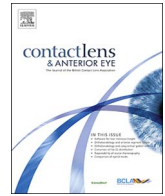




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The efficacy of tea tree face wash, 1, 2-Octanediol and microblepharoxfoliation in treating *Demodex folliculorum* blepharitis

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ABSTRACT

Purpose: To compare the efficacy of Dr Organic Tea Tree Face Wash, OcuSoft Lids Scrub Plus and the BlephEx™ device at treating of *Demodex folliculorum* blepharitis.

Methods: Eighty-six subjects (33 males/36 females) were enrolled in a randomised controlled interventional treatment study. Subjects completed a dry eye symptom questionnaire and were assessed for presence of *Demodex folliculorum*. Subjects were divided into three groups according to treatment: Dr Organic Tea Tree Face Wash (A) (n = 28), OcuSoft Lid Scrub Plus (B) (n = 30), or in-house lid scrub with the BlephEx™ device before nightly lid scrubs with OcuSoft Lid Scrub Plus (C) (n = 28). Subjects were advised to clean their eyelids nightly for four weeks. Each subject was re-assessed for symptoms and *Demodex folliculorum* blepharitis after two weeks and four weeks of treatment.

Results: The quantity of *Demodex folliculorum* was significantly reduced after four weeks of treatment in all three groups (p < 0.05). Overall, there was no difference in efficacy between the three treatments (p > 0.1). Symptoms reported by subjects were significantly improved after two and four weeks of treatment (p < 0.05). Overall, there was no difference in efficacy between the three treatments to reduce symptoms after two or four weeks (p = 0.813 and p = 0.646 respectively).

Conclusion: All three methods tested have shown good ability to reduce *Demodex folliculorum* quantity, improve subjective symptoms and help treat *Demodex folliculorum* blepharitis.

1. Introduction

Demodex folliculorum (DF) is a microscopic, host-specific ectoparasites that lives in the pilosebaceous units of humans. The mites are translucent and worm-like with a head, four pairs of legs, and a longer body tail [1,2]. Adult DF is approximately 0.4 mm in length [3,4], most frequently found on the eyelashes, and is associated with anterior blepharitis [2,5–7].

Demodex feeds on epidermal skin cells and sebum, and are therefore most commonly found in areas rich in sebaceous glands – cheeks, nose, chin and the periocular area [2,8]. The pathogenicity of the mites has long been debated [9–12]. While DF may begin as a saprophytic commensal organism that does not require intervention, it does appear to have pathogenic potential. It has been postulated that DF mites become pathogenic when the number of mites increases beyond a critical level (> 5 mites/cm²) [11], with higher densities associated with immunodeficiency [13]. Studies have also found DF and DB to be associated with blepharitis [2,5–7], chalazia [14–16], rosacea [17,18] and other dermatologic conditions [19]. In ocular rosacea, DF infestation

has been reported to cause corneal neovascularisation, infiltration, opacities and scars [20,21]. DF use their claws to scrape at the internal walls of the lash follicles resulting in follicular distention, epithelial hyperplasia and reactive hyperkeratinisation which is visible as a translucent cuff at the base of the eyelash [22]. This finding is clinically known as cylindrical dandruff (CD) and is now considered a pathognomonic sign for the presence of DF [4].

To date, the majority of treatment studies to date have investigated treatment of *Demodex* skin infestation, with varying results [23–30]. It has emerged in recent years that tea tree oil (TTO) is quite effective at killing DF [31,32], and its use in treating DF blepharitis is growing [20,33–35]. Other studies have looked at the efficacy of acaricidal substances such as ivermectin and metronidazole with varying reports of success with each [36–38]. However the use of TTO, ivermectin and other systemic acaricidal drugs are not without their complications and may not be suitable for all patients. Alternative therapies need to be available for those not suitable, or in countries where the drug has not yet been licensed for human use.

There are many products available marketed for the treatment of

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Table 1
Lid Scrub Instructions. Step-by-step instructions provided to subjects for nightly lid scrubs at home.

Group A (TTFW)	Group B (OLSP wipes) and Group C (BlephEx™)
Step 1: Place a small amount of TTFW on a cotton pad	Remove the OLSP wipe from its packet
Step 2: Gently but thoroughly scrub the eyelid and lash margin in circular movements, ensuring to scrub along the base of the eyelashes	Gently but thoroughly scrub the eyelid and lash margin in circular movements, ensuring to scrub along the base of the eyelashes
Step 3: Begin with the eyes closed to scrub along the top of the lashes. To scrub along the inner layer of lashes, look downwards to avoid contact with the cornea and gently pull the upper eyelid upwards. To scrub along the lower eyelashes, look upwards and gently pull down on the lower lid.	Begin with the eyes closed to scrub along the top of the lashes. To scrub along the inner layer of lashes, look downwards to avoid contact with the cornea and gently pull the upper eyelid upwards. To scrub along the lower eyelashes, look upwards and gently pull down on the lower lid.
Step 4: Using a clean cotton pad, rinse the TTFW from the eyelids	This is a leave-on formula, do not rinse until morning
Step 5: Repeat on other eye	Repeat on other eye

blepharitis and dry eye, which seem to be low risk, first choice of treatments in many cases. However, it has been noted that many of these commercial products are available, without substantial evidence of efficacy, and further research in this area has been recommended [39].

The aim of the current study is to investigate the efficacy of three different treatment methods at reducing the quantity of DF. This study will provide evidence based results on the performance of commercial products available to patients and practitioners for the treatment of DF blepharitis in a clinical setting.

2. Materials and methods

This study was conducted under the *Tenets of Helsinki Declaration of Human Studies* [40] after approval by the Dublin Institute of Technology Research Ethics Committee. Written informed consent was obtained from all subjects prior to enrolment.

Eighty-six subjects were recruited through the National Optometry Centre of Dublin Institute of Technology. All subjects were over 18 years of age. Subjects were excluded if they had ocular surgery in the past six months, or were undergoing current ophthalmic treatment.

The subjects were divided into groups according to treatment:

- Group A: Dr Organic Tea Tree Face Wash (TTFW) (n = 28);
- Group B: OcuSoft Lid Scrub Plus (OLSP) (n = 30);
- Group C: BlephEx™ microblepharoexfoliation device (n = 28);

Each subject chose a number from the list, which corresponded to the treatment assigned to the subject. The examiner was blind to the treatment throughout all stages of the study for group A and group B. The examiner performed the BlephEx™ treatment on subjects from group C and was therefore not blind to the treatment in this group.

Dr Organic TTFW contains 38% terpinen-4-ol, the most active ingredient in tea tree shown to be effective at killing DF in a dose dependent manner [32]. The active ingredient in OLSP wipes is 1, 2-Octanediol; a substance which has been shown to have pediculicide potential [41]. BlephEx™ is a patented [42] hand-held device, developed for the treatment of ocular surface disorders including blepharitis. The apparatus consists of a hand-held electromechanical unit and a disposable micro-sponge inserted in the chuck that spins rapidly to

Table 2
In-house microblepharoexfoliation procedure with BlephEx™ as per manufacturer's guidelines.

Group C: BlephEx™ Microblepharoexfoliation procedure	
Step 1:	Soak the sterile micro-sponge tip in cleaning solution (OcuSoft Lid Scrub Plus foam was used for this study)
Step 2:	Once soaked, insert one tip into the BlephEx™ chuck
Step 3:	Instruct the patient to lean their head back. Treat one eyelid at a time, using a new tip for each lid. For the upper eyelid; gently pull up on the upper eyelid and instruct the patient to look downwards. For the lower eyelid; gently pull down on the lower eyelid and instruct the patient to look upwards.
Step 4:	To scrub; apply the spinning micro-sponge to the edge of the eyelid and lash line, and sweep from nasal to temporal and back again in a scrubbing motion for 20–30 s or until as much debris as possible is removed.
Step 5:	After scrubbing with BlephEx™, clean the patient's eyelids with saline to rinse off the formula.

provide debridement and exfoliation at the lash margin. This treatment is referred to as microblepharoexfoliation [43].

2.1. Examination

All examinations were conducted by one optometrist, the author (OM). Subjects completed a modified version of the OSDI dry eye questionnaire. The OSDI questionnaire is graded on a 4-point Likert scale indicating frequency of the symptom in question: none of the time (0), some of the time (1), half of the time (2), most of the time (3), and all of the time (4). The total OSDI score is calculated using the following formula: total symptom number x 25/number of questions answered [44,45]. This creates a score on a scale of 0–100, with higher scores indicating increased severity of symptoms. The severity of symptoms were then graded from grade 0 (normal) to grade 3 (severe) according to OSDI guidelines. Lee et al. [46] modified the OSDI questionnaire by adding questions relating to blepharitis (itchy eyes and matter along the eyelid margin), in order to increase the questionnaires sensitivity to detect DF. Similar to Lee et al. [46] questions relating to itchy eyes and matter along the eyelid margin were added to the questionnaire used in the current study (validation paper submitted for review). Habitual visual acuity (LogMAR) was measured. Slit lamp examination was conducted to assess and grade presence of CD. All subjects were then assessed for the presence of DF. This involved examining one eyelash from each eyelid; first through manipulation of the eyelash, and then epilation and microscopic examination. Manipulation of the eyelashes involved rotation of the lash in clockwise and counter-clockwise directions using a sterile forceps, stimulating DF tails, if present, to emerge from the lash follicle. The lash was then epilated and examined under a microscope to count DF. Adult DF count was recorded using the modified Coston method [4]. Presence of DF was defined as: DF seen on lash rotation and/or one or more DF counted on microscopic examination.

2.2. Lid scrubs routine

The lid scrub routine is outlined in Table 1.

In house microblepharoexfoliation was carried out on group C at the initial visit only. The procedure, as per manufacturer's guidelines, was as seen in Table 2.

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