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Eyelid margin cleaning using Deep Cleaning Device for the treatment of meibomian gland dysfunction-associated dry eye: a preliminary investigation*

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Abstract: Objective: To evaluate the safety and effectiveness of eyelid margin cleaning using Deep Cleaning Device for the treatment of meibomian gland dysfunction-associated dry eye. Methods: This was a prospective, randomized, open-label, investigator-masked, and self-controlled study. We randomly assigned one eye of patients with meibomian gland dysfunction-associated dry eye to the treatment group, and the other eye to the control group. Both groups received artificial tears and lid warming; the treatment group received an additional one-time in-office eyelid margin cleaning using Deep Cleaning Device. Non-invasive tear break-up time (NITBUT) and tear meniscus height (TMH) of each eye, and Standard Patient Evaluation for Eye Dryness II (SPEED II) score of each patient were evaluated before and at one week after treatment. Results: Thirty eyes of 15 patients were enrolled. No adverse effects occurred during the treatment. Compared with the baseline values, the SPEED score decreased significantly at one week after treatment (mean±95% confidence interval, 11.00±0.99 vs. 5.67±1.67, P<0.0001), the NITBUT-first in the treatment group increased significantly at one week after treatment ((4.74±1.27) s vs. (7.49±2.22) s, P=0.01). The NITBUT-first was significantly longer in the treatment group ((7.49±2.22) s) than in the control group ((5.17±0.91) s) at one week after treatment (P=0.042). No significant differences were found in other tear film parameters between the two groups. Conclusions: Eyelid margin cleaning using the novel Deep Cleaning Device is a convenient, effective, and safe treatment for patients with meibomian gland dysfunction-associated dry eye.

Key words: Eyelid margin cleaning; Deep Cleaning Device; Meibomian gland dysfunction; Dry eye
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1 Introduction

Dry eye is a common chronic ocular surface disease. Symptoms of dry eye include dryness, foreign body sensation, eye fatigue, and fluctuating visual impairment. These symptoms can greatly affect patients' quality of life (McDonald et al., 2016). In China, nearly a third of people between the ages of 5 and 85 years are suffering from dry eye symptoms (Song et al., 2018). Evaporation and aqueous tear-deficiency are two main causes of dry eye, and meibomian gland dysfunction is the most common etiology of the evaporative dry eye (Lemp, 1995; Gipson et al., 2007; Knop et al., 2011; Chhadva et al., 2017; Craig et al., 2017; Stapleton et al., 2017).

Terminal duct obstruction is one of the characteristics of meibomian gland dysfunction (Nelson et al., 2011; Bron et al., 2017), and lid hygiene is suggested to manage this condition (Geerling et al., 2011). The application of lid warming, mechanical

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expression, and cleaning of eyelashes and lid margin are important components of lid hygiene (Geerling et al., 2011). The routine use of artificial tears accounts for a large proportion of the treatment of evaporative dry eye (Jones et al., 2017; Nasser et al., 2018). Currently, artificial tears combined with lid hygiene or lid warming are the most common clinical management of meibomian gland dysfunction-associated dry eye (Geerling et al., 2011; Jones et al., 2017). Non-invasive tear break-up time is one of the most appropriate tests for monitoring dry eye disease (Wolffsohn et al., 2017).

Although lid margin cleaning plays an important role in the treatment of meibomian gland dysfunction, a standardized method that is safe and effective has not yet been fully established. Cleaning with baby shampoo is one of the common methods, but some of its ingredients can potentially trigger allergies or cause ocular discomfort (Paugh et al., 1990; Thode and Latkany, 2015; Ngo et al., 2018). Newly developed treatments include formulated eyelid shampoo (Kobayashi et al., 2016), eyelid cleaning with ointment (Kaido et al., 2017), eyelid scrubs with a lid cleaner (Lee et al., 2017), and debridement-scaling using a stainless steel golf club spud (Korb and Blackie, 2013). Some of these procedures are performed by patients themselves. Therefore, the treatments are inevitably unstandardized and patient compliance is uncertain, which may affect the treatment outcome. In this study, we used a novel technique which is less invasive and driven by electricity to remove the debris and clear the obstruction of the meibomian gland orifices. The purpose of this study was to evaluate the safety and effectiveness of this newly developed Deep Cleaning Device (Ocuface Medical Co., Ltd., Guangzhou, China) in the treatment of meibomian gland dysfunction-associated dry eye.

2 Methods

2.1 Participants

This was a single-center, prospective, randomized, open-label, investigator-masked, and self-controlled study. It was approved by the ethics committee of the Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University (Hangzhou, China) and the research process was in full accordance with the Declaration of Helsinki. Participants in the study were selected from the patient population at Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University in Hangzhou, China. All participants took part in the study were required to read and sign an informed consent.

Participants needed to meet all these inclusion criteria: (1) age above 18 years; (2) dry eye symptoms should have persisted for at least three months prior to commencement of the study, which were assessed by the Standard Patient Evaluation for Eye Dryness II (SPEED II) questionnaire, and the SPEED score was greater than or equal to 6; (3) the non-invasive tear break-up time measured by Keratograph 5M (Oculus Optikgeräte GmbH, Wetzlar, Germany) was lower than 10 s (Qi et al., 2017); (4) the meibomian gland secretion grade was greater than or equal to 4 and/or an expressibility grade of 1 or more; (5) the grade of meibomian gland dropout measured by Keratograph 5M was greater than or equal to 2; (6) there was more than one evidence of meibomian gland obstruction observed by slit-lamp examination or Keratograph 5M, such as lid irregularity, plugging or pouting of the meibomian gland orifices, and changes in lid morphology (Tomlinson et al., 2011; Wolffsohn et al., 2017).

The exclusion criteria included: (1) history of ocular surgery or trauma; (2) presence of ocular infection or inflammation; (3) eyelid structural abnormalities affecting lid function; (4) systemic diseases affecting ocular surface such as Sjogren's syndrome; (5) use of facial cosmetics or contact lens within one week prior to commencement of the study, or frequent users (≥5 times per month); (6) pregnancy or lactating mother.

2.2 Study design

Each participant's basic information and clinical data were recorded. We randomly assigned one eye of these participants to the treatment group and the other eye to the control group. Both groups received artificial tears (HYLO-COMOD, HYCOSAN, 0.1% (1 g/L) sodium hyaluronate, Ursapharm Arzneimittel GmbH, Saarbrücken, Germany) four times daily and lid warming (Steam Eye Mask, Ocuface Medical Co., Ltd., Guangzhou, China) 15 min per night. The treatment group received an additional one-time in-office lid

margin cleaning using Deep Cleaning Device. All device-related adverse events and discomfort/pain during or after treatment were recorded. Ocular surface staining was evaluated before and after the treatment. Participants were re-evaluated at one week after treatment. Because of the significant difference in the therapeutic method, double-mask was not viable.

2.3 Evaluation of clinical data

Keratograph 5M was used to measure the non-invasive tear break-up time (including non-invasive tear break-up time-first and non-invasive tear break-up time-average) and tear meniscus height at the baseline visit and at one week after treatment. Non-invasive tear break-up time-first is the time at which the first distortion of Placido rings occurs as measured by the device; non-invasive tear break-up time-average is the mean time of first break-up incidents in different locations in a corneal diameter of 8 mm (Qi et al., 2017; Xie et al., 2018a). The instrument was calibrated by the manufacturer prior to the study, and the reliability of this instrument had been described in detail in our previous study (Xie et al., 2018a).

2.4 Deep cleaning procedure

All cleaning treatments were performed by the same doctor, and the following observations and data collection were performed by another trained masked doctor. The obstructions of the meibomian orifices in the upper and lower eyelid were observed under slit-lamp examination, and then participants were instructed to lie comfortably on a therapeutic bed. The Deep Cleaning Device was composed of an electric cleaning handle and a brush head. The rated voltage of this device was 220 V alternating current, and the rated frequency was 50 Hz. The power of this device was 15 W. The brush head (made of sponge) was fully wetted with 0.9% (9 g/L) normal saline. The rotation speed, which could be between 0–4500 r/min was adjusted by a controller when the brush head was moving. The speed was adjusted according to the cleanliness of the lid margin and the comfort of the participant. The top of the brush head was used to gently rub the upper and lower lid margin, the meibomian orifices, and the root of the eyelashes (Fig. 1). The participants were asked to look down when cleaning the upper lid margin and look up when cleaning the lower lid margin to avoid touching the cornea, using a new brush head for each lid. After cleaning, the lid margin was again observed under the slit-lamp. There was no apparent discomfort throughout the whole process, so no anesthetic was needed. Finally, the participants were informed to use the artificial tears and lid warming in both eyes and made an appointment for a one-week follow-up.

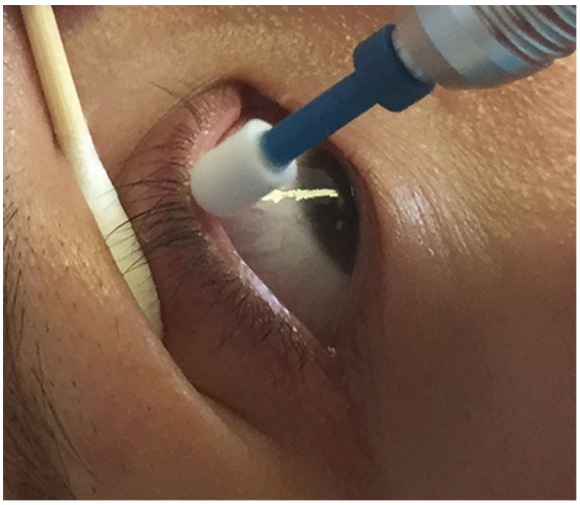

Fig. 1 Handle and brush head of Deep Cleaning Device
The brush head should be held perpendicularly to the skin of the eyelid margin

2.5 Statistical analysis

Data analysis was performed by the Statistical Package for the Social Sciences (SPSS, Version 20.0; IBM SPSS Statistics, IBM Corporation, Chicago, IL, USA). Results are expressed as mean±95% confidence interval. The Kolmogorov-Smirnov test was used to test the normality of the data. Paired *t*-tests were performed to determine if there were any significant differences between baseline parameters of different groups and between pre- and post-treatments. The statistical significance was set to $P<0.05$.

3 Results

A total of 30 eyes of 15 participants (11 women and 4 men) were enrolled in this study. The mean age was (44±10) years, ranging from 24 to 69 years. The mean duration of dry eye symptom was (28±14) months, ranging from 3 to 96 months. The mean SPEED score was 11.00±0.99, ranging from 6.00 to 17.00 at the

baseline visit. No complications or adverse effects occurred during the treatment process for these 15 participants. Fig. 2 shows images arising from the same patient before and after the procedure. Fig. 2a shows the obstructions of the meibomian orifices, and plugs were removed after the Deep Cleaning Device treatment (Fig. 2b). Results of clinical data of the treatment and control groups are summarized and compared in Table 1; no significant differences were found between the two groups at the baseline visit.

At one week after treatment, the mean SPEED score was 5.67±1.67, ranging from 0 to 12.00. Compared with the baseline visit, the SPEED score decreased significantly (P<0.0001; Fig. 3). The box plots of the non-invasive tear break-up time-first are shown in Fig. 4. Compared with the baseline values, non-invasive tear break-up time-first in the treatment group increased significantly at one week after treatment ((4.74±1.27) s vs. (7.49±2.22) s, P=0.01). Non-invasive tear break-up time-first was significantly longer in the treatment group ((7.49±2.22) s) than in the control group ((5.17±0.91) s) at one week after treatment (P=0.042). There was no significant difference in the non-invasive tear break-up time-first of the control group between the one week and baseline visits ((5.17±0.91) s vs. (4.50±1.44) s, P=0.402).

Table 1 Baseline clinical data of subjects in different groups

Group	NITBUT-first (s)	NITBUT-average (s)	TMH (mm)
Treated eyes (n=15)	4.74±1.27	6.84±1.88	0.23±0.04
Control eyes (n=15)	4.50±1.44	7.84±2.52	0.23±0.03
P	0.723	0.369	0.597

Data are expressed as mean±95% confidence interval. NITBUT, non-invasive tear break-up time; TMH, tear meniscus height

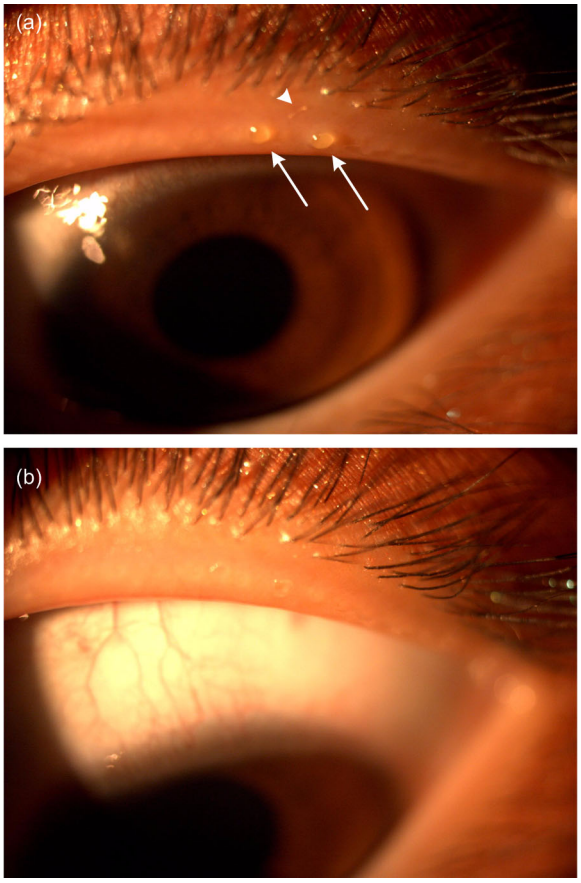

Fig. 2 Eyelid margin before and after treatment
(a) Meibomian gland obstructions (arrows) and eyelid flaking (arrowhead) before treatment; (b) The obstructions and flaking were removed after treatment

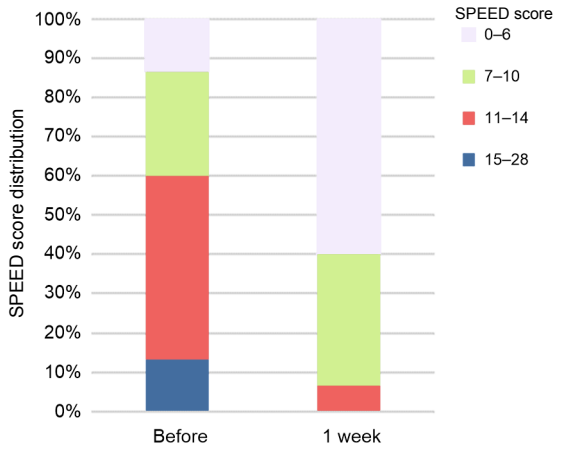

Fig. 3 Changes of SPEED score between the baseline visit and one week after treatment

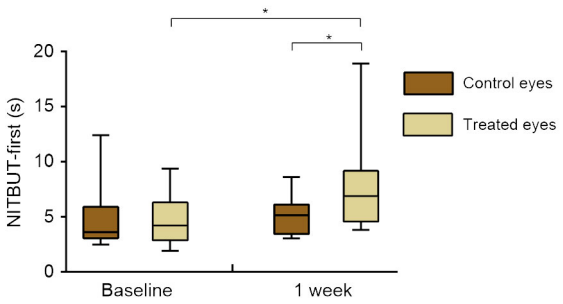

Fig. 4 Box plots of the non-invasive tear break-up time-first of different groups before and after treatment
Data are expressed as mean±95% confidence interval. * P<0.05 (paired t-test)

Non-invasive tear break-up time-average increased at one-week visit compared to the baseline in the treatment and control groups, but the differences were not statistically significant ((8.74±2.53) s vs. (6.84±1.88) s, P=0.148; (9.01±2.23) s vs. (7.84±2.52) s, P=0.239, respectively). No significant differences were found in the tear meniscus height of the treatment ((0.23±0.03) mm vs. (0.23±0.04) mm, P=0.721) and control ((0.25±0.05) mm vs. (0.23±0.03) mm, P=0.721) groups between the one week and baseline visits. No significant difference in the tear meniscus height was found between the treatment and control groups at the one-week visit ((0.23±0.03) mm vs. (0.25±0.05) mm, P=0.348).

4 Discussion

The lipid secreted by the meibomian gland constitutes the outermost layer of tear film, and reduces the evaporation of the tear film and enhances tear film stability (Bron et al., 2004; Chhadva et al., 2017). When the ductal epithelium undergoes hyperkeratinization and the meibum viscosity increases, blockage of the meibomian gland reduces the available meibum in the lid margin and tear film, resulting in tear film instability, increasing evaporation and a serious dry eye symptom (Shimazaki et al., 1995; Knop et al., 2011; Nichols et al., 2011; Bron et al., 2017; Willcox et al., 2017). Meibomian gland obstruction is considered as an important reason for meibomian gland dysfunction-associated dry eye (Baudouin et al., 2016). Eyelid debridement or scrubbing can help remove keratotic obstructions and dead cells, making the secretion of lipid more smooth (Greiner et al., 1999; Kaido et al., 2017).

Compared with normal eyes, meibum lipid collected from meibomian gland dysfunction participants has a higher phase-transition temperature (Borchman et al., 2011). Lid warming can heat the lipids to accelerate secretion and promote blood flow around tissues of the meibomian glands (Blackie et al., 2008). Artificial tears are supplementary to the tear film, and work for all types of dry eye (Geerling et al., 2011; Jones et al., 2017). However, neither of these treatments solves the problem of obstruction of meibomian gland terminal ducts. The combination with the application of lid margin cleaning may greatly improve the overall treatment effect. According to our results, non-invasive tear break-up time-first was significantly improved after artificial tears and lid warming treatment combined with lid margin cleaning with the Deep Cleaning Device, and the treatment effect was superior to using artificial tears and lid warming alone at one week after treatment. The SPEED II questionnaire has been proven to be a repeatable and valid diagnostic test for detecting dry eye symptoms (Ngo et al., 2013; Finis et al., 2014; Asiedu et al., 2016), and is more suitable for meibomian gland dysfunction-associated dry eye (Wolffsohn et al., 2017). Fourteen of the 15 participants in our study had a significantly decreased SPEED score at one week after treatment, and they felt that the treated eye was better than the control eye; only one participant reported that the difference between two eyes was not significant after the lid margin cleaning.

Various lid margin cleaning methods have been introduced previously (Korb and Blackie, 2013; Kobayashi et al., 2016; Kaido et al., 2017; Lee et al., 2017). Among these treatments, doctors only gave instructions, and the specific procedure was usually performed by patients themselves at home. This meant that the therapeutic effect was mainly dependent on patient compliance. Furthermore, improper manipulation may cause ocular surface damage. By contrast, our treatment procedure was standardized and performed by the doctor. Compared with other in-door treatment methods (Zhao et al., 2016; Syed and Sutula, 2017; Wang et al., 2018; Aketa et al., 2019), the device we used has the advantages of being less invasive, lower cost, and more convenient. It is easily managed because of its electric characteristic.

The results of this study suggested that the Deep Cleaning Device is a safe and effective tool for the treatment of meibomian gland dysfunction-associated dry eye. No ocular or periocular symptoms were reported during or after the treatment progress. Only a few participants reported feeling a transient itchiness when the brush head was rubbing the lid margin. Although it did not occur in this study, the brush head has a potential risk of inadvertently touching and damaging the cornea. Wearing a safety contact lens can effectively protect the cornea during treatment.

There are some limitations to our study. First, since this was a self-control study, it was impossible to mask the participants, and we could not distinguish the SPEED score between the treated and control eyes.

Second, the relatively small sample size might cause the non-significant differences in non-invasive tear break-up time-average and tear meniscus height within and between the groups. Because of the small differences of tear meniscus height between the groups, it may need a very large sample size to find a possible difference (Xie et al., 2018a, 2018b). Finally, the long-term treatment effect of Deep Cleaning Device was not evaluated due to inadequate number of participants completing a longer follow-up. Ten of the 15 participants in our study were followed for one month after treatment, and the mean non-invasive tear break-up time-average of the treated eyes was significantly increased at the one-month visit compared with the baseline visit (data not shown), but there were no significant differences in other tear film parameters between the two groups. These preliminary results suggested that the treatment effect of Deep Cleaning Device might only last for about one month, and the participants may need to return to the clinic one month after primary treatment to maintain a good effect. Further studies with larger sample sizes and longer follow-up time are planned to investigate the long-term effect of this treatment method.

5 Conclusions

Lid margin cleaning using the novel Deep Cleaning Device combined with artificial tears and lid warming was a convenient, effective, and safe method for the treatment of meibomian gland dysfunction-associated dry eye, and the treatment effect was superior to using artificial tears and lid warming alone at one week after treatment.

Contributors

Yu-feng YAO and Ye-sheng XU designed the study. Xia ZHANG and Lou-jing JIANG performed the experimental research and collected the data. Lou-jing JIANG carried out data processing and performed data analysis. Wen-jia XIE and Lou-jing JIANG wrote and edited the manuscript. All authors edited and approved the final manuscript and, therefore, had full access to all the data in the study and take responsibility for the integrity and security of the data.

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Compliance with ethics guidelines

Wen-jia XIE, Lou-jing JIANG, Xia ZHANG, Ye-sheng XU, and Yu-feng YAO declare that they have no conflict of interest.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Informed consent was obtained from all patients for being included in the study.

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中文概要

题　目：深度清洁装置清洁睑缘治疗睑板腺功能障碍相关干眼症的初步研究

目　的：评价深度清洁装置清洁睑缘治疗睑板腺功能障碍相关干眼症的安全性和有效性。

创新点：评估了一个干眼症治疗新方法的疗效。

方　法：将睑板腺功能障碍相关干眼症患者的两只眼随机分入治疗组和对照组。对照组进行人工泪液和眼睑热敷治疗，治疗组在上述治疗基础上加用深度清洁装置进行一次睑缘清洁。在基线和治疗一周后测量非侵入性泪膜破裂时间和泪河高度，用问卷调查表对每个人干眼症状进行评分。

结　论：深度清洁装置睑缘清洁是一种安全有效的方法，适用于睑板腺功能障碍相关干眼症患者。

关键词：睑缘清洁；深度清洁装置；睑板腺功能障碍；干眼症