EFFICACY OF A NOVEL WATER PROPELLED, HEATING EYE MASK MASSAGER ON TEAR FILM AND OCULAR ADNEXA

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ABSTRACT

Purpose: to determine the effectiveness of the Aurai water propelled, heating Eye Massager (AEM) in managing dry eye disease and its effects on the ocular adnexa.

Methods: This was a prospective, randomised cross-over study that enrolled 15 participants (aged 25.8 ± 5.45 years, 5 male). Participants wore a smart watch 24 hours a day to track their sleeping cycle and heart rate for 4 weeks, using the AEM twice a day for 2 of those weeks. A cycle of 6 minutes of a controlled heat and vibration pattern in the morning and another cycle in the evening were applied with the AEM. Primary outcomes of symptomatology (Ocular Surface Disease Index (OSDI) and Symptom Assessment iN Dry Eye (SANDE)), tear film homeostasis markers (osmolarity, non-invasive breakup time (NIKBUT), tear meniscus height (TMH), lipid layer thickness and ocular staining) and safety measures (ocular redness and intraocular pressure), were assessed at baseline, after 2 weeks of AEM use and after 2 weeks of no treatment (in random-sequence). Sleeping tracking (ST) and heart rate/blood oxygen detection over these periods was also assessed.

Results: There was a significant change in OSDI score from 34.3±19.5 at baseline to 18.8±17.5 after treatment ($p = 0.001$) and also for the SANDE (5.7 ± 2.4 vs 3.7 ± 2.1; $p = 0.001$). Heart rate was not affected by treatment ($p=0.956$), nor sleep pattern ($p=0.529$), but this varied by day ($p=0.001$). Tear film homeostasis, the ocular adnexia and safety measures were not affected by treatment ($p>0.05$).

Conclusion: The Aurai water propelled Eye Massager may relieve symptoms of dry eye and its severity, but there were no detectable effects on tear stability from two weeks use.

Keywords: Dry eye, Warm compress, Symptoms, Signs, Heating devices

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Introduction

Meibomian Gland Dysfunction (MGD) has been defined as the "*chronic*, *diffuse abnormality of the meibomian glands*, *commonly characterized terminal duct obstruction and/or qualitative quantitative changes in the glandular secretion. It may result in alteration of the tear film*, *symptoms of eye irritation, clinically apparent inflammation*, *and ocular surface disease*"[1]. It is a subset of dry eye disease[2].

As a chronic condition that requires ongoing management, patient compliance has a significant impact on treatment efficacy [3, 4]. Many studies have assessed different efficacies of lid heating treatments and there is an established relationship between the use of eyelid warming devices and improvement of tear film stability and MGD [5]. In MGD, the meibum is altered to consist of lower levels of unsaturated fatty acids and non-polar lipids)[6, 7], raising the melting point, causing the lipid secretions to solidify and become inspissated. The mechanism of action appears to be a clearing of the ducts through raising the temperature of the glands beyond the melting point of the altered meibum, followed by physical massaging of any remaining gland plugs [8]. Many management and therapy options had been developed to warm the lids. Such treatments include infrared devices [8, 9], warm compresses [10, 11], disposable eyelid warming devices [12] and warm moist air devices [13]. The efficacy of warm compresses are presented in Table 1 [10, 12-24]. Studies regarding what the most optimal temperature to melt the meibum of the glands might be suggest reasonable variability[25], perhaps greater in patients with MGD[26], affecting the efficacy of lid warming treatments.are in place [27, 28]. Massaging in general has many health benefits and few known risks, so could massage of the eyelids and adnexia benefit sleep or blood circulation?[29] Hence, new approaches to lid warming and massage are of great interest to manage this chronic, debilitating condition.

The aim of this study was to investigate the efficacy of a novel water propelled eyelid warming device after 2 weeks use in patients with dry eye disease.

Methods

This prospective, randomised cross-over trial adhered to the tenets of the Declaration of Helsinki and was given a favourable opinion by Aston University Ethics Committee and governance approval. It was registered as a clinical trial on www.researchregistry.com UIN #5167.

Participants were required to be 18 years or older with a positive diagnosis of dry eye disease (DED) using the diagnostic criteria of TFOS DEWS II (symptoms of dry eye ≥13 on the Ocular Surface Disease Index (OSDI) and at least one of the global signs/homeostasis markers)[30]. Exclusion criteria included use of contact lenses, current eyelid warming therapies, current artificial drop use, ocular pathologies (excluding blepharitis and MGD) and systemic issues such as diabetes and inflammatory conditions). Prior to commencement participants had signed the informed consent and were enrolled if eligible. Fifteen participants were (67% female, age 25.8 ± 5.45 years, range 20-37 years) recruited, based on the minimum sample size recommendation for repeated measure analysis of variance [31]. This number of participants has also been shown to be adequate to detect a clinically significant difference for the inter-group comparisons at 80% power with an alpha of 0.05 [30, 32]. Data were measured from the right eye only except for osmolarity where the highest value between the eyes are recommended variables. All participants had had DED for at least 2 years

The baseline measurements, conducted in the following order, were: OSDI; Symptom Assessment iN Dry Eye (SANDE)[33]; Osmolarity, highest value from 2 eyes collected from the lower meniscus [34] using a TearLab station (TearLab Ltd, California, USA) with calibration performed every day following the manufacturer's instructions and TearLab chips were placed beside the station for humidity and temperature regulation; Ocular Hyperaemia in the nasal and temporal bulbar and limbal regions (OH); Tear meniscus height (TMH) illuminated with infrared light, calculated from a calibrated digital image; Non-Invasive Breakup Time (NIKBUT) - average of 3 readings after two non-forceful blinks; and Lipid layer thickness (LLT) evaluated by tear film interferometry and graded as: 0 (absent), 1 (open meshwork), 2 (closed meshwork), 3 (wave), 4 (amorphous), or 5 (coloured fringes), all evaluated objectively (except LLT) using the Keratograph 5M (Oculus, Wetzlar, Germany)[35].

Ocular staining with fluorescein, corneal staining (CornS) was assessed by wetting a fluorescein strip with saline, shaking off the excess, and instilling it at the outer canthus. Lissamine green, conjunctival staining (ConjS), was assessed by wetting a Lissamine strip (GreenGlo, HUB Pharmaceuticals, LLC, Rancho Cucamonga, California, USA) with a single drop of saline solution, keeping the drop on the strip for 5 seconds to elude the dye, and instilling it at the outer canthus. Assessment was performed with a slit lamp and the number of punctate spots counted[30].

The Aurai Eye Massager (AEM) has an integral silicon mask which contains water which can be warmed/cooled and vibrated (Figure 1). The water-propelled massager is marketed as relaxing muscular tension around the eyes, to improve blood circulation and relaxation. All measurements were performed by the same clinician in the same order. The assessment was conducted in a room where temperature and humidity remained constant between 20-22°C and 30-45% respectively, to ensure that the measurements were not affected by ambient humidity. Participants spent a minimum of 10 min acclimatising to the room conditions before being tested as factors such as humidity can affect measurements [36].

Participants were required to wear a watch (IP68 Fitness Activity Tracker, Smart Watch, Teepao.com), 24h a day, which captured Heart Rate and Blood Oxygen (O2 – using red and infra-red light pulse oximetry) and sleeping time (ST – through inactivity of movement). All participants wore the watch for 4 weeks; for 2 weeks no intervention was undertaken (control condition) and for the other 2 weeks, participants were instructed to use the AEM 6 minutes twice daily, using the warm and vibration cycle as recommended in the manufacturers instructions. The AEM warms to 40℃ +3/-2℃ within 2 minutes and remains at this temperature for the rest of the 6 minute vibration cycle. The order of the control condition and AEM treatment was randomised between participants. After each two weeks participants returned and the measures captured at baseline were repeated by a masked researcher. Participants were not masked due to the appearance of the device and the physical sensation. After returning the AEM, participants were asked how often they had used the AEM. Patient compliance was recorded (number of times the system was used during the 2 weeks).

Heart rate, Blood Oxygen (O2) and Sleeping Time (ST) were gathered from the watch. Intraocular pressure was measured at each visit with Ocular Response Analyser (ORA) (Reichert Technologies, Germany). In addition, IOP was measures before and at minute intervals after eye massager use for 3 minutes at the end of the study to examine for any immediate pressure spikes.

Figure 1*: AURAI Mask Massager*

Data analysis

Statistical analysis was performed using IBM SPSS Statistics version 25 (New York, USA). The distributions of the data was assessed using one-sample Kolmogorov-Smirnov test. Symptomology, intraocular pressure, heart rate, blood oxygen and sleeping time were found to be normally distributed and therefore analysed with a repeated measured Analysis of Variance, while the other metrics were assessed with a related sample Friedman's Analysis of Variance by Ranks. All tests were two-tailed and $p<0.05$ was considered significant.

Results

All participants completed the study and reported good compliance (a maximum of one missed treatment). They had mild to moderate symptoms (Table 2) and had had DED for at least 2 years.

Summary statistics of clinical measurements at baseline, after 2 weeks of no treatment, and 2 weeks post-treatment are presented in Table 2. Dry eye symptoms decreased with treatment (OSDI and SANDE severity metric; $p<0.001$). Interestingly, there was an apparent placebo effect of just wearing the fitness monitoring watch (OSDI: $p=0.042$; SANDE severity; $p=0.006$).

Table 2: Measurement Pre and post treatment. *Average ± SD or median (range) of dry eye symptoms and signs at baseline, after 2 weeks of watch control, and after 2 weeks of treatment. N=15. SANDE = Symptom Assessment in Dry Eye (consisting of a frequency of symptoms and severity of symptoms visual analogue scale), TMH = Tear Meniscus Height, NIKBUT = Non-Invasive Keratometric Break-Up Time, LLT = Lipid Layer Thickness, IOP = Intra Ocular Pressure, , O2 = Blood Oxygen, ST = Sleeping Time*

	Baseline	Post control period	Post AEM	Significance (p-value)
OSDI	34.3±19.5	26.5±19.8	18.8±17.5	0.001
SANDE Frequency	4.05±2.20	4.03±2.46	2.55±1.61	0.262
SANDE Severity	5.70±2.43	4.35±2.40	3.65±2.12	0.001
Osmolarity (mOsm/l)	293 (284-348)	291 (285-312)	291 (280-307)	0.888
Bulbar redness temporal (grade)	0.6 (0.0-1.1)	0.5 (0.3-1.5)	0.6 (0.4-0.8)	0.534
Bulbar redness nasal (grade)	0.6 (0.4-1.7)	0.6 (0.3-2.1)	0.5 (0.0-1.7)	0.775
Limbal redness temporal (grade)	0.3 (0.0-1.1)	0.3 (0.0-1.4)	0.3 (0.2-1.7)	0.971
Limbal redness nasal (grade)	0.4 (0.2-0.7)	0.4 (0.2-2.0)	0.3 (0.2-0.6)	0.472
TMH (mm)	0.22 (0.12-0.63)	0.24 (0.11-0.45)	0.23 (0.13-0.42)	0.247
NIKBUT (s)	6.3 (4.2-10.8)	5.4 (3.8-13.7)	5.3 (1.0-12.7)	0.430
LLT (grade)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	0.975
Corneal staining (grade)	0.0 (0.0-3.0)	0.0 (0.0-3.0)	0.0 (0.0-1.0)	0.949
Conjunctival staining (grade)	1.0 (0.0-3.0)	1.0 (0.0-3.0)	1.0 (0.0-3.0)	0.575
Lid margin staining (grade)	1.0 (0.0-3.0)	1.0 (0.0-3.0)	1.0 (0.0-3.0)	0.298

IOP (mmHg)	13.91±1.89	13.29±2.02	13.83±2.59	0.349
Heart rate (beats per minute)	N/A	81.33±9.16	81.10±9.84	0.828
O2 (%)	N/A	98.87±36.11	97.37±3.69	0.268
ST (hours)	N/A	6.94±1.89	7.38±1.30	0.529

Intraocular pressure did increase immediately after use of the AEM ($F=4.113$, $p=0.017$) by 1.5 ± 2.0 mmHg, but this reduced rapidly (difference from baseline: 2 minutes, +1.3 ± 2.3mmHg; 3 minutes, -0.49 ± 2.3mmHg).

Discussion

This study investigated the efficacy of a novel water propelled eyelid automated warming device after 2 weeks use in patients with dry eye disease. The OSDI scores at baseline ranged from 13 to 66 indicating mild to moderate DED severity. Two weeks use, twice a day, has previously been shown to be an effective duration of treatment of the meibomian glands to observe improvements in symptoms and signs such as tear stability, lipid layer thickness and meibomian gland expressability, but generally not ocular surface staining or meibomian gland drop-out (Table 1)[10, 12-24]. Several studies have shown immediate patient benefit from even a single session of eyelid warming [10, 20, 37] including in non-dry eye individuals [4, 11], making this an attractive treatment option.

There was a clear reduction on symptoms having used the AEM device for 2 weeks. The improvement of 15.5 points on the OSDI is comparable with previously reported warm compress studies (Table 1). Comfort was the only subjective measure and in the repeated-measures design it also appeared to improve in the period when there was no treatment (the control condition), hence a possible 'placebo' effect of being monitored. However, when just the participants who were randomised to have the no treatment period monitoring before using the AEM device are considered, no improvement in symptoms was seen (the difference in symptomatology was only -0.4±6.5 for the OSDI and 0.1±1.6 for the SANDE Severity score [minus indicates worsening symptoms]); this suggests that the improvement in symptoms following use of the AEM was a real and sustained effect, as the participant randomised to use the AEM device first followed by 2 weeks of no treatment had little reason to believe that the benefit in symptomatology would occur even when assessed two week after last using the device. Compliance was reported as being good by all participants which may have been aided by the reduction in symptoms resulting from the AEM use.

Unlike previous studies (Table 1), no improvement was seen in ocular surface signs. It is well known that the signs & symptoms of dry eye disease do not correlate well [38], however the finding does not allow the mechanism of the improvement in symptoms to be explained. Perhaps the massaging of the skin around the eyes might be contributing to the benefit on symptomatology [29].

Previous studies had not looked at other possible general health benefits such as improved lower levels of stress as indicated by heart rate, blood oxygen and sleep duration (Table 1). Most participants, unprompted, reported a feeling of being relaxed after the use of the mask, but the number of hours to sleep prior or after the use of AEM did not change statistically. In this study, no difference was seen in these possible general health benefits, but that might be because of the short-term use of the eye mask. Future longer duration studies could examine these potential general health benefits more in depth. It is known that rubbing the eyes can increase the IOP [39]; the lack of any change seen on this study suggests that there are no immediate or long-term safety concerns from the massaging action.

In conclusion a considerable improvement in subjective symptom severity has been shown after the use of the AEM device, sustained over at least 2 weeks, even though no improvement in clinical signs were detectable in this study. Further randomised studies with longer term use of the AEM are required to fully explore the potential benefit of novel eye warming and massaging devices.

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Table 1: Comparison of dispensing warm compress efficacy studies. Symptom improvement reported for dry eye group from warm compress therapy. *MGD meibomian gland dysfunction; IPL intense pulse light therapy; LLT lipid layer thickness; NIBUT non-invasive breakup time; TBUT fluorescein tear breakup time; MG meibomian gland; OSDI ocular surface disease index; SANDE symptom assessment in dry; SPEED standard patient evaluation of eye dryness; DEQS dry eye–related quality-of-life score; TMH tear meniscus height; IOP intraocular pressure.*

Study	Participants	Warm Compress	Comparison	Duration	Sign Improvements	Symptom Improvement with warm compress	Measures Unchanged	Additional Comments
Murphy et al., 2020 [40]	42 MGD	MGDRx EyeBag & OPTASE Moist Heat Mask	Warm face cloth	8 weeks, 10 min 2x/day for 2 weeks	MG quality & expressability, Demodex (OPTASE only)	-23.1 from 39.8 OSDI Eyebag -12.5 from 39.0 OPTASE mask	Osmolarity, NIBUT, Schirmer I test	Face cloth cohort OSDI baseline was 24 vs 40 in commercial compress groups
Wang et al., 2019 [14]	20 dry eye	MGDRx Eyebag	Contralateral eyelid massager vs manual massage	2 weeks, 10 min a day	LLT, NIBUT	Not measured	Visual acuity, TMH, redness, corneal staining, MG dropout	Measures 15 minutes post treatment
Tichenor et al., 2019 [15]	51 contact lens dry eye	Bruder moist heat compress	Single vs two applications vs washcloth	4 weeks, 10 min applications	Comfortable wear time and MG expressability with Bruder mask regardless of frequency of use	-8.9 from 22.9 OSDI 1x/day, -16.3 from 33.8 2x/day	TBUT	
Gao et al., 2019 [16]	82 MGD	Tobramycin/dexamethasone + warm compress	IPL	4 weeks, 10 min compress nightly	TBUT, MG expressability (1 month) and cytokines (1 wk) with IPL	-16.7 from 38.1 OSDI	OSDI, corneal staining, MG dropout	Warm compress not as good as IPL Both groups applied sodium hyaluronate eye drops 4x/day
Badawi, 2018 & 2019 [18, 19]	24 dry eye, 12 in extension	Heat mask	Tearcare system	4 weeks, 5 min daily followed up after 6 months	TBUT, MG expression, corneal & conjunctival staining with Tearcare, worsening TBUT with heat mask	-8.4 from 33.0 OSDI. SPEED & SANDE also improved	None reported	No changes in IOP at 6 months. Tearcare retreatment at 6 months boosted benefits. Sole author employee of device company
Arita et al., 2017 [20]	35 dry eye, 20 controls	Heat mask	Contralateral eyelid with or without menthol	2 weeks, 10 min 2x/day	MG quality improved in all patients, but TMH and TBUT only increased with menthol mask	-25.5 from 49.7 with heat, -17.8 from 41.0 with	Corneal staining	Effects were also seen after a single 10 min application

						heat & menthol DEQS		
Zhao et al., 2016 [21]	50 dry eye	Washcloth & lid scrubs n=25	Lipiflow n=25	12 weeks, 2x/day vs single session Lipiflow	TBUT (at 4 but not 12 weeks) in both groups, Schirmers in the washcloth group, MG expression (only examined in Lipiflow group)	-15.9 from 52.4 modified SANDE	Corneal staining, LLT	Not randomised & baseline staining higher in washcloth group. Lid hygiene encourage in both group. Duration of warm compress and frequency of use not reported
Blackie et al., 2016 [22]	200 MGD dry eye	Warm compress & lid hygiene n=99	Lipiflow n=99	12 weeks, 10 min 2x/day vs single session Lipiflow	MG expression greater with Lipiflow	-17.8 from 51.8 OSDI	None reported	Lipiflow followed for up to 12 months and positive benefit still apparent. Baseline OSDI 6.2 points greater in warm compress group
Villani et al., 2015 [23]	50 MGD	Warm compress	Blephasteam	3 weeks warm compress 10 min 2x/day followed by 3 weeks Blephasteam	18 had no improvement in BUT or acinar diameter with warm compress, but did with Blephasteam. No further improvement in warm compress responders	-13.6 from 36.3 OSDI in n=32 responders; ~-8.7 across all patients	None reported	Corneal staining, Schirmer * MG expression in methodology but not further reported
Bilkhu et al., 2014 [10]	25 MGD	MDGRx Eyebag	Contralateral unheated MDGRx Eyebag	2 weeks, 5 min 2x/day followed for 6 months	NIBUT, LLT, osmolarity, MG dropout and expression, hyperaemia and staining	-33.0 from 52.5 scaled to 100	Visual acuity & corneal topography	Improvement in OSDI from day 1 but continued to improve daily
Lane et al., 2012 [24]	139 MGD	iHeat warm compress	Cross-over Lipiflow	2 weeks, 5min/day	MG expression and TBUT only with Lipiflow;	-7.8 from 34.7 OSDI. Symptom improvement greater with Lipiflow	Staining, IOP, visual acuity	
Matsumoto et al., 2006 [13]	10 MGD, 10 controls	Warm moist air compress	Hot towel	2 weeks, 10 min 2x/day	LLT (more with warm moist compress) TBUT (warm moist compress only)	-53.8 from 77.3 in ocular fatigue out of 100	Staining	
Mori et al., 2003 [12]	17 MGD, 8 controls	Eye Warmer prototype	-	2 weeks, 5 min 2x/day	BUT, LLT, MG expressability	-24 from 52 scaled to 100	None reported	