ISRCTN18065902 Basic Results

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Title	**Evaluation of Eyelid Cleansing Wipes for Meibomian Glands Dysfunction Management.**
Protocol ID	ID18-18/ HPCLIDM182018001
Investigators and Study sites	Principal investigator Dr. Ali Mearza, and co-investigators; Kishan Patel BSc (Hons) MCOptom Ruchi Gupta MOptom (Hons) MCOptom, Priya Bhagani BSc (Hons) MCOptom and Anand Patel BSc (Hons) MCOptom. OCULAR TECHNOLOGY GROUP - International (OTG-i), 66 Buckingham Gate, London, SW1E 6AU UK.
Objective(s)	The primary objectives of the study were to quantify the effects the eyelid cleansing wipes on: i. Symptomatology; ii. Meibomian gland status. The secondary objective of the study was to quantify the effects of the eyelid cleansing wipes on: i. Corneal, conjunctival and palpebral tissues.
Study Design:	The study was a one-month dispensing, bilateral use, single arm, open label, interventional study design.
Study Products:	ILAST® Lingettes Wipes hyaluronic acid 0.2% and allantoin, CE marked cleansing wipes for eyelid hygiene used as per its CE marking indication and modality of use. • The eyelid cleansing wipes were rubbed in to both closed eyelids margin daily in the morning upon waking and in the evening prior to sleep.
Evaluation Criteria:	The primary end points were: i. OSDI score; ii. MGD score. The secondary end points were: i. Eye lashes contamination grade. The other endpoints of interest were: i. Oxford ocular surface staining score; ii. Lid margin staining score; iii. Palpebral redness score; iv. Overall ocular comfort & dryness; v. Ocular comfort & dryness upon waking; vi. End of day ocular comfort & dryness.
Visit Schedule:	Two study visits over a one-month period: Visit 1: Enrolment/Baseline/Study Product Dispensing ~1.5 hours Visit 2: Follow up test/discharge visit ~ 1.0 hour (30 ± 3 days from Visit 1)
Study Population	33 symptomatic dry eye participants were enrolled and 30 completed the study. 19 (63%) were female and 11 (37%) were male. The average age was 53.6 ± 14.5 years, median 56.0 years, ranged between 20 and 78 years.
Statistical Methods	The efficacy of the eyelid wipes was measured by comparing the endpoint data recorded prior to product usage at the dispensing visit (Baseline) to the data recorded at the 30-Day follow-up visit (Response).

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Sample Size Justification	This was an exploratory study and no formal sample size calculation was performed.
Results	Following one month use of the eyelid wipes, the main study findings are summarized below: i. OSDI score was 37.8 ± 17.6 (mean ± std) at baseline. After one-month use of the eyelid wipes, the OSDI score decreased significantly to 28.8 ± 20.7 (p=0.002). ii. MGD mean score was 14.9 ± 6.4 at baseline. After one-month use of the eyelid wipes, the MGD score decreased significantly to 10.8 ± 5.5 (p<0.001). iii. Eyelash contamination was significantly reduced after one month use of eyelid wipes compared with the baseline (p=0.005). iv. Oxford ocular surface staining score showed less staining after one-month use of the eyelid wipes compared with baseline (median 2.0 vs. 3.0, p=0.063). v. Lissamine green lid margin staining was unchanged by the one-month of use of the eyelid wipes (upper lid p=0.953; lower lid p=0.713) vi. There was no significant difference in palpebral redness after one month use of the eyelid wipes compared to baseline (p=0.959). vii. Overall comfort rating at baseline was 45.8 ± 16.2. After one-month use of the eyelid wipes, the overall comfort rating increased significantly to 59.3 ± 18.7 (p < 0.001). viii. Overall dryness rating at baseline was 53.7 ± 15.8. After one-month use of the eyelid wipes, the overall dryness rating decreased significantly to 41.6 ± 18.9 (p =0.003).
Adverse Events	One subject (ID18), both eyelids had mild irritation after 1-week use. Resolved after cessation of product use. Subject discontinued. One subject (ID8) had non-ocular non-device related AE and the subject completed the study.
Device Deficiencies	None.
Conclusions	The data obtained over this one-month treatment period clearly demonstrated the efficacy and rapid accomplishment of twice daily use of ILAST® WIPES in managing lid margin anomalies and producing improvement in the ocular comfort of dry eye sufferers with eyelid anomalies.