

Efficacy of Self-Administration of a Personal Mechanical Eyelid Device for the Treatment of **Dry Eye Disease, Blepharitis and Meibomian Gland Disease**

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Key words: Dry eye disease, blepharitis, Meibomian gland disease



The NuLids System

An effective doctor directed, at home, treatment for Evaporative Dry Eye

ABSTRACT

Purpose: A prospective study to evaluate the safety and efficacy of a novel mechanical eyelid device (NuLids® by NuSight Medical, LLC, Rancho Santa Fe, CA) used at home for the treatment of dry eye disease (DED), blepharitis and meibomian gland disease (MGD).

Methods: Seventy-four (74) eyes of thirty-seven (37) patients were self-treated with the NuLids® device at home. Inclusion criteria included blepharitis, MGD and/or DED. After an initial training session, each eyelid was treated for 15 seconds (total of 1 minute per treatment session per day). The following tests were collected before the first treatment and after the final treatment: OSDI survey, BCVA, Tear Osmolarity Test (Tear Lab), Tear Break Up Time (TBUT), Mei-

bomian Gland Score (MGS), Meibomian Glands Yielding Liquid Secretions (MGYLS), Sicca Ocular Staining Score. A satisfaction with treatment survey was taken at the conclusion of treatment.

Results: Symptoms improved based on an average decrease in OSDI score from 54.2 ± 19.5 (mean \pm SD) to 26.7 ± 18.4 ($P < 0.001$). Tear osmolarity improved from 315 ± 15.7 to 306 ± 13.9 ($P = 0.002$). A significant improvement in TBUT was noted from pre-treatment 4.8 ± 1.7 seconds to post-treatment of 7.9 ± 4.1 seconds ($P < 0.001$). MGS improved from 8.9 ± 5.1 to 7.0 ± 5.9 ($P = 0.01$). MGYLS improved from 8.7 ± 6.2 to 15.8 ± 6.9 ($P = 0.002$). Sicca Ocular Staining Score improved from 2.7 ± 2.1 to 1.4 ± 1.5 ($P = 0.002$).

There were no adverse events. No corneal or conjunctival trauma. No patients dropped out of the trial due to discomfort. 91% of participants agreed or strongly agreed that the device was easy and convenient to use. Of those previously using manual lid scrubs, 82% felt the NuLids® device was easier and more comfortable to use. 89% described little or no discomfort. 95% were satisfied or very satisfied with the overall treatment.

Conclusions: A mechanical device was safely used by patients at home for 1 minute daily for 30 days to treat DED, blepharitis and MGD. There was a statistically significant improvement in signs and symptoms of DED as shown by improved OSDI, tear osmolarity, TBUT, MGS, MGYLS and Ocular Staining Score. High patient satisfaction along with low risk of adverse events supports the use of this device as a valid tool to treat DED, blepharitis and MGD.

INTRODUCTION

Dry eye disease (DED), blepharitis and Meibomian gland disease (MGD) are some of the most common disorders encountered in an eye care practice. It is estimated that over 16 million U.S. adults have diagnosed DED.¹ MGD is the most common etiology of DED, accounting for 86% of all dry eye patients.² MGD results in decreased and poor quality oil production, which leads to evaporative DED.³ The lipids produced by the Meibomian glands are essential to maintain tear film stability, reduce evaporation and maintain a healthy ocular surface with improved visual acuity.⁴

Eyelid hygiene is one of the cornerstones of MGD treatment.⁵ The principal goal of treatment of MGD

is to improve the quantity and quality of oil secretion from the glands which then decreases dry eye symptoms. Early treatment is very important⁶ as this can prevent long-term dry eye disease. There is a relatively high level of meibomian gland disease in the pediatric population.⁸ Therefore, early detection and patient education as to the long-term ramification of DED is paramount. Meibomian gland disease is under diagnosed and there is an unmet need for additional treatment modalities besides warm compresses and manual eyelid scrubs. Recently, office-based lid treatments have emerged, but these are both costly and inconvenient for the patient. A therapy that is less expensive and not requiring office visits should increase patient compliance. This study evaluates a novel new device for personal self-administrated treatment of Meibomian gland disease, blepharitis and dry eye disease.

MATERIALS AND METHOD

This was a multicenter, prospective study to evaluate the safety and efficacy of a mechanical device, NuLids® (NuSight Medical, Ranch Santa Fe, CA) for at home treatment of DED, blepharitis and MGD.

Patients were recruited from the private practices of the authors of this paper. Informed consent was obtained in accordance with the institutional review board committee approval. Inclusion criteria were age 18 years and above and the ability to cooperate for the study. Also patients we're required to have an OSDI score greater than 25. A visual acuity of 20/40 or better was needed in both eyes. Subjects were also required to have a tear osmolarity greater than 308 mOsm/L in at least one eye using

the TearLab Osmolarity System (TearLab, San Diego, CA) and a tear break up time (TBUT) of seven seconds or less in one eye.

This study was performed in compliance with the ethical principles of the declaration of Helsinki and Good Clinical Practice and was approved by Western Institutional Review Board (Puyallup, WA).

Exclusion criteria included any eye surgery in the last three months, history of previous herpetic eye disease or unwillingness to use a mechanical device near their eye. The patient's clinical chart review was also performed to collect relevant information regarding the patient's ocular history (including surgery, medication use and ocular or systemic disease). The patients were maintained on all existing therapies.

Each patient was asked to complete an Ocular Surface Disease Index (OSDI) questionnaire to assess the degree of dry eye symptoms. In addition patients had visual acuity testing. Tear osmolarity was performed before examining the patient and before any drops were applied. Subjects were instructed not to use any drops in the eye on the day of examination. Slit lamp examination included Tear Breakup Time (TBUT) after instillation of sodium fluorescein solution. Also a Meibomian gland score was assessed using the central five (5) Meibomian glands of the lower lid. Scores range from 0 (clear; normal) to 3 (inspissated; like toothpaste). When assessing the expression of a fixed number of glands, the sum of scores is recorded for each expressed gland to achieve a composite score. Thus to grade the central five (5) glands of the lower eyelid, the scores range from 0–15 for each lower eyelid.

Meibomian glands yielding

liquid secretions (MGYLS) were assessed for the nasal and central regions of the upper and lower eyelids using a standardized pressure device (Meibomian Gland Analyzer, Tear Science, Johnson and Johnson). A score of 0-16 was recorded for each eyelid, counting the number of glands from which fluid meibum may be expressed, with a total score of 0-32 per eye. Ocular surface staining was evaluated using fluorescein and lissamine green using the Sicca Ocular Staining Score (SOSS)

After in office training the patients were asked to use the NuLids® device (NuSight Medical, Rancho Santa Fe, CA) at home on a daily basis treating each eyelid margin for 15 seconds on a daily basis. Subjects were instructed to pull and evert the lower lids away from the eye for lower lid treatment and to close lids and evert upper lid for upper eyelid treatment. Hypochlorous Acid Gel 0.2% (Ocusoft *Hypochlor*™) was used to apply on the Soft Tip head. At the end of 30 days the patients returned for an evaluation where pretreatment testing was repeated and an exit survey administered

RESULTS

A total of 74 eyes of 37 participants were evaluated. The mean age of subjects was 54.9 ± 13.3 years. 30 patients were female and 7 male.

The OSDI has a possible total scores ranging from 0 to 100 (severe dry eye). All subjects completed the OSDI questionnaire before and at the conclusion of a 30-day treatment. The average entrance OSDI score was 54.2 ± 19.5 . After 30 days of treatment the average OSDI score decreased to 26.7 ± 18.4 ($P < 0.001$). 92% of patients showed an approved OSDI. Tear

osmolarity improved from 315 ± 15.7 to 306 ± 13.9 ($P = 0.002$). Tear breakup time improved from the pretreatment of 4.8 ± 1.7 seconds to post-treatment of 7.9 ± 4.1 seconds ($P < 0.001$). Meibomian glands score (MGS) improved from 8.9 ± 5.1 to 7.0 ± 5.9 ($P = 0.01$). Meibomian glands yielding liquid secretion (MGYLS) improved from 8.7 ± 6.2 to 15.8 ± 6.9 ($P = 0.002$). Sicca ocular staining score (SOSS) improved from 2.7 ± 2.1 to 1.4 ± 1.5 ($P = 0.002$).

TABLE 1.

	PRE-TREATMENT	POST-TREATMENT	P-VALUE
OSDI	54.2 ± 19.5	26.7 ± 18.4	$P < 0.001$
TOT (mOsm/L)	315 ± 15.7	306 ± 13.9	$P = 0.002$
TBUT (seconds)	4.8 ± 1.7	7.9 ± 4.1	$P < 0.001$
MGS	8.9 ± 5.1	7.0 ± 5.9	$P = 0.01$
MGYLS	8.7 ± 6.2	15.8 ± 6.9	$P = 0.002$
SOSS	2.7 ± 2.1	1.4 ± 1.5	$P = 0.002$

No adverse events reported. There was no trauma to the cornea or bulbar conjunctiva. The patient satisfaction survey revealed that 91% of patients agree or strongly agree that the device was easy and convenient to use. 89% noted little or no discomfort. Of those previously using manual lid scrubs, 82% felt the NuLids® device was easier and more comfortable to use. 91% were comfortable using the NuLids device within one week. 95% of patients were satisfied or very satisfied with the overall treatment.

DISCUSSION

Since the original discussion by Wolff in 1946,⁸ most maintain that the main role of the tear film lipid

layer is to decrease evaporation of the tears from the eye.⁹ Tear film instability, generally relates to the functionality of the tear film. The DEWS report describes that tear film instability is evidenced by early tear film break up time, as well as tear hyperosmolarity, representing the two of the main mechanisms of DED.¹⁰ In addition, in later stages ocular staining can be seen.

The normal tear film lipid layer reduces evaporation by about

90–95%.¹¹ Normally, clear oil (meibum) can be expressed from the meibomian orifices by pressing on the glands through the lids.¹² Simple obstructive Meibomian gland disease is the most common form of MGD.¹³ In these cases pressure on the eyelid margin will not yield oil from the glands.

Lid hygiene has been shown to produce decreased dry eye symptoms¹⁴ and is commonly recommended as a first line treatment for blepharitis and MGD. However, many patients with DED report no dry eye symptoms when evaluated for routine eye care. In one study, only 57% of patients with DED reported dry eye symptoms.¹⁵ Thus, it is imperative to evaluate the eye-

lids and Meibomian glands during routine eye exams even when no dry eye symptoms are described. Evaluating Meibomian gland function has been shown to improve the ability to predict DED.¹⁶ If Meibomian glands disease is diagnosed early and treated early, even without symptoms of dry eye, then DED may be avoided. Continued patient education about eyelid health can play an important role in long-term total ocular health.

The NuLids® device resulted in improvements both in the signs and symptoms of DED. The mechanisms of action for this treatment include:

- Cleaning bacteria and desiccated skin from the eyelid margin
- Decapping or opening Meibomian gland orifices
- Massaging or sonic stimulation of lid margin thus mechanically breaking up stagnant meibum in the glands and improving circulation.

Self-Administration of a personal mechanical eyelid device (NuLids®) to treat DED, blepharitis and MGD improved both signs and symptoms of dry eyes after treatment of 1 minute per day for 30 day. Patients safely used this mechanical device at home daily for 30 days to treat DED, blepharitis and MGD and required only minimal initial instruction. There was a statistically significant improvement in OSDI, tear osmolarity, TBUT, MGS, MGYS and Ocular Staining Score. This data along with a high patient satisfaction along and a low risk of adverse events supports the use of this device as a valid tool to treat DED, blepharitis and MGD. Further controlled studies and longer follow up could yield additional information. ●

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