DOI:10.14744/bej.2025.30306
Beyoglu Eye J 2025; 10(2): 59-65

Original Article

Thermal Pulsation Therapy (Lipiflow®): A Retrospective Analysis of Its Impact on Meibomian Gland Dysfunction and Dry Eye Disease

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Abstract

Objectives: The study aimed to evaluate the short-term effects of thermal pulsation therapy on dry eye parameters and meibomian gland dysfunction (MGD) in patients with evaporative dry eye.

Methods: A retrospective, single-center study included 250 eyes of 125 symptomatic patients with evaporative dry eye disease (DED) due to MGD. Patients received a single 12-min thermal pulsation therapy (LipiFlow®) (TearScience Inc., Morrisville, NC, USA). Before and at 1 and 6 months after treatment, the presence of DED and MGD was evaluated using the Schirmer-I test, tear break-up time (TBUT), oxfordstaining score, and meibomian gland secretion (MGS) score. Subjective dry eye complaints were measured using the ocular surface disease index (OSDI) score.

Results: The LipiFlow treatment improved both clinical signs (Schirmer I test, Oxford staining score, MGS score, and TBUT, respectively, p=0.000, p=0.000, p=0.000, p=0.000) and symptoms (OSDI scores p=0.000) up to 1 month post-treatment. While TBUT and MGS scores (respectively p=0.008, p=0.035) continued to improve until the 6th month, improvements in Schirmer I test, Oxford staining, and OSDI scores (respectively p=0.000, p=0.000, p=0.000) were sustained through 6 months.

Conclusion: It has been observed that single-session thermal pulsation treatment provides improvement in MGD and dry eye parameters up to 6 months and decreases in OSDI scores, indicating subjective complaints of patients. This treatment is thought to be an effective treatment option in evaporative DED secondary to MGD.

Keywords: Blepharitis, dry eye syndromes, meibomian gland dysfunction, thermal pulsation therapy

Introduction

Dry eye disease (DED) is one of the most commonly encountered ophthalmic conditions in clinical practice. It typically causes ocular irritation and pain, which can lead to blurred vision and interfere with daily activities. The prevalence of DED varies between 5% and 35%, depending on the population studied and the diagnostic criteria used (1,2). It is more common in women and increases with age, affecting over 70% of individuals over 60 (3,4).

DED is a multifactorial disease of the ocular surface, characterized by the loss of tear film homeostasis. This condition involves tear film instability, hyperosmolarity,

How to cite this article: Savran Elibol E, Haciagaoglu S. Thermal Pulsation Therapy (Lipiflow®): A Retrospectıve Analysis of Its Impact on Meibomian Gland Dysfunctıon And Dry Eye Disease. Beyoglu Eye J 2025; 10(2): 59-65.

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Submitted Date: October 22, 2024 **Revised Date:** April 04, 2025 **Accepted Date:** April 13, 2025 **Available Online Date:** June 25, 2025

Beyoglu Eye Training and Research Hospital - Available online at www.beyoglueye.com

ocular surface inflammation, damage, and neurosensory abnormalities, all of which play etiological roles in its development (5). Etiologically, DED can be classified as aqueous tear deficiency, evaporative tear deficiency, or a combination of both. According to the 2017 report from the tear film and Ocular Surface Society dry eye workshop, evaporative DED is noted to be more prevalent than aqueous tear deficiency DED(5). Evaporative DED occurs due to excessive tear evaporation from the ocular surface, even though tear production from the lacrimal glands remains normal. In this condition, tear hyperosmolarity develops, activating inflammation that contributes to tear film instability and further exacerbates tear hyperosmolarity. The causes of evaporative DED include meibomian gland dysfunction (MGD), inadequate eyelid dynamics, reduced blink frequency, use of systemic retinoids, wearing contact lenses, Vitamin A deficiency, and more. MGD, recognized as the leading factor contributing to evaporative DED, results in the breakdown of the tear film's lipid layer (6). Chronic inflammation of the glands, thickened meibum, blockage of the terminal ducts, and gland atrophy linked to MGD result in abnormal meibomian gland secretions (MGS) and instability of the tear film. The therapeutic approach aimed at restoring meibomian gland (MG) function and the natural flow of meibum in MGD provides potential therapeutic relief for the signs and symptoms of DED (7).

Conventional treatments such as warm compresses, gland expressions, and infrared therapy provide limited relief and are often time-consuming or uncomfortable (8-10). In addition, these treatment modalities are often hindered by significant burdens stemming from patient-provider time commitments and treatment discomfort. However, the introduction of a non-pharmacological thermal pulsation system (TPS) technology has minimized these treatment barriers.

LipiFlow (TearScience Inc., Morrisville, NC, USA) applies heat (42.5°C) to the inner eyelid surfaces while simultaneously delivering pulsation pressure through an inflatable air bladder on the outer eyelids (11). As reported in a multicenter clinical study, a single TPS treatment has resulted in sustained improvement in both the signs and symptoms of evaporative DED secondary to MGD (12). A number of other studies have demonstrated the efficacy and safety of LipiFlow treatment in managing MGD (13,14). No other treatment modality has been reported to provide such sustained relief from evaporative dry eye symptoms after a single treatment. This study aims to evaluate the persistence of clinical and subjective benefits for DED associated with MGD in a selected group of dry eye patients 6 months after TPS treatment.

Methods

This is a single-center, retrospective study that included patients who underwent thermal pulsation therapy between December 2020 and November 2021. The study was designed in accordance with the Helsinki Declaration and approved by the Ethics Committee (E-10840098–772.02–2586, Date: April 22, 2022). Informed consent forms were obtained from all participants. The sample size was calculated using G*Power software (version 3.1.9.2, Universität Düsseldorf, Germany) with a power of 0.8 and a significance level of $\alpha = 0.05$, determining a required sample size of approximately 30–35 patients.

A total of 250 eyes from 125 patients aged 18 years and older, diagnosed clinically with inflammatory MGD, were included in the study. All participants agreed to adhere to the study protocols and follow-up schedule and had reported dry eye symptoms within 3 months prior to the baseline examination. In addition, eligibility criteria required a standard patient evaluation for eye dryness of 6 or higher at the baseline visit and evidence of MG obstruction, defined as a total MGS score of 12 or lower for 15 glands in the lower eyelid. All patients were clinically diagnosed with inflammatory MGD.

Patients with a history of eye injury, ocular surgery performed within the last 3 months, herpes infection of the eye or eyelid, chronic recurrent ocular inflammation within 3 months before LipiFlow treatment, current eye infection or inflammation, eyelid abnormalities affecting the eyelid, or surface abnormalities that could affect the integrity of the ocular surface, as well as those with a history of topical cyclosporine or corticosteroid eye drop use and contact lens wear in the past month, were required to discontinue use of systemic antihistamines or isotretinoin for at least 1 month, other dry eye or MGD related medications (e.g., antibiotics, non-steroidal anti-inflammatory drugs, and corticosteroids) for at least 2 weeks, systemic diseases resulting in dry eye such as Sjögren's disease were excluded from the study, along with patients with incomplete data in their files.

Patients included in the study underwent bilateral LipiFlow treatment. Measurements of tear break-up time (TBUT), corneal staining, and MG assessment were collected at the initial visit, as well as 1 month and 6 months after LipiFlow treatment. Patients were permitted to maintain any ongoing dry eye treatments that they had been using for at least 6 months prior to the study, but no new treatments were introduced during the study period.

The clinical evaluation of MGD and DED includes the ocular surface disease index (OSDI), TBUT, Schirmer test

I, corneal and conjunctival staining, and eyelid assessment (noting changes such as lid margin pitting, telangiectasia, and MG orifice obstruction). Ophthalmological examinations included patient history, best-corrected visual acuity using the early treatment diabetic retinopathy study (ETDRS) fast method under standard lighting with the ETDRS logMAR chart, slit-lamp biomicroscopy, and ophthalmoscopy. Patients also underwent an extended retinal assessment both before and after the procedure.

Schirmer Test I was performed using a sterile Schirmer test strip for 5 min without topical anesthesia. Corneal and conjunctival staining was evaluated by instilling fluorescein dye, with the strip moistened with distilled water. TBUT was measured 3 consecutive times following fluorescein instillation and assessed under a slit-lamp biomicroscope with a blue filter using a stopwatch, with the median value recorded.

The OSDI questionnaire, which consists of 12 questions, was administered to the participants. The OSDI questionnaire consists of three main sections: ocular symptoms, vision-related functions, and environmental factors. The OSDI score is derived by multiplying the total score from 12 questions by 25 and dividing by the number of questions answered. This score ranges from 0 to 100, with 0–12 points indicating normal, 13–22 points indicating mild, 23–32 points indicating moderate, and 33–100 points indicating severe ocular surface disease (15).

The Oxford grading scheme is used to quantify the amount of ocular epithelial surface damage in patients with DED. According to the Oxford grading scheme, ocular surface staining is evaluated in a range from 0 (absent) to 5 (severe) (16).

The meibum secretion capacity of five MGs located in the central region of the lower eyelid was assessed following the application of firm digital pressure. The assessment utilized a scoring system (MGS score) ranging from 0 to 3, based on the number of glands expressible out of the five central glands. A score of 0: No secretion, 1: Toothpaste-like consistency, 2: Cloudy secretion, 3: Clear secretion (Fig. 1) (17).

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences for Mac version 25.0. Descriptive statistics of the data included mean and standard deviation values. The Kolmogorov–Smirnov test was applied to determine if the variables followed a normal distribution. Repeated measurements of normally distributed variables were analyzed using repeated measures analysis of variance and Bonferroni tests. For variables that were not normally distributed, the Friedman test and Wilcoxon Signed-Rank test were used to analyze repeated measurements. A $p<0.05$ was considered statistically significant for all analyses.

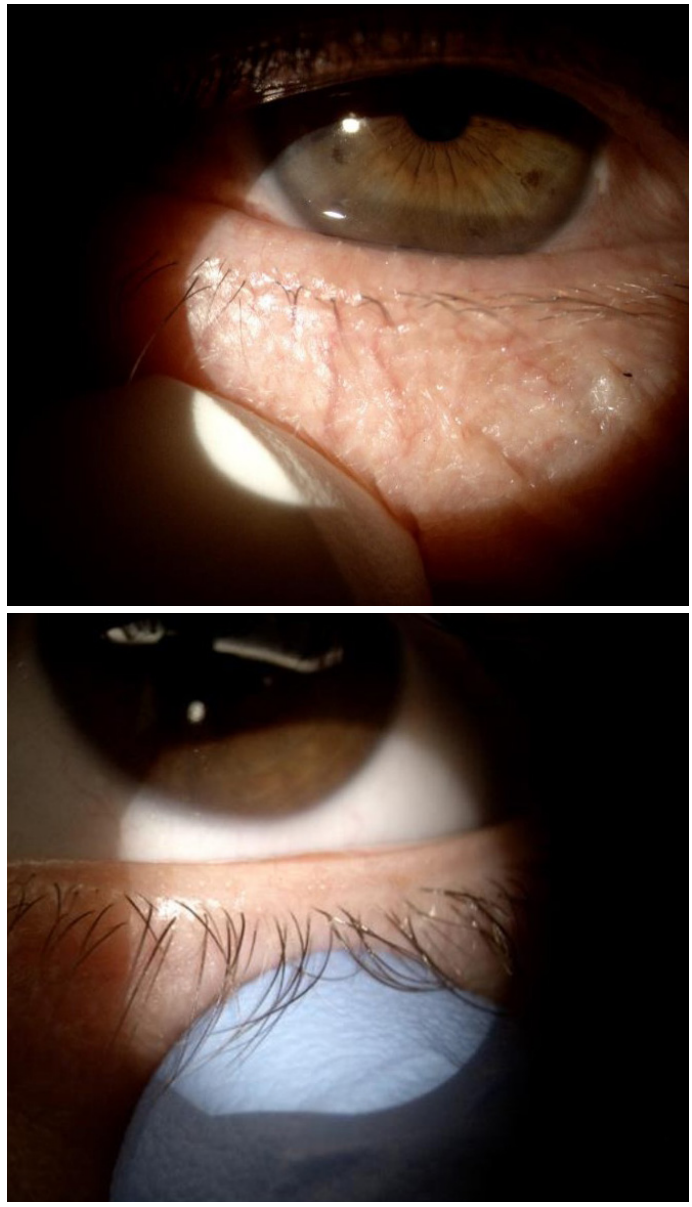

Figure 1. Meibomian gland secretion stage 1(upper) and stage 3(bottom).

Results

A total of 250 eyes from 125 patients with a mean age of 42.9±15.5 years were included in the study. Among the participants, 69 (55.2%) were female, and 56 (44.8%) were male.

The thermal pulsation treatment resulted in improvements in both signs (Schirmer I test, Oxford staining score, MGS, and TBUT scores) and symptoms (OSDI dry eye questionnaire scores) up to 1 month post-treatment. Improvements in TBUT and MGS values continued to increase up to the 6th month, while enhancements in Schirmer I test, Oxford staining score, and OSDI scores were maintained until the 6th month. All relevant P-values assessing statistical significance were below the 0.05 level (Table 1).

Table 1. Summary of objective clinical parameters before and after treatment

	Baseline	1 month	6 month	Change baseline to 1 month	Change baseline to 6 month	Change 1 month to 6 month	p*
	Mean (SD)	Mean (SD)	Mean (SD)	p*	p*	p*	
Schirmer	7.96±7.25	12.10±8.50	12.29±9.17	P3=0.000*	P3=0.000*	P3=0.753	P1=0.000*
Tear break-up time	5.01±1.70	7.41±2.50	7.08±2.60	P3=0.000*	P3=0.000*	P3=0.008*	P1=0.000*
Oxford staining score	0.69±0.69	0.30±0.53	0.29±0.54	P3=0.000*	P3=0.000*	P3=0.480	P1=0.000*
Meibomian gland secretion	1.31±0.56	2.33±0.66	2.26±0.66	P3=0.000*	P3=0.000*	P3=0.035*	P1=0.000*
Total OSDI score	48.60±20.60	38.73±23.71	40.41±22.92	P4=0.000*	P4=0.000*	P4=0.061	P2=0.000*

SD: Standard deviation; 1: Friedman Test; 2: Repeated measures analysis of variance; 3: Wilcoxon test; 4: Post hoc Bonferoni test *P<0.05. OSDI: Ocular surface disease index.

Schirmer I Test

There was a statistically significant increase in the Schirmer I test results between the pre-treatment visit (7.96±7.25 range: 1–35) and the 1-month follow-up visit (12.10±8.50 range: 3–35) (p=0.000) as well as between the pre-treatment visit and the 6-month follow-up visit (12.29±9.17 range: 3–35) (p=0.000). However, there was no statistically significant difference between the 1-month and 6-month follow-up visits (p=0.753). It was observed that the improvement achieved post-treatment was maintained at the 6-month mark (p=0.000).

TBUT

A significant improvement was observed in the TBUT at the 1-month follow-up (7.41±2.50 range: 2–14) and the 6-month follow-up (7.08±2.60 range: 2–10) compared to the pre-treatment score (5.01±1.70 range: 1–9) (respectively p=0.000, p=0.000). Although a statistically significant decrease in TBUT was noted between the 1-month and 6-month follow-up results (p=0.008), the improvement remained statistically significant compared to baseline values (p=0.000).

Oxford Staining Score

The change in the Oxford staining score significantly decreased from the pre-treatment value (0.69±0.69 range: 0–2) to the 1-month follow-up (0.30±0.53 range: 0–2) (p=0.000) and the 6-month follow-up (0.29±0.54 range 0–2) (p=0.000). Improvement was maintained at both the 1-month and 6-month follow-ups (p=0.480).

MGSscore

The MGSscore significantly increased at both the 1-month follow-up (2.33±0.66 range: 0–3) and the 6-month follow-up (2.26±0.66 range: 1–3) compared to the pre-treatment value (1.31±0.56 range: 0–2) (respectively p=0.000, p=0.000). When comparing the 1-month and 6-month results, although the improvement in MGS showed a statistically significant decrease (p=0.035), it was generally maintained up to the 6th month.

OSDI Score

The OSDI score showed a statistically significant decrease from the pre-treatment value (48.60±20.60 range: 4.16–88.63) to the 1-month follow-up (38.73±23.71 range: 0–86) and the 6-month follow-up (40.41±22.92 range: 0–63.63) (respectively p=0.000, p=0.000). The improvement observed at the 1-month follow-up was maintained at the 6-month follow-up (p=0.061).

Discussion

This study aimed to investigate the effectiveness of a single in-office LipiFlow treatment. Participants who received only LipiFlow treatment were followed for 6 months. All objective assessments – including Schirmer I test, TBUT, fluorescein corneal staining score, and MGS score – along with subjective tests (OSDI score) demonstrated that LipiFlow significantly improved symptoms. Although this study was not designed to evaluate the long-term duration of the effect, it was promising to observe that both symptoms and findings maintained the initial improvement throughout the 6-month study period. The tendency for further improvement in symptoms and findings at the 6-month visit compared to the 4-week visit offers a positive prognosis for future studies with longer-term assessments. We hypothesize that this ongoing improvement may be attributed to the restoration of function in previously obstructed and dysfunctional MGs, leading to enhanced gland function, which, in turn, improves tear film stability. This situation positively affects other objective and subjective measures of ocular surface health.

The primary effect of thermal pulsation, like other heating techniques, is to liquefy thickened meibum. The peristaltic movement of the LipiFlow activator from proximal to distal applies pressure to the eyelids, aiming to evacuate obstructed gland contents while delivering a nominal therapeutic temperature of 42.5°C directly to the palpebral surfaces of the upper and lower eyelids, where the MGs are

located. Various sensors are in place to regulate heat and pressure throughout the treatment. The gland evacuation effect and the more precise heating mechanism explain the more lasting and potent effects of thermal pulsation compared to manually applied eyelid heating, as demonstrated in various studies (18,19).

No unexpected or serious device-related adverse effects were reported during any of the studies, treatments, or follow-ups. Specifically, Lane et al. (11). found the average discomfort score during LipiFlow treatment to be 1.4 on a scale of 0–10, which falls within the pressure awareness category (scores of 1–2). Similarly, no publications or summaries reported any pain during the placement, treatment, or removal of the device.

Currently, the treatment of dry eye is based on long-term regimens of multi-dose pharmacological or non-pharmacological preparations (topical or systemic) or patient-administered eyelid hygiene regimens, or a combination of these two treatment modalities. A well-known treatment for MGD/obstruction has long been the necessity of evacuating gland contents to ensure optimal efficacy (20). However, until recently, the only known method for evacuating gland contents was manual compression using physical force. While this procedure was effective, it was also extremely uncomfortable. Studies have reported that pain is a primary limitation of the effectiveness of manual expression (21).

Another long-established adjunctive treatment for MGD has been the use of warm compresses (22). However, standardization of the application is another issue in manual warm compression. There are different concerns about the temperature at which manual compression should be performed, the temperature variation during application, and whether the heat application should be applied dry or wet. In addition, warm compresses do not evacuate gland contents, but when applied correctly, they can heat and liquefy the gland contents, providing some therapeutic benefits (23,24).

The Tear Film and Ocular Surface Society Dry Eye Workshop II group's management and therapy report recommends treating all aspects of the disease and suggests thermal pulsation for MGD when over-the-counter options (such as warm compresses) have failed (25).

This study supports the notion that thermal pulsation therapy can be effective in treating MGD and DED. Previous studies have also demonstrated its efficacy in managing MGD within the general evaporative dry eye population (26-29).

A study demonstrates that a single session of vector thermal pulsation therapy has significant treatment effects lasting up to 12 months. No other single-dose treatment with a comparable level of efficacy is currently available for MGD or DED(26). Greiner and colleagues followed MGD patients for 9, 12, and 36 months after a single LipiFlow treatment. OSDI scores improved during the first 9–12 months but showed a decline thereafter, with scores returning to baseline levels at the 12-month follow-up. Significant improvements in MGS scores were observed at both 1 month and 1 year post-treatment compared to baseline measurements. Baseline TBUT significantly increased at 1 month; however, this improvement was lost by 1 year. The significant improvement observed in the OSDI questionnaire at 1 month was maintained at the 1-year follow-up (29).

A recent systematic review examining eight different treatments, MGD reported that all treatments effectively alleviate dry eye symptoms, with thermal pulsation providing the longest-lasting effect, although it incurs the highest cost per treatment (30). Another study indicates that the best outcomes for MGD are achieved when treatment is initiated in the early stages of disease progression, similar to other chronic, treatable, progressive conditions (7).

Thermal pulsation therapy may result in significantly higher treatment costs per session compared to warm compress options. This is particularly true for thermal pulsation, as the lid heater and eye cup are single-use items that are consumed after each treatment. However, the primary advantage of thermal pulsation is the minimal requirement for patient compliance; despite the higher cost per treatment, improvements lasting at least 6 months can be achieved in a single 12-min session. As a treatment for moderate-to-severe MGD, it significantly reduces or virtually eliminates dependence on traditional dry eye treatments typically associated with daily multiple-dose artificial tear regimens or warm compress therapy, or a combination of both.

The limitation of this study is that our assessment of patients was conducted at three specific time intervals, a duration deemed insufficient for accurately delineating the onset and subsequent decline of potential treatment effects. Future investigations encompassing a larger cohort of MGD disease patients, inclusive of a placebo-controlled group, could provide deeper insights into the efficacy of the treatment.

Conclusion

LipiFlow thermal pulsation therapy is recognized as an effective treatment option for improving symptoms and signs of MGD and DED. This study demonstrates that a single LipiFlow treatment can provide potential therapeutic benefits for up to 6 months in both clinical signs and subjective assessments. LipiFlow has been found to have a more lasting and significant effect compared to other traditional treatments. While the cost of LipiFlow may be higher than alternative therapies, its minimal compliance requirements and long-term improvement benefits position it as a significant option for treating moderate to severe MGD.

Disclosures

Ethics Committee Approval: The study was designed in accordance with the Helsinki Declaration and approved by the İstanbul Medipol Universtiy Ethics Committee (E-10840098–772.02–2586, Date: April 22, 2022). Informed consent forms were obtained from all participants.

Conflict of Interest: None declared.

Use of AI for Writing Assistance: Not declared.

Author Contributions: Concept – E.S.E., S.H.; Design – E.S.E., S.H.; Supervision – E.S.E., S.H.; Resource – E.S.E.; Materials – S.H.; Data Collection and/or Processing – E.S.E., S.H.; Analysis and/or Interpretation – E.S.E., S.H.; Literature Search – E.S.E.; Writing – E.S.E., S.H.; Critical Reviews – E.S.E., S.H.

Peer-review: External peer-reviewed.

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