

A Paradigm Shift in the Treatment of Meibomian Gland Dysfunction

The LipiFlow Thermal Pulsation System can improve multiple measures of dry eye signs and symptoms.

BY STEPHEN S. LANE, MD

Currently, dry eye is defined by the National Eye Institute as, “when the eye does not produce tears properly, or when the tears are not of the correct consistency and evaporate too quickly.”¹ The prevailing philosophy in the past decade was that aqueous deficiency was the primary cause of dry eye, and only recently has the emphasis on the correct consistency of tears taken center stage.² Meibomian gland dysfunction (MGD) is becoming recognized as not only a major cause of dry eye but also the most important factor contributing to dry eye disease. An evidence-based approach to the study of dry eye is creating a paradigm shift with regard to how we diagnose and treat patients and places an emphasis on MGD. Although the current popular view of MGD includes meibomian gland infection and/or inflammation of the posterior eyelid margin, evidence suggests that MGD frequently occurs in the absence of overt inflammation and infection.³

THE LIPIFLOW THERMAL PULSATION SYSTEM (NOT AVAILABLE IN THE US)

TearScience (Morrisville, NC) has developed an innovative in-office treatment (Figure 1A) designed to safely administer therapeutic levels of heat and pressure to relieve obstruction of the meibomian glands, while simultaneously applying graded pulsatile pressure to the outer eyelid surfaces, thereby expressing the meibomian glands during heating (Figure 1B).^{4,6} The delivery of heat to the inner surface of the eyelid is intended to provide directed heating of the meibomian glands’ contents to improve upon the methodology of the insufficient heating provided by warm compress therapy to the anterior surface of the eyelids.⁷

MGD TREATMENT

Historically, treatments for MGD consisted of off-label pharmacotherapy aimed at delivering oral or topical antibi-

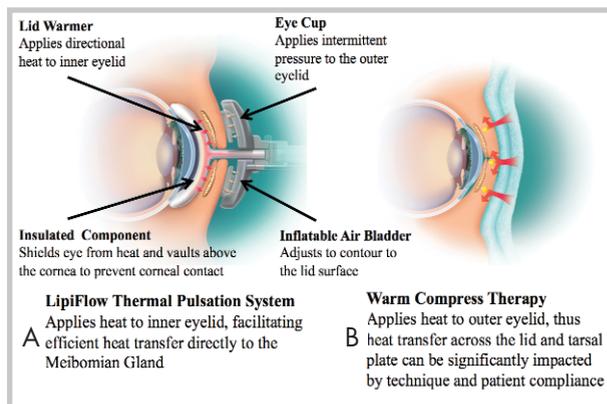


Figure 1. The delivery of heat to the inner surface of the eyelid by the LipiFlow Thermal Pulsation System (A) allows for adequate heating of the meibomian gland’s contents, overcoming the insufficient heating provided by warm compress therapy (B) to the anterior surface of the eyelids.

otic/anti-inflammatory regimens to treat the presenting signs.^{8,9} Although these treatments may reduce symptoms associated with MGD, they do not address restoration of function of the normal secreting meibomian gland by clearing the obstruction. Current methods to relieve meibomian gland obstruction involve delivering heat in the form of warm compresses or some form of heated pad or goggle. While warm compresses and self-administered lid massage are efficacious, the combined treatment is frequently disappointing, most likely related to poor compliance and/or inadequately performed technique by the patient.

CLINICAL TRIAL RESULTS

An open-label, randomized, multicenter clinical trial compared the LipiFlow System with warm compress therapy (iHeat Portable Warm Compress System; Advanced Vision

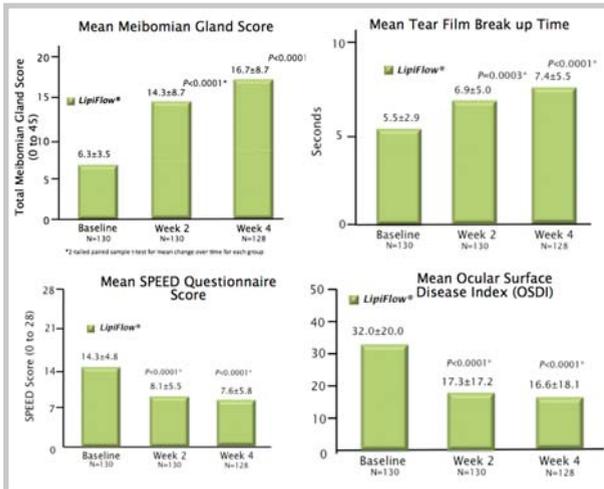


Figure 2. The LipiFlow Thermal Pulsation System shows statistically significant improvement from baseline in multiple measures of dry eye: mean change in meibomian gland score; tear film breakup time; mean SPEED score; and mean OSDI score.

Research, Inc., Woburn, MA) as an active control. The trial was prospectively designed to cross over the control arm to LipiFlow System treatment. A total of 139 subjects were enrolled at nine sites in the United States. The study objective was to evaluate the clinical utility, safety, and effectiveness of the LipiFlow System compared to standard warm compress therapy in adults with chronic cystic conditions of the eyelids, including MGD and chalazia.

A total of 69 subjects (138 eyes) received treatment with the LipiFlow System, consisting of a single, 12-minute in-office treatment. The control arm consisted of 70 subjects (140 eyes) who received warm compress therapy. Control subjects received treatment with warm compress therapy for 5 minutes daily over 2 weeks. After the 2-week assessment visit, control subjects stopped the warm compress therapy, and 68 subjects (136 eyes) were crossed over to receive a single, 12-minute LipiFlow crossover treatment. All subjects were then assessed at 4 weeks.

The LipiFlow System met the primary effectiveness endpoint with a statistically significant mean improvement in meibomian gland score and tear film breakup time (Figure 2) from baseline to week 2 and week 4 with an effect better than warm compress control. The control group did not show statistically significant mean improvement in these objective measurements.

There was a statistically significant mean improvement from baseline to posttreatment in the patient-reported outcome measurements (secondary endpoints) using the SPEED and OSDI questionnaires for both the LipiFlow and control groups (Figure 2). However, the mean change in symptoms was statistically significantly greater for the LipiFlow group compared with the control group. Similar and statistically significant improvements were observed for the control group after crossover treatment with the LipiFlow System (Figure 3).

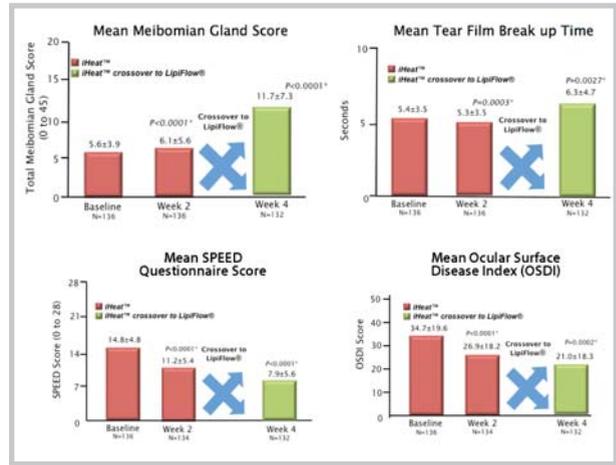


Figure 3. The LipiFlow Thermal Pulsation System shows statistically significant improvement in multiple measures of dry eye after crossover treatment of the control group: mean change in meibomian gland score; tear film breakup time; mean SPEED score; mean OSDI score.

There was no statistically significant difference in the incidence of device-related adverse events for the LipiFlow System-assigned subjects compared with the warm compress control group.

THE BOTTOM LINE

- Alleviating the obstruction of the meibomian gland is key to treating MGD.
- Current approaches to MGD treatment lack the ability to liquefy and evacuate significant obstruction within the ducts of the meibomian glands.
- The LipiFlow Thermal Pulsation System has shown the potential to improve multiple measures of dry eye signs and symptoms in a randomized controlled trial. ●

Stephen S. Lane, MD, is a managing partner of Associated Eye Care in St. Paul, Minnesota, and an adjunct clinical professor for the University of Minnesota in Minneapolis. He is a consultant to TearScience. Dr. Lane may be reached at (651) 275-3000; sslane@associatedeyecare.com.

1. National Eye Institute. Facts about dry eye. <http://www.nei.nih.gov/health/dryeye/dryeye.asp>. Accessed December 6, 2010.
2. Lemp MA. Report of the National Eye Institute/industry workshop on clinical trials in dry eyes. *CLAO J*. 1995;21(4):221-232.
3. Blackie CA, Korb DR, Knop E, et al. Nonobvious obstructive meibomian gland Dysfunction. *Cornea*. 2010;29(12):1333-1345.
4. Korb DR, Blackie CA. Restoration of meibomian gland functionality with novel thermodynamic treatment device—a case report. *Cornea*. 2010;29(28):930-933.
5. Friedland BR, Fleming CP, Blackie CA, Korb DR. A novel thermodynamic treatment for meibomian gland dysfunction (MGD). *Current Eye Research*. In press.
6. Majmudar PA, LipiFlow Study Group. A novel thermal pulsation treatment for obstructive meibomian gland dysfunction: applying heat to the inner eyelid surfaces. Paper presented at: The Annual Meeting of the Association for Research in Vision and Ophthalmology; May 6, 2010; Fort Lauderdale, FL.
7. Blackie CA, Solomon JD, Greiner JV, et al. Inner eyelid surface temperature as a function of warm compress methodology. *Optom Vis Sci*. 2008;85(8):675-683.
8. Dougherty JM, McCulley JP, Silvary RE, et al. The role of tetracycline in chronic blepharitis. Inhibition of lipase production in staphylococci. *Invest Ophthalmol Vis Sci*. 1991;32:2970-2975
9. Luchs J. Efficacy of topical azithromycin ophthalmic solution 1% in the treatment of posterior blepharitis. *Adv Ther*. 2008;25:858-870.