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Temperature profiles of patient-applied eyelid warming therapies

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ABSTRACT

Purpose: To compare temperature profile characteristics (on and off eye) of two patient-applied heat therapies for meibomian gland dysfunction (MGD): an eye mask containing disposable warming units (EyeGiene®) and a microwave-heated flaxseed eye bag® (MGDRx EyeBag®).

Methods: In vitro evaluation: surface temperature profiles of activated eye masks and heated eye bags® (both $n = 10$), were tracked every 10 s until return to ambient temperature.

Heat-transfer assessment: outer and inner eyelid temperature profiles throughout the eye mask and eye bag® treatment application period (10 min) were investigated in triplicate. The devices were applied for 12 different time intervals in a randomised order, with a cool-down period in between to ensure ocular temperatures returned to baseline. Temperature measurements were taken before and immediately after each application.

Results: In vitro evaluation: on profile, the eye bag® surface temperature peaked earlier (0 ± 0 s vs. 100 ± 20 s, $p < 0.001$), cooled more slowly and displayed less variability than the eye mask (all $p < 0.05$).

Heat-transfer assessment: the eye bag® effected higher peak inner eyelid temperatures (38.1 ± 0.4 °C vs. 37.4 ± 0.2 °C, $p = 0.04$), as well as larger inner eyelid temperature increases over the first 2 min, and between 9 and 10 min (all $p < 0.05$).

Conclusions: The eye bag® surface temperature profile displayed greater uniformity and slower cooling than the eye mask, and was demonstrated to be significantly more effective in raising ocular temperatures than the eye mask, both statistically and clinically. This has implications for MGD treatment, where the melting points of meibomian secretions are likely to be higher with increasing disease severity.

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1. Introduction

Evaporative dry eye disease is a common chronic condition [1] and meibomian gland dysfunction (MGD), through its adverse effects on the tear film lipid layer, is a leading cause [2,3]. Meibomian secretions of MGD patients have been reported to contain lower levels of unsaturated fatty acids and non-polar lipids than normal subjects [4,5]. The altered composition raises the melting points, and can cause the lipid secretions to solidify and become inspissated. This contributes towards blockage of the meibomian gland ducts and orifices, reducing the delivery of lipids into the tear film [4,6]. The subsequent deficiency of the lipid layer leads to increased evaporation from the tear film [7,8], and the development of dry eye symptoms [2,6]. Eyelid warming therapy provides symptomatic relief by liquifying the thickened meibum, and encouraging the secretion of lipids into the tear film [9,10]. This increases the thickness of the lipid layer, and thereby improves tear film quality and stability [9,11]. However, the melting points of the meibomian secretions have been found to display considerable variation [12], and are believed to be higher with increasing severity of MGD [13], influencing the efficacy of warm compress treatment [14]. Although many techniques for applying warm compresses have been developed [9,15–20], there is currently no agreement on a standardised option [21].

Two currently available patient applied eyelid warming therapies for managing MGD in clinical practice are the portable eye mask (EyeGiene® Insta-Warmth System™) containing disposable pressure-activated exothermic crystallization warming units, and the microwave-heated flaxseed eye bag® (MGDRx EyeBag®). Recent studies have independently described the efficacy [19,21,22] and comparability [23] of both methods. Ocular temperatures effected after ten minute application of the eye bag® are higher than that of the eye mask [23], however, cooling profiles and uniformity during the application period remain unknown. The aim of this two-phase study was to compare the surface

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cooling profiles of the two devices in an in vitro evaluation, and to assess their properties of heat transfer onto the ocular surface.

2. Methods

2.1. Phase 1: in vitro evaluation

In a parallel in vitro experiment, surface temperature profiles of activated eye masks ($n = 10$) and heated eye bags® ($n = 10$), were evaluated. The eye mask warming units were pressure activated to commence heat emission, while the eye bags® were heated for 30 s at full power in a 908 W microwave oven and then shaken to evenly distribute the contents, according to the instructions of the respective manufacturers.

The temperatures of the device surfaces intended to be in contact with the eyelids were recorded using infrared thermography (NEC Handy Thermo TVS-200EX). Measurements were recorded every 10 s following activation until return to within 5 °C of room temperature. All measurements were conducted in the same location, with a mean ambient temperature of 22.0 ± 1.5 °C, and relative humidity 48.5 ± 5.5%.

2.2. Phase 2: heat-transfer assessment

To evaluate the heat-transfer properties, we investigated outer and inner eyelid temperature profiles throughout the 10 min eye mask and eye bag® application period. This phase followed the tenets of the Declaration of Helsinki, and was approved by the University of Auckland Human Participants Ethics Committee. Six subjects of at least 18 years of age, with no dry eye symptoms, no contact lens use 48 h prior to study participation, and no systemic medications or conditions affecting the eye, were recruited from volunteers that provided written consent. Three subjects each were assigned to eye mask and eye bag® application, respectively. The two subject groups were matched for age, gender and ethnicity.

Warm compresses were applied within 5 s of activation to the closed eyelids for 12 different time intervals ranging between 30 s and 10 min. Time intervals were applied in a randomised order, and each application was separated with an adequate cooling period to ensure outer and inner eyelid temperatures had returned to within 1 °C of baseline. All measurements for an individual subject were conducted in a single session. Outer and inner eyelid temperatures (OLT and ILT) were measured at the geometric corneal centre, with the eyelids closed and then immediately on eye opening. Inner eyelid temperatures were taken to be the same as adjacent corneal temperatures due to the proximity of the two tissues in the closed eye state. Measurements were recorded before, and immediately after, each application. All measurements were conducted in the same location, with a mean room temperature of 21.6 ± 1.4 °C, and relative humidity 50.5 ± 6.0%.

2.3. Statistics

Statistical analyses were performed using Graph Pad Prism version 6.02 (http://www.graphpad.com). Comparisons of continuous variables were made using paired t tests. For the in vitro evaluation, area under the curve was calculated using ambient temperature (22.0 °C) as baseline. Non-linear regression (one-phase exponential decay) was performed to determine the half-life of the descending limbs. Comparisons of variances in the first 1000 s were undertaken using the F-test. For the heat-transfer assessment, two-way analysis of variance (ANOVA) testing was performed to test the significance of device, time and their interaction (device by time) effects. Post-hoc analysis for significance of the device effect at each time point was conducted using Sidak's test. All tests were two-tailed and $p < 0.05$ was considered significant. All data are presented as mean ± SD, unless otherwise stated.

3. Results

3.1. phase 1: in vitro evaluation

Table 1 and Fig. 1 summarise the eye mask and eye bag® surface temperature profiles. There were no significant differences between the peak surface temperatures of the eye mask and the eye bag® ($p = 0.12$), although peak temperature was reached later for the eye mask than the eye bag® (1 min 40 s ± 20 s vs. 0 s ± 0 s, $p < 0.001$). At 10 min the eye bag® exhibited higher surface temperatures ($p < 0.001$) and a greater area under the temperature profile curve than the eye mask ($p = 0.003$).

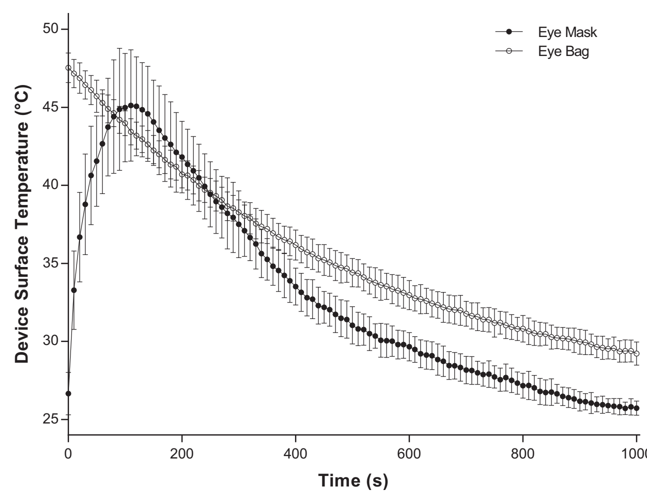

Fig. 1. In vitro evaluation results showing device surface temperature profiles of the eye mask and eye bag® during the first 1000 s post activation. Each point represents the mean temperature at a given time point: solid circles represent the eye mask, and hollow circles represent the eye bag®. Error bars represent the standard deviation.

Table 1
In vitro evaluation results describing device surface temperature profile characteristics of the eye mask and eye bag®. Data are presented as mean ± SD.

	Eye mask	Eye bag®	P
Time to peak temperature (s)	100 ± 20	0 ± 0	<0.001*
Peak temperature (°C)	45.7 ± 3.6	47.6 ± 0.9	0.12
Temperature at 10 min (°C)	33.0 ± 0.9	29.7 ± 0.9	<0.001*
Area under curve at 10 min (°C s)	8,900 ± 1000	10,000 ± 500	0.003*
Time to return to within 10 °C of ambient temperature (s)	470 ± 50	690 ± 80	<0.001*
Half-life of descending limb (s)	270 ± 60	370 ± 40	<0.001*
F-test of variances			<0.001*

*Indicates statistically significant findings ($p < 0.05$).

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