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The effects of a hydrating mask compared to traditional warm compresses on tear film properties in meibomian gland dysfunction

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1. Introduction

Meibomian gland dysfunction (MGD) is a commonly encountered optometric complication, which may lead to alterations in the tear film, symptoms of eye irritation, inflammation and ocular surface disease [1]. The prevalence of MGD ranges from 3.5% to almost 70%, but is more commonly observed in Asian populations [2]. The primary cause of MGD is considered to be the terminal duct obstruction of the glands arising from hyperkeratinisation and increased viscosity of meibum, which leads to qualitative and quantitative changes in the meibomian gland secretions and ocular surface complications including dry eye [3].

Management of MGD is important, to improve patient comfort and prevent potentially sight-threatening complications [4]. The goal of treatment is aimed at improving the flow of meibomian gland secretions and consequently increasing tear film stability [5]. Treatment options are additive dependent upon MGD severity and include lid hygiene, eyelid warming, topical lubricants and corticosteroids, topical and oral antibiotics [1]. However, the mainstay treatment for MGD is the application of heat to the eyelids [4–6]. Findings of greater tear film stability and increased tear film lipid layer thickness in patients with MGD following treatment have been well supported by several studies in the literature [7–10].

As long-term management is required to achieve adequate improvement of symptoms, patients have been found to frequently discontinue warm compress treatment[10] due to the time and labour intensive nature of the regime, with compresses having to be reheated every 2 min to maintain a therapeutic temperature [9,11]. To improve patient compliance, portable eyelid-warming devices have been developed to be more convenient to use than conventional warm compress therapy. These include: dry, chemically activated (EyeGiene®[12] and iHeat[13]), oxidation activated (Hot Eye Mask)[7] or self-activated radiation heat compresses [14]; dry microwave heated compresses (MediBeads® Bruder eye hydrating compress, Eye-ssential Thera-Pearl eye mask[15,16], MGDRx EyeBag®[17], The Eye Doctor®[16]; dry electronically powered devices (IWCD[10], Eye Hot R and Azuki no Chikara[7]); moist heat microwave heated compresses (Bundle method and Tranquileyes™ XR)[15]; moist goggle devices heated electronically [18]. including Blephasteam® goggles[6,12]: and the Memoto Este (Panasonic, Osaka, Japan) which combines dry electronic warming and massage with a wet water sponge [7].

A recent study showed that some warm compresses are more effective in increasing eyelid temperatures than others, with the Bundle method being the only technique of those assessed able to sustain temperatures of 40 °C or above after 10 min [15]. However, the Bundle method involves a cumbersome technique that requires 5 to 6 dampened towels to be rolled and folded in a particular way prior to being placed in a covered container and heated in the microwave. This would appear to be a move away from offering more convenient methods for performing warm compression, which is desirable to ensure patients do not discontinue treatment [14]. Although it has been suggested that reaching temperatures over 40 °C may be required to melt severely obstructed material[19], meibomian lipids start to spread at 35 °C [20]. All of the warm compresses evaluated by Murakami et al. sustained average eyelid temperatures above 35 °C for up to 10 min[15] and would therefore be expected to be effective in melting meibomian gland secretions in mild to moderate cases of MGD. However, clinical signs and symptoms were not evaluated in the study. MediBeads (Bruder Healthcare Company, Alpharetta, GA) microwave heat activated eye masks showed equivalence to the Bundle method in terms of internal lid heating until the 8 min mark [15]. However, no studies have evaluated the effect of MediBeads warm compresses on clinical signs in MGD. According to the manufacturer, the Bruder® Eye Hydrating Compress features patented MediBeads which absorb water molecules from the air and release them as moist heat when microwaved.

Therefore, the aim of this study was to compare the MediBeads or Bruder® Eye Hydrating Compress against traditional warm compress therapy in regards to their effect on tear film properties at various timepoints up to one hour after treatment in individuals with MGD.

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2. Method

2.1. Study design

This was a randomised, investigator masked crossover study comparing various tear film properties after a single in-office treatment with the Bruder® Eye Hydrating Compress and traditional warm towel compresses. All procedures were conducted in accordance with the Declaration of Helsinki and were approved by the University of New South Wales Human Research Ethics Committee. Informed consent was obtained from all subjects prior to conducting any study related procedures.

2.2. Study participants

A sample size of 31 participants was required to detect a change in tear film lipid layer thickness of 15 nm, with a standard deviation of 21nm[21] as measured using the LipiView® interferometer, with 95% confidence and 80% power. Subjects were eligible to participate if they met all of the inclusion criteria and none of the exclusion criteria. Inclusion criteria included: minimum 18 years of age; at least one observable plugged/capped meibomian gland on the eyelids; and a minimum dry eye classification of "mild" according to the Ocular Surface Disease Index (OSDI)© questionnaire (a minimum score of 13.0) [22]. Exclusion criteria included: the use of topical medications other than ocular lubricants; active eye infection or inflammation; current contact lens wearer or use within 1 month prior to the study; eye surgery within the past 6 months; pregnancy or lactating (self-report); and sensitivity to flashing strobe-like lights.

2.3. Study Procedures

Study participants attended two study visits separated by a two week wash-out period. At the first visit, study participants completed the OSDI questionnaire, visual acuity was measured for safety purposes using standard computerized letter charts[23], and slit lamp biomicroscopy (Zeiss SL-120, Carl Zeiss Meditech, Jena, Germany) was performed to determine participant eligibility. Baseline assessments prior to treatment were obtained for non-invasive keratography tear break up time (NIKBUT) and tear meniscus height (TMH) using the Oculus® Keratograph 5 M (Oculus®, Arlington, WA, USA), while tear film lipid layer thickness (TFLLT) was measured using the Lipiview® (TearScience Inc, Morrisville, NC, USA). The order of tear film measurements was not randomised, but rather was conducted from the least invasive to the most invasive technique at all time-points both before and each after treatment i.e. (i) TFLLT (ii) TMH and (iii) NIKBUT. The order in which the eyes were selected for assessment was randomised. NIKBUT, defined as the time between the last blink and the first break-up or distortion of the mires projected onto the tear film, was objectively timed by the instrument using infra-red illumination, and was recorded in seconds. Three NIKBUT measurements were taken consecutively with a short interval between repeated measurements, during which participants were asked to blink normally to ensure the tear film layer had fully reformed between measurements. The three consecutive NIKBUT measurements were averaged. TMH was measured using the integrated measuring guide software and recorded in millimetres. Measurements were taken from directly under the pupil centre and defined as the distance between the lower lid margin and the highest point of the reflective zone. Average TFLLT was obtained in interferometric color units (ICU) where 1 ICU is approximately 1 nm of TFLLT [24]. Objective measurements were conducted by a masked investigator, while an unmasked investigator conducted the randomization and applied the treatment to each study participant.

Study participants were randomised to receive either the test Bruder® Eye Hydrating Compress treatment (Bruder Healthcare Company, Alpharetta, GA, USA) or control traditional warm towel compress as a single in-office treatment. The Bruder® Eye Hydrating Compress was wrapped in two sheets of paper towels and heated for 20 s in a 1000W microwave oven as recommended by the manufacturer. Immediately after heating, the temperature of the Bruder® Eye Hydrating Compress was measured to be within 40 ± 2 °C using the Bodichek Digital Thermometer (Aaxis Pacific, Sydney, Australia), and placed on the participant's closed eyelids for five minutes without reheating. For the traditional warm towel compress, identical cotton cloths (33 × 33 cm) were immersed in heated water to achieve a maximum temperature of 42 °C. The towel was folded in half and placed over the closed eyelids. At two minute intervals the towel was replaced with a new preheated warm towel compress and this was repeated until treatment had been applied for a total of five minutes. The primary outcome measures NIKBUT, TMH and TFLLT were measured three times after treatment: immediately after treatment, 15 min post treatment and one hour post treatment. Ambient room temperature and humidity were kept to a constant 22 °C and within a range of 35% to 50% respectively, as these environmental factors have been shown to affect tear film characteristics [25,26].

On completion of the first visit, participants underwent a 2 week washout period before attending for the second visit which was scheduled at approximately the same time of day as the first visit. Baseline assessments were repeated, participants were crossed over to receive the alternate treatment, and the three post-treatment measurements were obtained.

2.4. Statistical analysis

Two way Analysis of Variance (ANOVA) was used to compare the outcome measures between treatments and also over time. The level of significance was set at alpha = 0.05 and Bonferroni correction was used to adjust for multiple comparisons where applicable. Statistical analysis was performed using the Statistical Package for the Social Sciences software (SPSS 23.0 for Windows, Chicago, IL, USA).

3. Results

A total of 31 participants (10 males and 21 females) with an average age of 26.1 ± 10.0 years (range 19 to 58 years) and OSDI score range at the Baseline visit of 13 to 50 (inclusive) were enrolled and completed the study. No significant differences were observed between the right eye and left eye data ($p > 0.05$) and therefore, data are presented for the right eye only. No adverse events occurred during the study.

Table 1 summarizes the NIKBUT, TMH and TFLLT measurements for the Bruder Eye Hydrating Compress and warm towel compress treatments at Baseline before treatment, immediately after treatment, and 15 min and 1 h post-treatment.

There were no significant differences in NIKBUT between treatments or over time up to 1 h post-treatment (ANOVA $p > 0.05$, Fig. 1).

There was no significant difference in TMH between treatments (ANOVA $p > 0.05$). Overall there was a significant change in TMH over time (ANOVA $p = 0.04$), but there were no significant differences between any particular timepoints after adjustment for multiple comparisons (Fig. 2).

There was no significant difference in TFLLT between treatments (ANOVA $p > 0.05$). However, there was a significant difference in TFLLT over time (ANOVA $p < 0.01$). TFLLT significantly increased immediately after treatment compared to Baseline by an average 17.7 nm with the Bruder® Eye Hydrating Compress and 16.9 nm with the warm towel compress (post-hoc $p < 0.01$) (Fig. 3).

4. Discussion

This is the first study to evaluate the effect on tear film characteristics of the Bruder® Eye Hydrating Compress compared to traditional warm towel compresses in subjects with MGD. Although no differences