Long-Term (3 Year) Effects of A Single LipiFlow Thermal Pulsation System Treatment on Meibomian Gland Function and Dry Eye Symptoms

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INTRODUCTION

Dry eye diseases are chronic and may have irreversible structural and functional damage; thus, the long-term impact of dry eye disease is important for its overall management. The LipiFlow Thermal Pulsation System provides a novel, non-invasive treatment that uses a combination of temperature and pressure to impact meibomian gland function. Reports have shown promising outcomes when this treatment was applied for short-term periods, with improvements in symptoms and signs of dry eye disease. However, the long-term effects of this treatment are not yet known. The objectives of this study were to evaluate the long-term (3 years) effects of a single treatment with the LipiFlow Thermal Pulsation System on meibomian gland function and dry eye symptoms.

METHODS

Patients with MGD and a diagnosis of moderate to severe evaporative dry eye were recruited for a non-significant risk, prospective, open-label, randomized multicenter clinical trial. The data herein reported represent a sub-cohort (n=20-40 eyes) of the study patients from a larger clinical trial that was conducted in compliance with the study protocol. Declaration of Helsinki, Good Clinical Practice guidelines and U.S. Code of Federal Regulations (CFR) 21 CFR Parts 50, 54, 56 and 812. The sub-cohort was derived from a cohort of 30 patients enrolled between March 4, 2009 and May 14, 2009 at Boston Ocular Surface Center in Winchester, MA, one of the sites of the multicenter clinical trial.

Inclusion criteria: ≥ 18 years of age; meibomian gland assessment defined by the presence or absence of secretion and the quality of the secretion of 15 glands on the lower eyelid with a total meibomian gland secretion score of ≥ 12; dry eye symptoms in both eyes within 3 months prior to the Baseline visit with a total symptom score of ≥ 10 for each eye on a Dry Eye questionnaire (SPEED questionnaire) willingness to comply with study procedures and the follow-up visit schedule.

Exclusion criteria: presence of ocular conditions that may increase the risk of injury related to the device and procedure; ocular surface abnormalities that may compromise corneal integrity; eyelid abnormalities affecting lid function; co-existing ocular or systemic conditions that may limit the effectiveness of the device treatment. The clinical trial defined a 4-week follow-up period to assess safety and efficacy prior to study termination; however, 20 of the 30 enrolled patients were re-examined 3 years after a single LTPS treatment to assess the duration of effect on signs and symptoms of dry eye.

Clinical outcome measures:

Meibomian gland function was assessed on all patients using a meibomian gland evaluator (MGE). The MGE allows standardization of meibomian gland secretion of the lower eyelid. The MGE permits determination of the number of meibomian glands yielding liquid secretion and the quality of the meibomian gland secretion for the temporal, central and nasal regions (Table 1). Five consecutive glands were evaluated for each of the 3 regions of the lower eyelid. The MGE grading scale ranges from 0 (no secretion) to 4 (clear liquid secretion). The MGE questionnaire score was calculated by summing the scores of the lower eyelid glands as follows: (minimum score = 0; maximum score = 45).

RESULTS

Twelve of the 30 enrolled patients from Boston Ocular Surface Center were re-examined at 3 years after the initial LTPS treatment. Signs (meibomian gland scores (Figure 6a) and TBUT (Figure 6b) and symptoms (SPEED scores (Figure 7a) and OSDI scores (Figure 7b). Data for this sub-cohort of patients were presented with means ± standard deviation.

CONCLUSION

The LipiFlow thermal pulsation system (LTPS) treatment provides an extended duration of efficacy in patients with evaporative dry eye symptoms for up to 3 years after a single treatment. This unexpected observation is further supported by 9-month,12-month, and 24-month24 post-LPTS studies. These findings involve simultaneous applications of regulated levels of heat and pressure applied to the upper and lower eyelids.

REFERENCES