



## Efficacy of Thermo Mechanical Pulsations in Management of Meibomian Gland Dysfunction: A Comparative Study

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### Abstract

**Objectives:** To evaluate the efficacy of thermo mechanical pulsations in the management of meibomian gland dysfunction.

**Materials and Methods:** Fifty-two adult patients of dry eye clinic at Elite Hospital Riyadh, Saudi Arabia with established diagnosis of meibomian gland dysfunction were recruited between September 2016 and January 2018. All patients had a detailed past ocular and systemic history and full ophthalmological examination. If one eye was eligible for treatment this eye would be selected for Lipi Flow treatment and if both eyes were eligible, one eye was randomized to receive the thermal pulsation (Lipi Flow) treatment while continuing the usual treatment of lid hygiene, lubricant eye drops in the other eye.

**Results:** From the 52 patients who were eligible for the treatment at least in one eye 31 (59.6%) were females while only 21 (40.4%) were males; with mean  $\pm$  standard deviation (SD) age  $49.9 \pm 6.0$  range 39 to 61 years. The mean  $\pm$  SD preoperative SPEED score was  $11.4 \pm 1.5$  and showed reduction in the first postoperative assessment (2 weeks) to  $9.2 \pm 1.4$  ( $p < 0.001$ ). In control group: the mean  $\pm$  SD SPEED score was  $13.2 \pm 3.7$ , with first postoperative mean  $\pm$  SD of SPEED score being slightly higher  $14.5 \pm 3.8$ , which did not reach statistical significance. ( $p = 0.065$ )

**Conclusion:** There exists a significant subjective improvement noted by SPEED score as well as significant drop of frequency of lubricant eye drop needed to be used to alleviate the dry eye symptoms.

**Keywords:** Meibomian Gland Dysfunction; Dry Eyes; Lipi flow Thermal Pulsation; Saudi Arabia

### Introduction

Meibomian gland dysfunction is one of the most common and complex causes for dry eye symptoms and signs [1-12]. Normal Meibomian gland secretion has been postulated through integration of both continuous secretion and the action of lid muscles surrounding gland orifices at the lid margins [13,14]. Two Core mechanisms has been postulated to be the principle pathogenic pathway for Meibomian gland dysfunction (MGD), either through low delivery due to obstruction of gland orifices mainly through hyper keratinization of gland orifices or low secretion secondary

to stagnation of alteration of meibomian secretions with resultant dilatation and acinar atrophy [15]. Both Mechanical lid hygiene and thermal compressions are regarded the mainstay for managing MGD while addressing the pathogenic pathway however standardized parameters for either optimal mechanical pressure and temperature rise have not yet agreed upon [16-18-25]. Lipi Flow (Thermal Pulsation system) (Tear Science, Inc. Morrisville, NC, USA) is newly introduced and promising alternative to above mentioned strategies which provides controlled heat and pressure to both lid sides that enables to melt and express inspissated meibo-

mian secretion in a large number of meibomian glands in both eye lids simultaneously and hence allow them to regain their function and possibly improving meibomian gland dysfunction dry eye [26,27].

Although MGD and management have been studied thoroughly through the last decade, very few studies discussed thermal and mechanical lid hygiene and even fewer discussed the newly introduced Lipi Flow thermal pulsation system. This study sought to evaluate the efficacy of thermo mechanical pulsations in the management of MGD using the other eye of each patient as a control to be able to appreciate the real subjectivity and objectivity in the difference between treated and untreated control eyes.

## Materials and Methods

### Patient selection

Fifty-two adult regular patients of dry eye clinic at Elite Hospital Riyadh, Saudi Arabia with established diagnosis of meibomian gland dysfunction were recruited for the time between September 2016 and January 2018. After detailed explanation of the procedure and the study aim, patients were invited for screening and signing an informed consent.

All patient had a detailed past ocular and systemic history and full ophthalmological examination including visual acuity, slit lamp anterior and posterior segment examinations with special emphasis on lids, conjunctival sac and the cornea. The frequency of application of artificial tear eye drops was also noted during history taking.

Inclusion Criteria: Adult age, patients with long standing MGD diagnosed by the following symptoms; Dryness, Grittiness, Soreness, scratchiness, irritation, burning, watering, eye fatigue and Schirmer test: to exclude significant aqueous deficiency dry eye (values  $\leq 10$ mm) [28].

Additionally, Fluorescein Breakup time: with traditional volumes of fluorescein drops instilled in the conjunctival sac with cobalt blue filter of full width and length and after several blinks the average time between the last lid stroke and the appearance of the first dry spot in three consecutive times was recorded and the test was considered abnormal if the value is  $\leq 10$  seconds [29-33] and lid marginal changes in the form of either Anterior Blepharitis with

erythema and lid debris or Posterior Blepharitis with plugged MG orifices, turbid or thickened secretions [34].

Exclusion Criteria included ocular surgery, ocular infection or herpes of the eye within 3 prior months: including: intraocular, oculo-plastic, corneal or refractive surgery and active ocular inflammation or history of chronic, recurrent ocular inflammation within prior 3 months of the cornea, conjunctiva, lacrimal gland or sac, eyelids including a hordulium, stye, blepharochalasis, staphylococcal blepharitis or seborrheic blepharitis).

Also, active inflammation of sclera, episcleral, choroid, or the retina, eye abnormalities affecting lid function or preventing correct and stable placement of the Lipi Flow activator (e.g., entropion, ectropion, severe trichiasis, severe ptosis, lagophthalmos, blepharospasm, tumors or edema), compromised corneal integrity (prior chemical burn, recurrent corneal erosion, corneal epithelial defect), associated significant aqueous deficiency specially with inserted plugs (Sjogren's syndrome) or ocular surface disorder were among the exclusion criteria.

Additionally, patients with systemic disease condition that cause dry eye (e.g., Steven s-Johnson syndrome, Vitamin A deficiency, rheumatoid arthritis, Wegener's granulomatosis, sarcoidosis, leukemia, Riley-Day syndrome, systemic lupus erythematosus) and those taking medications known to cause dryness (e.g., isotretinoin and systemic antihistamines) were also excluded.

Before the procedure appointment patients are to be reminded that on the day of their appointment they should have:

- No eye drops in the last 4 - 6 hours.
- No contact lenses use in the last 4 hours.
- No swimming in chlorinated in the last 4 hours
- No eyeliner or make-up or facial cream.

All patients included underwent 3 step pretreatment evaluation including SPEED questionnaire, Meibomian gland evaluator MGE and LIPIVIEW interferometric measure of lipid layer thickness as follows:

1. SPEED (Standard Patient Evaluation of Eye Dryness) was given to each patient and a score from 0-28 was marked for each eye. All patients with score 6 - 12 were included (Figure 1).

2. Standardized force diagnostic expression to determine meibomian gland functionality: a newly introduced instrument MGE (Meibomian Gland Evaluator) (Figure 2) which apply force of 1.25 g per square mm (0.3 PSI) which mimics force applied to gland orifices of normal individuals during blinking either forcible or spontaneous to express meibum. The device tip is of an area of which roughly covers one third of lower eye lid (about 5 glands orifices) temporal, central and nasal. Examination was performed under slit lamp visualization to ob-

serve the presence or absence and type of meibomian secretions while applying gentle pressure at an angle of 45 degrees for 10 to 15 seconds 1 - 2 mm below lid margin. Lid margin is wiped with Q tips before assessment. A score was given as follows;

1. For no secretions (Blocked or Atrophied glands)
2. For inspissated (paste like or semisolid) secretions
3. For cloudy however liquid secretions
4. For clear liquid secretions.

## SPEED™ QUESTIONNAIRE

Name: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_ Sex: M F (Circle) DOB: \_\_\_/\_\_\_/\_\_\_

*For the Standardized Patient Evaluation of Eye Dryness (SPEED) Questionnaire, please answer the following questions by checking the box that best represents your answer. Select only one answer per question.*

**1. Report the type of SYMPTOMS you experience and when they occur:**

Symptoms	At this visit		Within past 72 hours		Within past 3 months	
	Yes	No	Yes	No	Yes	No
Dryness, Grittiness or Scratchiness						
Soreness or Irritation						
Burning or Watering						
Eye Fatigue						

**2. Report the FREQUENCY of your symptoms using the rating list below:**

Symptoms	0	1	2	3
Dryness, Grittiness or Scratchiness				
Soreness or Irritation				
Burning or Watering				
Eye Fatigue				

0 = Never    1 = Sometimes    2 = Often    3 = Constant

**3. Report the SEVERITY of your symptoms using the rating list below:**

Symptoms	0	1	2	3	4
Dryness, Grittiness or Scratchiness					
Soreness or Irritation					
Burning or Watering					
Eye Fatigue					

0 = No Problems  
 1 = Tolerable - not perfect, but not uncomfortable  
 2 = Uncomfortable - irritating, but does not interfere with my day  
 3 = Bothersome - irritating and interferes with my day  
 4 = Intolerable - unable to perform my daily tasks

**4. Do you use eye drops for lubrication?**     YES     NO    If yes, how often? \_\_\_\_\_

Cornea, 2013 Sep;33(9):1204-10  
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 13-ADV-123 A

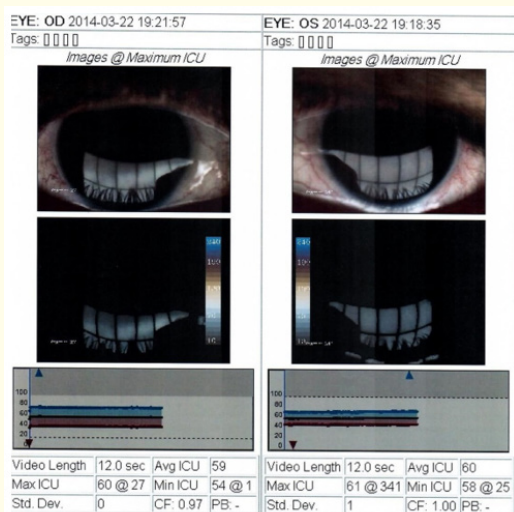
For office use only  
 Total SPEED score (Frequency + Severity) = \_\_\_/28

**Figure 1:** SPEED (Standard Patient Evaluation of Eye Dryness).



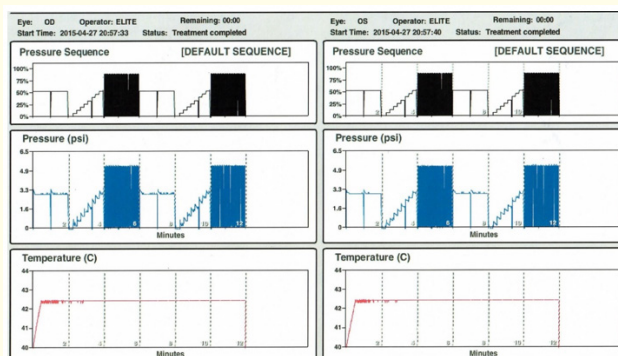
**Figure 2:** Standardized force diagnostic expression to determine meibomian gland functionality: a newly introduced instrument MGE (Meibomian Gland Evaluator).

- If unsure, lid margin is to be re-wiped while keeping MGE depressed.
  - A minimum score of 6 is required to continue for the next step.
1. Li pi View (Tear Science, Inc. Morrisville, NC, USA) (Figure 3): patients are asked to maintain fixation while the Li pi View system would obtain 20 seconds video recording including:
    - Total number of blinking and partial blinking Interferometric measure of lipid layer thickness in nm And a measure  $\leq 70$  nm is required to proceed for the treatment session.



**Figure 3:** LipiView (TearScience, Inc. Morrisville, NC, USA).

In all patients if one only was eligible for treatment this eye would be selected for Li pi Floe treatment and if both eyes were eligible, one eye was randomized to receive the thermal pulsation (Li pi Flow) treatment while continuing the usual treatment of lid hygiene, lubricant eye drops in the other eye. The method of randomization was by closed envelope. Li pi Flow (Thermal Pulsation system) (Tear Science, Inc. Morrisville, NC, USA) (Figure 4).



**Figure 4:** LipiFlow (Thermal Pulsation system) (TearScience, Inc. Morrisville, NC, USA)

The device is comprised of a console that has touch screen and contains the hard ware that controls the treatment session to which is connected the activator, an eye piece made of biocompatible polycarbonate and silicone that is inserted around the patient's eyelids. The Lipi Flow System provides controlled heat to the inner eyelid surface to not exceeding 44 °C while insulating and keeping the corneal temperature by vaulting above the eye and intermittent pressure to the outer eyelid surface supplied by linear air pressure within a range of 0-6 PSI for a force on the eyelids between 0- 282 mmHg which will apply the pressure between the lid wormer and the eye cup without pressure on the eye globe to facilitate release of lipid from cystic meibomian glands.

Post procedural follow up was done on 2- and 4-weeks interval including.

### SPEED questionnaire

MGE assessment of functioning Meibomian glands Li pi View assessment of Lipid layer thickness In addition to frequency of application of artificial eye drops.

### Statistical analysis

Data were collected, stored and managed in a spreadsheet using Microsoft Excel 2010® software. Data were analyzed using SPSS® version 22.0 (IBM Inc: Chicago, Illinois, USA).

Descriptive analysis was done, where categorical variables were presented in the form of frequencies and percentages and continuous variables in the form of mean (± Standard Deviation) and Range (minimum to maximum). Paired sample t-test was used to compare the pre and postoperative assessments Any output with a *p* below 0.05 was interpreted as an indicator of statistical significance.

### Results

From the 51 patients who were eligible for the treatment at least in one eye 30 (58.8%) were females while only 21 (41.2%) were males; with mean ± standard deviation (SD) age 49.9 ± 6.0 range 39 to 61 years. Only 18 patients had both eyes eligible for treatment according to the study protocols for which one eye was randomized for the treatment with Lipi Flow system while the remainder 23 patients had only one eye with eligibility criteria for the study protocol and hence was selected for treatment and both groups had their other eye as a control.

#### Speed score

For the 51 treated eyes the mean ±SD preoperative SPEED score was 11.4 ± 1.5 and showed reduction in the first postoperative assessment (2 weeks) to 9.2 ± 1.4 (*p* < 0.001) which is considered extremely statistically significant. The second postoperative value (4 weeks) of the mean ± SD SPEED score was slightly higher; 9.4 ± 1.2 (*p* < 0.001), statistically significant.

In control group: the mean ± SD SPEED score was 13.2 ± 3.7, with first postoperative mean ±SD of SPEED score being slightly higher 14.5 ± 3.8, which did not reach statistical significance. (*p* = 0.065). In the second post assessment the mean ± SD SPEED score was 13.3 ± 3.7 (*p* = 0.872), which was not statistically significant.

#### Lipid layer thickness

In the treated group the mean ± SD preoperative thickness was 56.2 ± 11.6 which increased statistically significant after 2 weeks to a mean ± SD of 70.4 ± 14.5 u (*p* < 0.001). The second postoperative value was slightly reduced (4 weeks) of the mean ± SD; 67.7 ± 14.0u (*p* < 0.001).

When applying the same analysis to the control eyes: the mean ±SD preoperative average preoperative lipid layer thickness was 60.7 ± 17.4 u which was maintained over the next 2 weeks with mean ± SD of 60.7 ± 17.7u (*p* = 0.996) which is not statistically significant and showed almost the same parameters over the next 4 weeks with mean ± SD of 60.7 ± 16.2 u (*p* = 0.995) which was not statistically significant.

#### MGE

In the treated group the mean ± SD preoperative functioning meibomian gland score was 6.5 ± 1.2 which increased after 2 weeks to a mean ± SD of 7.6 ± 1.3 (*p* = 0.288) which was not statistically significant. In the second follow up the mean ± SD score was 2.2 ± 2.3 (*p* < 0.001) which is considered statistically significant. The second postoperative value was slightly reduced (4 weeks) with a mean ± SD; 7.2 ± 1.4 (*p* = 0.009) this difference is statistically significant.

In control group the mean ± SD preoperative functioning meibomian gland score was 5.5 ± 2.8 and the first postoperative score was of a mean ± SD of 5.4 ± 2.5 (*p* = 0.853) which is not statistically significant and showed almost the same parameters over the next 4 weeks with mean ±SD; 5.6 ± 2.5 (*p* = 0.795).

Figure 5 shows the trends on both treated and control groups for all the parameters and show a similar trend between the two groups.

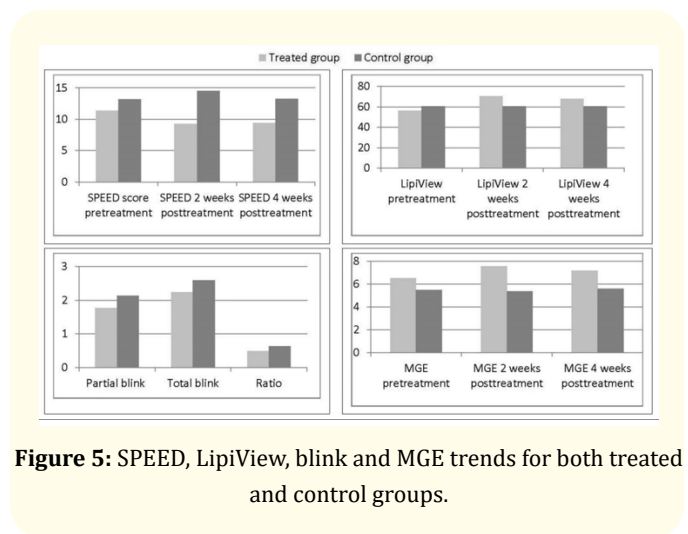


Figure 5: SPEED, LipiView, blink and MGE trends for both treated and control groups.



In both groups the ratio of partial blinks to total blinks was assessed however not compared pre and postoperatively where in treated group the mean  $\pm$  SD ratio was  $0.5 \pm 0.5$  and in control group the mean  $\pm$  SD ratio was  $0.6 \pm 0.4$ .

In each patient the relative subjective improvement was assessed by the difference in frequency of artificial tear installation and in all patients the average frequency was 2.3 in both eyes which remained stable in the untreated eye while showed significant drop to 1.6 in the treated eyes postoperatively.

## Discussion

Although MGD and management have been studied thoroughly through the last decade, very few studies discussed thermal and mechanical lid hygiene and even fewer discussed the newly introduced Lipi Flow thermal pulsation system, our study – to our knowledge- is the only controlled study with the other eye of each patient serving as a control to be able to appreciate the real subjective as well as the objective difference between treated and untreated control eyes.

Our study has shown an extremely statistically significant improvement in subjective as well as objective parameters measuring MGD.

Several authors demonstrated change of lipid compositions of meibum in MGD for example, low levels of phosphatidyl ethanol [35], significant reduction in triglyceride and cholesterol as well as monounsaturated fatty acids specially oleic acid resulting in characteristic change in viscosity of lipid expressed and its melting point and hence explain at least partially the potential beneficial effect of Lipi Flow system in by applying optimum pressure and warmth to MG for evacuation of inspissated meibomian secretions and subsequent regain of normal meibomian gland function [36-39].

Almost all our patients had observed the significant subjective improvement noted by SPEED score as well as significant drop of frequency of lubricant eye drop needed to be used to alleviate the dry eye symptoms of the treated eye however this may be partially false due to placebo effect as well as the in compliance with the traditional lid hygiene treatment of the control eyes.

Our study also observed from studying trends a higher difference in both subjective improvement and lipid layer thickness (func-

tional) than the difference noticed in meibomian gland evaluation (anatomical) between treated and control groups which in turn we believe increases the value of lipid layer thickness evaluation in correlating with severity of symptoms in patients with MGD rather than MGE. This difference can be explained by assuming that the thermal effect of the device that allows expression of biochemically altered meibomian gland secretions with higher melting temperature has a more therapeutic value than mechanical pulsations that allows the restoration of normal meibomian gland structure.

Additionally, the study noticed a decline in all parameters of improvement which is more steep in lipid layer thickness in the second follow up in comparison with the first follow up that may be blotted to be equal to the preoperative parameters with longer period of follow up which in turn may yield to a conclusion that the effect of the thermopulastion treatment is in fact a temporary solution and retreatment is eventually required for most of MGD patients.

Our results agree in clearer way with the previous yet few studies on Lipi Flow system on its subjective and objective improvement effect on MGD symptoms and signs [40,41].

However, our study we did not notice, in contrast, to a previous study a variation of results among different group of patients either in sex or patients with different grades of severity of MGD which can be explained by the fact that our study design did not have special emphasis on comparing different clusters of patients rather than obtaining an ultimate clinical and statistical highlight on the benefits and safety of Li pi Flow system [42].

## Conclusion

Tear Science Them pulsation treatment have shown to be subjectively and objectively a promising effective, fairly convenient and safe alternative to conventional available treatment for MGD.

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