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Effect of lipid-based dry eye supplements on the tear film in wearers of eye cosmetics

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ABSTRACT

Purpose: To compare the effects on tear film parameters and contamination in cosmetic eyeliner wearers, after single application of two lipid-based dry eye treatments: a lipid-containing lubricant eye drop and a phospholipid liposomal spray.
Methods: Fifty participants were enrolled in a prospective, randomised, paired-eye, investigator-masked trial. Pencil eyeliner (Body Shop® Crayon Eye Definer) was applied to the upper eyelid periocular skin of both eyes, anterior to the lash line. Baseline tear film quality was assessed fifteen minutes after eyeliner application. A lubricant drop (Systane® Balance) was then applied to one eye (randomised), and liposomal spray (Tears Again®) to the contralateral eye. Tear film contamination, lipid layer grade, non-invasive tear film break-up time and tear evaporation rate were evaluated fifteen minutes post-treatment and compared to pre-treatment values.
Results: Pre-treatment measurements did not differ between eyes assigned to lubricant drop and liposomal spray. Tear film contamination was observed in a greater proportion of eyes following both treatments (both $p < 0.05$), with no significant difference between treatments ($p = 0.41$). Both treatments improved lipid layer thickness (both $p \leq 0.01$), but effected no significant change in non-invasive tear film break-up time or tear evaporation rate (all $p > 0.05$). Changes in tear film parameters did not differ between treatments (all $p > 0.05$).
Conclusions: Both the lipid-containing lubricant eye drop and phospholipid liposomal spray result in clinically apparent tear film contamination in eyeliner cosmetic wearers. Although both treatments effected an increase in lipid layer thickness, neither displayed clinical efficacy in improving tear film stability.

1. Introduction

Eye cosmetics are used extensively to accentuate and highlight the eyes [1–5]. However, their use has been suggested to be associated with dry eye development [6–9]. Migration of periocular cosmetic products into the tear film and ocular surface has been reported [1,4,10,11], although the exact mechanism is not fully understood. Cosmetic product migration is thought to destabilise the superficial tear film lipid layer [3,4,8,10], thereby reducing tear film stability and increasing the rate of tear evaporation [12–14]. The resulting evaporative dry eye symptoms can adversely impact upon ocular comfort, vision and quality of life [12].

Due to their ease of application, pencil eyeliners, containing waxes, oils and pigments, are a popular cosmetic product [15]. They are commonly applied along the lid margin or lash line, in close proximity to the ocular surface [1,15]. The migration of eyeliner particles has been suggested to alter the lipid content and viscosity of the tear film, which may contribute towards reduced stability [2,16].

Many individuals present to optometric practice with symptoms of ocular discomfort due to dry eye. Aetiologically, dry eye is a complex disease, with the various components of the lacrimal functional unit susceptible to disruption from a wide range of factors [17]. Regardless of cause, affected individuals are observed to progress to a common vicious cycle of tear film instability, hyperosmolarity and inflammation, which, without intervention, can lead to ocular surface damage [12]. Evaporative dry eye is the most common dry eye subtype, arising from disturbances in tear film or ocular surface quality, and frequently as a result of meibomian gland dysfunction (MGD). Meibum inspissation and

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gland blockage in MGD has an adverse impact on the tear lipid layer, necessitating application of heat to encourage natural meibum restoration, and/or supplementation with artificial lipid products. Various treatments have been developed for evaporative dry eye to supplement the tear film lipid layer [18–22]. Lipid-containing lubricant eye drops contain an emulsion of mineral oils and phospholipids [18,19,23], while liposomal sprays deliver phospholipids across the lid margins [20–22].

Saline eye drop instillation has been reported to exacerbate the migration of a periocular mixture of hydroxyethyl cellulose gel and sodium fluorescein onto the ocular surface [10]. However, the effects of evaporative dry eye treatments on tear film contamination in eye cosmetic wearers have not been studied. The aim of the current study was to compare single application effects of a lipid-containing lubricant eye drop and a liposomal spray, on tear film parameters and contamination in eyeliner wearers, to inform clinical recommendations for dry eye treatment in patients concurrently wearing eye cosmetics. In order to investigate the potential destabilising effects of tear film contamination [3,4,10], slit lamp examination and clinical measurements of tear film stability, evaporation and the lipid layer were conducted.

2. Methods

2.1. Subjects

This prospective, randomised, paired-eye, investigator-masked trial followed the tenets of the Declaration of Helsinki, and was approved by the University of Auckland Human Participants Ethics Committee (UAHPEC-09631). Subjects were required to be female, 18 years or older, and non-contact lens wearers, with no history of major systemic or ocular disease, no previous ocular surgery, no topical or systemic medications affecting the eye, and no allergies to eye cosmetics or topical eye medications. Eligible participants were enrolled after providing written informed consent.

A total of 50 eligible participants was recruited, exceeding the sample size requirement for the desired study power. The designated outcome measure for determining sample size was non-invasive tear film break-up time. Power calculations showed that a minimum of 41 participants was required, to detect a clinically significant difference of 5 s, in any of the four pairwise comparisons, with 80% power ($\beta = 0.2$) at a two-sided statistical significance level of 5% ($\alpha = 0.05$). The SD of normal values being estimated to be at 8 s [24]. Sample size estimates were determined using a uniform non-parametric adjustment, with PASS 2002 (NCSS Statistical Software LLC, Utah, USA).

2.2. Materials

Participants were instructed not to apply facial cosmetic products prior to the laboratory session. A fresh pencil eyeliner (Crayon Eye Definer, The Body Shop®, New Zealand) was applied to the periocular skin of the upper eyelid of both eyes of each participant, anterior to the lash line. Pre-treatment clinical assessment was conducted fifteen minutes following eyeliner application.

2.3. Treatments

Random assignment of two lipid-based tear supplements to either the left or right eye of participants, occurred such that one eye was assigned a lipid-containing lubricant eye drop (Systane® Balance, Alcon®, Texas, USA), and the contralateral eye a phospholipid liposomal spray (Tears Again®, Optima Pharmazeutische GmbH, Germany). The lubricant eye drop contains an emulsion of phospholipids and mineral oils [18], while the primary active ingredient of the liposomal spray is phosphatidylcholine [20]. Following pre-treatment clinical assessment, a single drop of lubricant eye drop was applied to one eye, while the fellow eye received a single liposomal spray onto closed eyelids from a distance of 10 cm, according to the respective manufacturer's instructions. A midline nose bridge septum was used to minimise contamination of the other eye during spray application [25]. Post-treatment clinical assessment was conducted fifteen minutes following treatment application.

2.4. Measurements

The McMonnies Dry Eye Questionnaire and Ocular Surface Disease Index (OSDI) questionnaires were administered to grade the severity of dry eye symptoms at baseline.

The investigator conducting clinical assessments was masked to treatment randomisation. Clinical assessments were performed pre-treatment and post-treatment. Slit lamp examination was used to identify any tear film contamination (appearing as dark pigment particles), tear film debris, and lid margin foaming. The lower tear meniscus height was determined from a high magnification digital image, calibrated via graticule, by Image J software (National Institutes of Health, Maryland, USA). Non-invasive tear film break-up time and lipid layer grade were evaluated with the Tearscope Plus (Keeler, UK), with and without the fine grid insert, respectively. Non-invasive tear film break-up time was recorded as the time taken, after a blink, for the grid reflection to first show distortion, while the subject maintained fixation and was requested to refrain from blinking. Three consecutive break-up time measurements were averaged. Lipid layer grading was based on the Guillon-Keeler grading system: grade 1, open meshwork; grade 2, closed meshwork; grade 3, wave or flow; grade 4, amorphous; grade 5, colored fringes. Grade 0 was assigned to non-continuous layer due to non-visibility of lipid/abnormal colored fringes [26]. Tear evaporation rate was measured using a Vapometer (Delfin, Kuopio, Finland) with a swimming goggle housing. Evaporation rates in the open and closed eye states were recorded in order to factor out skin evaporation and allow quantification of evaporation only from the tear film of the exposed ocular surface.

To further classify dry eye status, sodium fluorescein and lissamine green dyes were then applied, in turn, to the bulbar conjunctiva in order to evaluate the localized corneal and conjunctival areas of epithelial dessciation. The staining was recorded using the modified Oxford grading scheme [27], where the nasal and temporal conjunctiva were each divided into three areas and the cornea into five areas. Staining was graded from 0 to 5 according to the level of confluence in each area, and summed to provide a maximum score of 55. Infrared meibography was performed using a meibographer (SDZ Ltd, Auckland, NZ), with the upper and lower eyelids everted in turn [28]. From the captured image, visible meibomian glands were outlined and the relative area of meibomian gland dropout calculated using Image J software. Percentage dropout was calculated by dividing the area with no visible glands by the entire conjunctival area [29,30].

2.5. Statistics

Statistical analyses were performed using Graph Pad Prism version 6.02 (http://www.graphpad.com). Comparison of continuous variables (tear meniscus height, tear evaporation rate) between and within treatment groups were performed using multiplicity adjusted Sidak's tests within a repeated measures analysis of variance model, where normal distribution had been confirmed by the Kolmogorov-Smirnov test ($p > 0.05$). Non-normally distributed measures (non-invasive tear film break-up

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