aux MGD.

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Introduction

The meibomian glands are modified sebaceous glands located in the tarsal plate of the eyelids. Their role is to actively synthesise and secrete lipids and proteins that promote stability of the tear film and, most importantly, to prevent its evaporation [1]. Meibomian gland dysfunction (MGD) is defined as a chronic, diffuse abnormality of the meibomian glands, commonly characterised by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion [2]. It may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease [2]. MGD is a major cause of dry eye disease [1]. Ocular symptoms include mild to persistent irritation, itching, burning, stinging, light sensitivity and blurred vision. The feeling of having the eyelids glued shut on waking is a major discomfort. The symptoms of MGD are a consequence of impaired quality or quantity of meibum provided to the ocular surface. When the meibomian acini become blocked or their function is otherwise impaired, the meibum produced has a deteriorated lipid structure with more branched chain fatty acids and cholesterol. This meibum has poorer physicochemical properties (more waxy and viscous) and is less effective in maintaining the tear film [3].

Treatments options for MGD include lid hygiene, lubricants, topical or systemic antibiotics, and topical steroids [4]. Lid hygiene, which includes eyelid warming using warm compresses, infrared or hot air sources and mechanical lid hygiene, is the mainstay of treatment. In patients with MGD the melting point of the meibum is raised from 32 °C to > 35 °C [5]. The aim of lid hygiene is to warm the eyelids up to 40 °C, to melt the meibum and facilitate its clearance through the application of pressure or massage. However, non-compliance with this approach is common due to the complexity of this process, inadequate eyelid warming and the requirement for long-term treatment.

Eyelid warming devices have been developed to overcome these barriers to treatment. Encouraging results have been observed with a novel eyelid warming device (Blephasteam®; Laboratoires Théa, Clermont-Ferrand, France), with improvements in tear film lipid layer thickness and ocular comfort in normal subjects and patients with dry eye disease [6,7] and may offer benefits over traditional compress therapy [8].

The aim of this multicentre study (Evaluation of Satisfaction Regarding Patient's Management of Ocular Surface Diseases, ESPOIR) was to collect information from patients

and ophthalmologists in order to investigate the efficacy and safety of the eyelid warming device in the management of patients with MGD in France. The ESPOIR study was conducted in Paris and Clermont-Ferrand, and the ESPOIR extension study was performed in 25 centres in France.

Methods

This prospective, open-label, uncontrolled, phase IV, study took place in a total of 28 centres in France. The ESPOIR study was conducted in accordance with Good Clinical Practice guidelines (ICH Guidelines and European directive 2001/20/CE) and the Declaration of Helsinki (2004). All patients provided written informed consent prior to participating in the study which was approved on March 2nd 2010 by the Ethics Committee "Comité de protection des personnes île-de-France V".

The primary objective of the study was to collect information from patients and ophthalmologists (involved in ocular surface and eyelid diseases) to validate the use of the eyelid warming device in the management of ocular surface diseases. Secondary objectives were: evaluation of the efficacy and acceptability of the eyelid warming device; to obtain information on treatment patterns and management of patients with symptomatic MGD and/or dry eye related to MGD; to collect information from patients and ophthalmologists on how to optimise the use of the eyelid warming device.

Inclusion and exclusion criteria

Patients with symptomatic MGD and/or dry eye related to MGD, which had been stable for at least one month, were eligible for inclusion in the study. Exclusion criteria included any of the following in either eye: active pathology requiring a change in ocular treatment within the previous month; history of surgical events, including refractive surgery, within the last 6 months; any ocular anomaly interfering with the ocular surface; best far corrected visual acuity (VA) \leq 1/10; history of trauma or infection within the previous 3 months; clinically relevant flare at inclusion. Patients with any medical or surgical history, disorder or disease, judged by the investigator to be incompatible with the study, or who had a known hypersensitivity to a component of the test products,

or who had participated in another clinical study within the last 3 months were also excluded.

Study treatment

The eyelid warming device under investigation consists of a pair of glasses, the eyepieces of which create a warm moist chamber (Fig. 1). This latent heat melts the meibum facilitating its release from the glands. The alternating current-supplied device is plugged in for 15 minutes before use; coloured lights indicate when the device is ready for use. Two disposable rings moistened with drinking water are inserted into each eyepiece, and the device worn for 10 minutes; the device times this period and provides constant moist heat therapy.

Patients were treated with the eyelid warming device twice a day for 21 days, allowing at least 4 hours between each session.

Concomitant use of tear substitutes was permitted; however, eye drops were not to be used for at least 15 minutes before or after the use of the eyelid warming device and contact lenses had to be removed during its application.

Efficacy parameters

At study entry (Visit 1; Day 0) investigators recorded details of patients' ocular medical history and treatment and ocular symptoms (recorded on a visual analogue scale) and signs (slit lamp examination, lid margin examination, visual acuity, tear osmolarity, and intraocular pressure). Patients were reassessed at the end-of-study visit, which took place at 21 days \pm 2 days (Visit 2; Day 21). Details of the study procedures conducted at Visits 1 and 2 are included in Table 1.

Patients were asked to complete a diary at day 0, 2, 4, 6, 12 and 20. Patients recorded details of: severity of ocular symptoms within the last 48 hours and in the morning; comfort during use of the eyelid warming device; and global efficacy assessment (Table 2).

Primary efficacy variable

The primary efficacy parameter was the evaluation of symptomatology, for both eyes together, within the last 48 hours

using a Visual Analogue Scale (VAS) on Day 21. Patients were asked by the investigator to "Please mark a vertical line on the horizontal line, indicating your level of ocular discomfort". The scale ranged from 0 mm = No discomfort to 100 mm = Maximal discomfort.

Secondary efficacy variables

Investigator-conducted assessments

Ocular symptoms during the past 48 hours were recorded on a 0–3 scale and comprising, burning and stinging sensation, sensitivity to light, watering, visual fatigue, grittiness, and erythematous/inflamed eyelids, best far and near visual acuity, refraction, tear film assessment (by TearLab®), Slit lamp examination, lid margin examination, fluorescein test including tear break-up time, Lissamine green test and Schirmer test and were undertaken on Day 0 before application of the eyelid warming device and on Day 21. In addition, tear film assessment and lid margin examination were undertaken on Day 0 after the use of the eyelid warming device.

Best far and near visual acuity

Measured for both eyes separately with the patient's best correction using a Snellen chart.

Slit lamp examination

Each eye was examined separately for bulbar conjunctival hyperaemia, and scored from 1 (normal) to 6 (very severe) points using a modified ordinal McMonnies photographic scale [9].

Chemosis, watering, conjunctival discharge, palpebral edema, folliculo-papillary conjunctivitis, anterior chamber flare, and other abnormalities, were scored on a 4-point ordinal score.

Lid margin examination

The quality of the meibum and severity of lid scales or crusts, lid redness, lid swelling and meibomian gland plugging were assessed on Days 0 (before and after use of the eyelid warming device) and 21. The quality of the meibum was scored according to the following 5-point scale: 0 = Fluid and clear aspect; 1 = Turbid; 2 = Granular; 3 = Pasty; 4 = Complete meibomian block.

The severity of lid scales or crusts, lid redness, lid swelling and meibomian gland plugging were graded from



Figure 1. The Blephasteam® eyelid warming device. The device comprises a pair of goggles, a control box and power supply. Moisture is provided by wetted disposable pads.

Table 1 Study assessments conducted by ophthalmologist at Visits 1 and 2.

Study procedures	Visit 1—Day 0		Visit 2—Day 21
	Before device application	After device application	
Symptomatology within the last 48 hours (VAS)	X		X
Ocular symptoms	X		X
Best far and near visual acuity	X		X
Refraction	X		X
Tear film assessment (tearlab)	X	X	X
Slit lamp examination	X		X
Lid margin examination	X	X	X
Fluorescein test and break up time measurement	X		X
Lissamine green test	X		X
Schirmer test	X		X
Tonometry	X	X	X
Global assessment of safety and efficacy			X
Adverse events		X	X

Table 2 Patient diary self assessment items.

	Day 0	Day 6	Day 12	Day 20
Ocular symptoms within the last 48 hours		X	X	X
Morning ocular symptoms		X	X	X
Comfort during the eyelid warming device use		X	X	X
Global efficacy assessment				X
Device optimisation questionnaire	X			X

VAS: Visual Analogue Scale; VA: visual acuity.

0 to 4: 0 = None; 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Very severe.

A total meibomitis score was obtained for each eye ranging from 0 to 20.

Fluorescein test including tear break-up time (BUT)

Each eye was examined separately after the application of Fluo Plus® (GECIS sarl, Neung sur Beuvron, France) and rated on a 4-point ordinal scale. BUT was measured three times for each eye separately and the mean of the three measurements was the value analyzed.

Lissamine green test

Assessment of punctuation by means of Lissamine Green Staining performed in each eye, in each of the 3 parts of the corneo-conjunctival exposed surface, on Days 0 and 21, making use of a 4-point ordinal scale. The analysis was based on the sum of the scores for the three parts.

Schirmer test

The Schirmer test is conducted in each eye separately.

Osmolarity

Tear film osmolarity was determined in each eye using a TearLab® (Tearlab Inc, San Diego, USA) device.

Subject-conducted assessments

Patients completed a diary to record:

- global symptoms in the last 48 hours: on Days 0 (before device application), 2, 4, 6, 12 and 20;
- global assessment of morning ocular symptoms: recorded on a 0–3 scale comprising, eyes scratched and burnt, painful eyes, watery eyes, visual fatigue, sandy feeling, red and irritated eyelids, crusts and secretions, and others. Recorded on Days 0 (before the application of the eyelid warming device, 2, 4, 6, 12 and 20);
- assessment of comfort: recorded on Days 2, 4, 6, 12 and 20 and including whether eyes were kept closed during the session, ability to read, watch television, use computer and perform other activities and improvements or deterioration in these activities;
- global efficacy assessment: recorded on Day 21 including benefit of the treatment based on the evolution of symptoms and ease of use (each assessed on a 4-point ordinal scale).

Global efficacy assessment by the patient

Patients were asked the following question during and after use of the eyelid warming device use on Day 20: “On the whole were you satisfied with the comfort provided by the eyelid warming device goggles during/after your sessions?” Patients were also asked the following question: “On the whole, were you satisfied with this treatment?” The responses were rated as follows: 0 = Very satisfied;

1 = Satisfied; 2 = No opinion; 3 = Rather dissatisfied; 4 = Very dissatisfied.

Safety parameters

The safety of the eyelid warming device was assessed using corrected VA and overall assessment by investigators. Best far corrected VA was measured for both eyes separately using a Snellen chart on Days 0 and 21. Investigators were asked the following question on Day 21, "After 21 days of use, how do you consider the safety of the eyelid warming device?" Responses were measured on a scale of 0 to 3 where: 0 = Very satisfactory; 1 = Satisfactory; 2 = Unsatisfactory; 3 = Very unsatisfactory.

Intraocular pressure was measured on Day 0 before and after application of the eyelid warming device and on day 21.

All adverse events occurring during the study were recorded and the relationship to the eyelid warming device and severity were determined by the investigator.

Statistical analysis

The efficacy and safety results were evaluated using the intention-to-treat (ITT) dataset, that was all patients enrolled in the study for whom there was evidence that they used the eyelid warming device and for whom any follow-up information was available.

Descriptive statistics were used for the quantitative variables and frequency distribution for the categorical variables. The symptomatology VAS between baseline (Day 0, before device application) and each post-baseline value were compared using a paired *t*-test. The statistical analyses were performed using SAS software for WINDOWS, version 9.2 or later, and statistical tests performed two-sided at the 5% significance level.

For the data recorded in both eyes, the analysis was performed separately for the worse eye and the other eye. The worse eye was defined as the eligible eye with the highest total score for the lid margin examination on Day 0 (sum of score from five examinations). If both eyes were eligible, and had the same total score, the right eye was selected.

Not all study centres were equipped to perform all the tests, for this reason the numbers of patients assessed for some parameters is lower than planned.

Results

A total of 102 patients (36 males, 66 females) with a mean age of 54.5 years \pm 20.8 from 28 centres in France were eligible for inclusion in this study. The mean time since MGD diagnosis was 38.0 \pm 49.2 months. MGD was the primary diagnosis in 49 patients and a secondary diagnosis in 53 patients (33 acne rosacea, 3 atopy, 1 psoriasis, 3 seborrheic dermatitis, 1 seborrheic dermatitis and acne rosacea, 12 others who had a secondary diagnosis of MGD), but without a determined cause (such as acne rosacea or atopy). Two of the patients wore contact lens wearers.

Efficacy

Primary efficacy variable

Symptomatology, as scored on the 0–100 VAS, was significantly ($P < 0.001$) lower on Day 21 than on Day 0 (59.97, 95% CI 55.64–64.30 vs. 39.71, 95% CI 34.78–44.65 on Days 0 and 21 respectively; 102 and 96 Patients respectively were evaluated in the intent to treat sample) (Fig. 2).

The mean symptomatology score as rated by a VAS fell significantly during the course of the study (mean decrease of 19.93 \pm 22.15 VAS units; $P < 0.001$). The proportion of patients without disturbing ocular symptoms also declined significantly during the study (Fig. 3).

Secondary efficacy variables

Investigator-conducted assessments

Slit lamp examination

The proportion of patients with normal/mild (score 1 and 2) bulbar conjunctival hyperaemia increased from Day 0 to Day 21 with a consequent reduction in patients with scores of 4 and 5 (Fig. 4). There was a significant improvement in the mean total hyperaemia score (-1.57 ± 1.96 in the worse eye and -1.45 ± 1.85 in the contralateral eye; both $P < 0.001$) between Days 0 and 21. By the end of the study there were no patients with hyperaemia of the most severe category.

Lid margin examination

The improvement in the quality of meibum is illustrated in Fig. 4 showing a consistent increase in the proportion of patients with meibum of fluid and clear aspect, and a corresponding reduction in the proportion of patients with granular or pasty meibum and complete meibomian block. Improvements were apparent after treatment on day 0, and particularly at the end of the study (Fig. 5).

The evolution of individual symptoms (lid scales or crusts, lid redness, lid swelling and meibomian gland plugging) is shown in Fig. 5. There was a significant improvement in the total meibomitis score from Day 0 to Day 21 in the worse

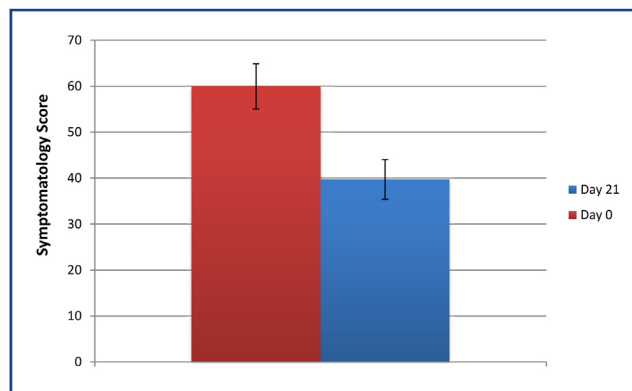


Figure 2. Symptomatology score. The symptomatology score was recorded by the investigator on a 0–100 visual analogue score at Day 0 and Day 21 (primary efficacy variable). Patients were asked "Please mark a vertical line on the horizontal line, indicating your level of ocular discomfort". The scale ranged from 0 mm = No discomfort to 100 mm = Maximal discomfort. Columns show mean values of 102 and 96 patients respectively, error bars show 95% CI.

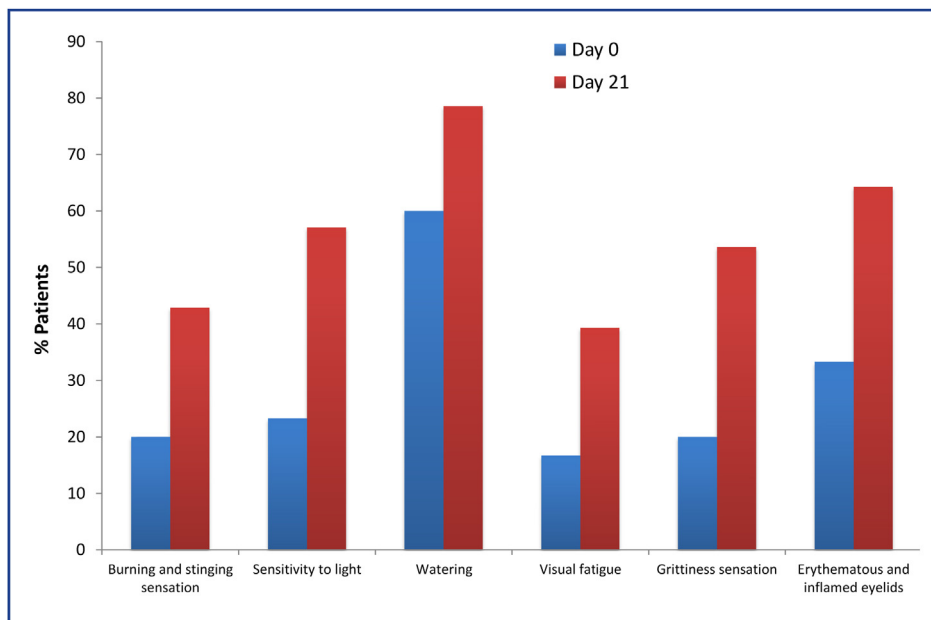


Figure 3. Ocular symptoms. Patients were queried by the investigator regarding ocular symptoms (burning and stinging sensation, sensitivity to light, watering, visual fatigue, grittiness, and erythematous/inflamed eyelids) experienced during the previous 48 hours on days 0 and 21.

eye (mean -4.03 ± 3.08 ; $P < 0.001$) and the contralateral eye (mean -3.32 ± 3.20 ; $P < 0.01$) (Fig. 6).

Fluorescein and BUT

Tear film break-up time was measured in 29 patients at Day 0 and 29 patients at Day 21. There were not significant changes in this parameter (8.41, 95% CI 6.29–10.53 and 8.24, 95% CI 6.62–9.87, at Days 0 and 21 respectively in the worse eye and 8.28, 95% CI 6.19–10.36 and 8.52, 95% CI 6.46–10.58, respectively in the contralateral eye), however mean BUT values at baseline were relatively high.

The frequency of punctate epithelial keratitis (mainly mild) decreased slightly; from 37.9 to 32.1% in the worse eye and from 31 to 21.4% in the contralateral eye.

Lissamine green

Lissamine green staining global score declined during the study (from 2.47, 95% CI 1.58–3.35 to 1.68, 95% CI 0.92–2.44 in the worse eye and from 2.2, 95% CI 1.27–3.13 to 1.54, 95% CI 0.78–2.29 in the contralateral eye). Only 30 and 28 patients were assessed at Days 0 and 21 respectively.

Schirmer

Schirmer test was undertaken in 28 patients at Day 0 and 27 patients at Day 21. There were no significant changes in the worse eye (14.36, 95% CI 10.49–18.22 and 14.41, 95% CI 10.45–18.38) at Days 0 and 21, respectively, and in the contralateral eye (14.93, 95% CI 11.23–18.63 and 13.96, 95% CI

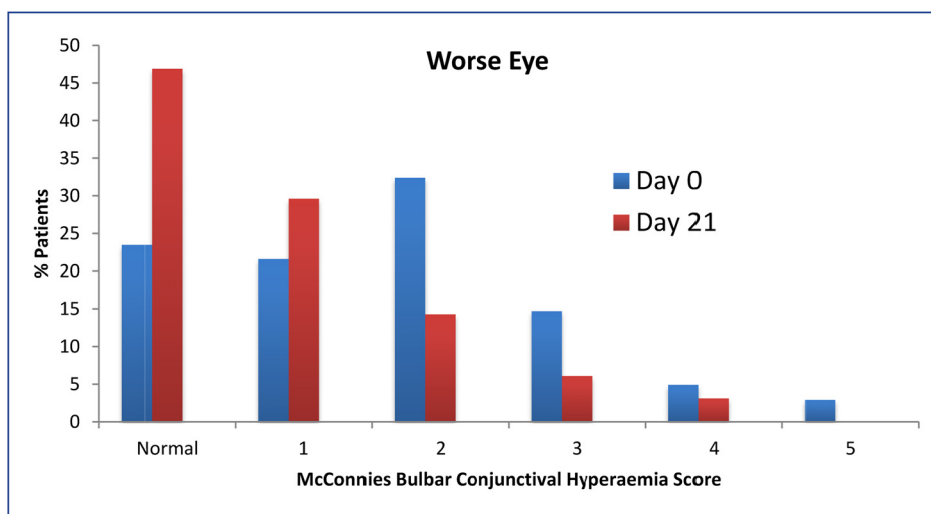


Figure 4. Conjunctival hyperaemia. Conjunctival hyperaemia assessed using the ordinal McMonnies photographic scale by slit lamp examination. Symptoms were scored from 0 (normal) to 5 (severe) on Days 0 and 21.

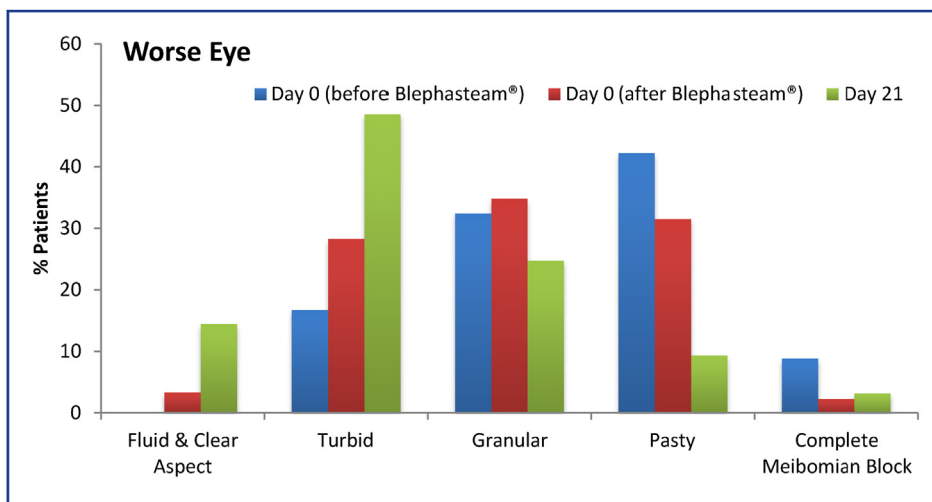


Figure 5. Meibum quality. The quality of meibum was assessed at ophthalmological examination on Days 0 and 21. Data presented are from the worse eye.

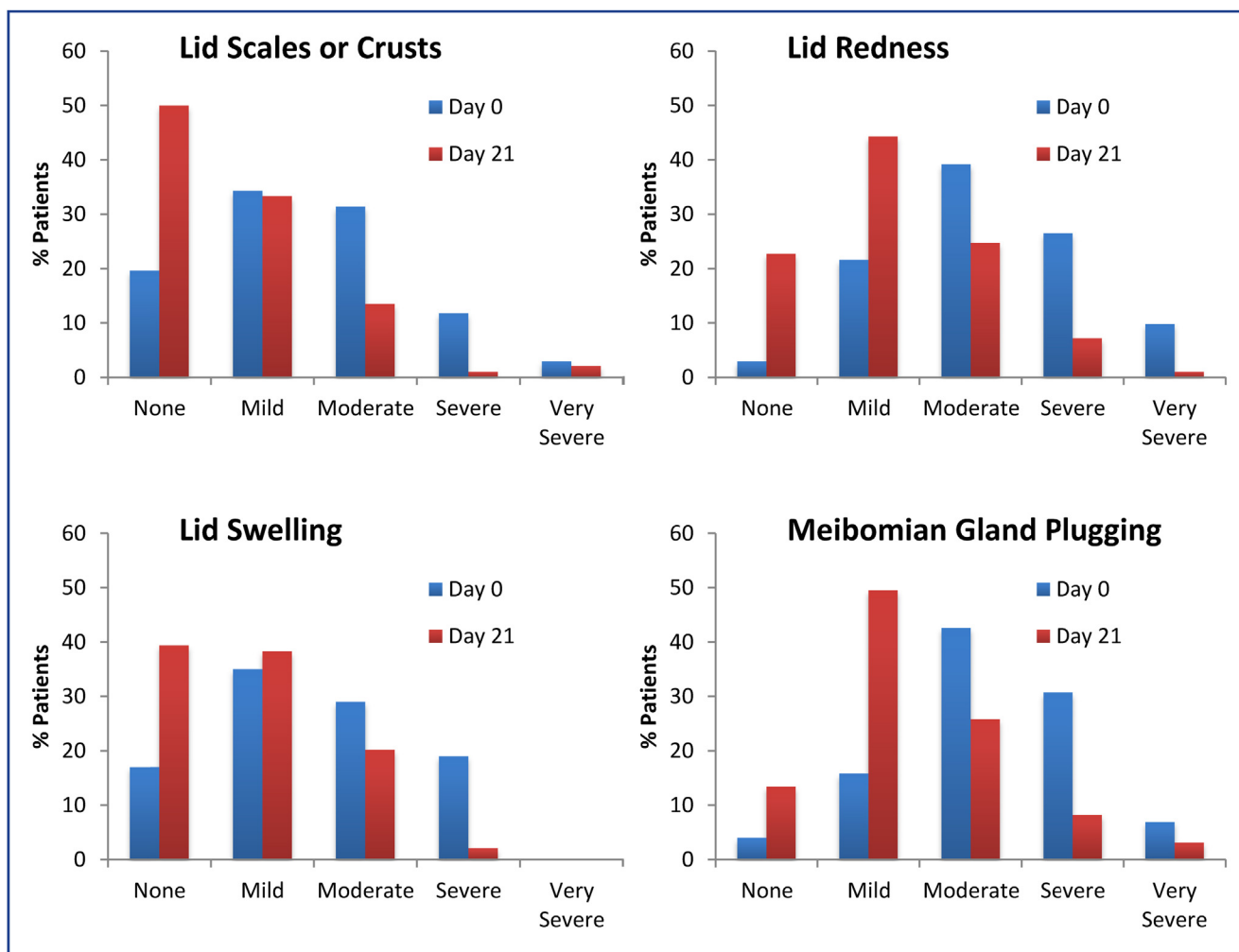


Figure 6. Lid margin examination. Individual symptoms (lid scales or crusts, lid redness, lid swelling and Meibomian gland plugging) were assessed as “None”, “Mild”, “Moderate”, “Severe” or “Very severe” at ophthalmological examination on Day 0 and Day 21. Data presented are those from the worse eye.

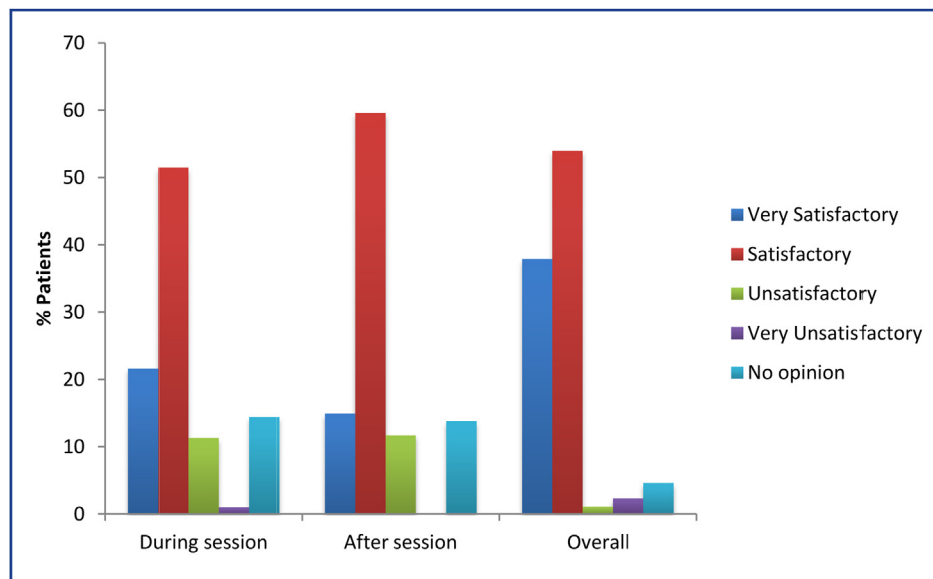


Figure 7. Global efficacy. Patients responded to the question “On the whole, were you satisfied with the comfort provided by the eyelid warming device goggles during/after your sessions?” and “On the whole, were you satisfied with this treatment?” using a 0–4 ordinal scale: 0 = Very satisfied; 1 = Satisfied; 2 = No opinion; 3 = Rather dissatisfied; 4 = Very dissatisfied.

9.86–18.07, at Days 0 and 21 respectively), mean Schirmer at baseline being relatively high.

Osmolarity

Tear film osmolarity reduced slightly on Day 0 after administration of the eyelid warming device (from 299, 95% CI 292–306, $n=29$ to 291, 95% CI 286–297, $n=26$ in the worse eye and from 297, 95% CI 290–304, $n=28$ to 293, 95% CI 283–302, $n=24$) in the contralateral eye. A small degree of reduction in tear film osmolarity was sustained at Day 21 (294, 95% CI 286–303, $n=24$ and 294, 95% CI 288–301, $n=25$) in the worse and contralateral eye, respectively.

Global efficacy assessment by the investigator based on evolution of symptoms

Of the 99 patients assessed, more than twice as many reported their symptoms had improved or disappeared (69.7%), compared with those whose symptoms had not changed or worsened (30.3%).

Subject-conducted assessments

Subjective ocular symptoms

Global symptomatology, rated on a VAS, declined during the course of the study (Fig. 6) and the proportion of patients without disturbing ocular symptoms increased during the study.

Global efficacy assessment by the patient

Overall, 92% (80/87) of patients were satisfied or very satisfied (54% [47/87] or 37.9% [33/87], respectively) with the treatment (Fig. 7). Fifty-four percent of patients said they planned to purchase the device in the future as a complement to their existing therapy whilst 32.9% said they would continue with their usual treatment alone or were thinking of following an entirely different treatment (12.2%).

Safety

There was no significant difference in corrected VA on Days 0 and 21 (mean change 0.2 ± 0.99). Overall, 95.9% (94/98) of investigators rated the safety of the eyelid warming device as satisfactory (50.0%, [49/98]) or very satisfactory (45.9% [45/98]). Of the four patients in whom the investigator rated the safety as less than satisfactory, one patient had an inflamed eyelid, one had lack of efficacy, one had missing data and no reason was recorded for the other. No adverse events were observed during the study and intraocular pressure did not increase during the study.

Discussion

Disorders of the eyelid are among the most common pathologies encountered in routine ophthalmological practice. Despite a growing understanding of the interacting pathologies that give rise to this group of disorders [10,11], eyelid hygiene and eyelid health in general remain the cornerstones of treatment and prevention [12]. The anatomical location of the lacrimal functional unit renders it less available to routine hygiene than the rest of the face. In patients with disorders of the eyelid, massage and cleansing are important, but may be insufficient to increase the flow from partially or completely blocked meibomian glands. The application of warm compresses is the most usual means of eyelid warming, but is likely to be poorly standardised in terms of duration, temperature and application technique.

The eyelid warming device provides a standardised approach to the treatment of MGD, with the application of an evenly heated ($\leq 40^\circ\text{C}$) and humid atmosphere at an appropriate and stable temperature, and a principal objective of improving the fluidity and quality of meibum.

This was not a controlled study and therefore the efficacy results should be considered with a degree of caution.

A proper controlled study is somewhat problematic with a device such as the Blephasteam®. Nevertheless, the results demonstrate that use of the eyelid warming device leads to an improvement in several aspects of ocular symptomatology compared with the baseline situation and overall satisfaction with treatment in patients with MGD, confirming the findings from a smaller pilot study [7]. Significant improvements over baseline were observed in symptomatology, bulbar conjunctival hyperaemia, eyelid condition and meibomitis. There were also improvements in tear film break-up time, Lissamine green staining, Schirmer test and osmolarity, though they did not achieve statistical significance, possibly due to the smaller number of patients who attended for these investigations. In the assessment of global efficacy by the investigator more than twice as many patients had improved or disappeared symptoms compared with those whose symptoms had not improved or had improved. Similarly, in the global assessment by patients, more than 90% of patients were satisfied or very satisfied with their treatment.

Whilst using the eyelid warming device patients were able to keep their eyes open and continue reading, watch television and use the computer, and 90% of patients thought that the goggles were easy to use. Moreover, the ability to blink freely during treatment aids the expulsion of meibum and spreading of lachrymal film across the ocular surface as well as improving comfort during use.

Impairment of vision-related quality of life is a major problem in dry eye patients who suffer important impairments in a number of domains, particularly in depression and anxiety [13]. Current eyelid hygiene practices are poorly standardised and require significant motivation on the part of the patient. The use of the eyelid warming device offers consistent temperature and humidity environment for the eyelids, but still permits the patient to engage in other activities during the treatment. Treatment of MGD is long-term, often lifelong, and requires continuing commitment from the patient.

In terms of safety of the eyelid warming device, there was no change in corrected VA, nor IOP, no adverse events were reported and more than 95% of the investigating ophthalmologists rated the safety of the device as satisfactory.

Conclusion

The eyelid warming device proved effective in decreasing ocular discomfort, ocular symptoms (such as burning and stinging, sensitivity to light), conjunctival hyperemia, eyelid symptoms and quality of the meibum compared with baseline measurements.

Patients were satisfied with their experience of the device and could continue other activities during use. The eyelid warming device is an effective device for providing warmth and humidity to the eye and appears to be a promising alternative or adjunct to classical lid hygiene routines.

Further controlled studies of this device will clarify its place in the therapy of MGD.

Disclosure of interest

Laboratoires Thea, the manufacturer of Blephasteam®, funded the study. The authors and investigators were remunerated for their participation in the study. Dr JF Stolz provided editorial assistance in the preparation of the manuscript and this work was remunerated by Laboratoires Thea.

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