Thermal Pulsation System in the Treatment of Meibomian Gland Dysfunction: A Post-hoc Analysis of a 12-month, Randomized, Multicenter Study

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Background:

To demonstrate the efficacy of iLux in change from baseline in meibomian gland score (MGS) at 12 months post single treatment in meibomian gland dysfunction (MGD) subjects with evaporative dry

eye disease (EDE).

Methods:

This is a post-hoc analysis of a previous prospective, randomized, assessor-masked, parallel group study that compared the efficacy and safety of iLux with LipiFlow in subjects with EDE. Subjects with MGS ≤12 in lower eyelids, IDEEL-SB module score >16, and non-invasive tear breakup time (NITBUT) of <10 seconds were randomized for bilateral treatment in a 1:1 ratio to receive a single treatment of either iLux or LipiFlow. The primary endpoint of this post-hoc analysis was to analyze the mean change from baseline in MGS at 12 months post single treatment. Mean change from baseline in NITBUT (first break-up, seconds) was the key exploratory endpoint. Subjects attended a total of 8 visits: screening/baseline, treatment, 2-week, 1-, 3-, 6-, 9-, and 12-months.

Results:

A total of 119 patients (n=238 eyes) were included in the analysis. The mean (SD) age was 58.4±13.4 years, with majority being female (79.0%). At baseline, mean MGS was 6.6±3.68. At 12 months, mean change from baseline of MGS increased to 16.3±11.47 (P <0.001). Similarly, at baseline, mean NITBUT was 5.4±1.97 seconds. At 12 months, mean change from baseline in NITBUT was 2.1±4.16 seconds (P <0.001). Furthermore, the mean change from baseline in MGS was observed as early as 2 weeks (12.9±9.84) and at 1 month (14.3±10.46), 3 months (16.5±10.59), 6 months (17.8±10.37), and 9 months (15.8±10.68) post-treatment.

Conclusion:

The study results demonstrated that a single treatment with iLux significantly improved MGS and NITBUT over a period of 12-months in subjects with evaporative dry-eye associated MGD.

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