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...
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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