

ISRCTN12394408 Basic Results

18/LO/0810, IRAS 246160

Title	Evaluation of Eyelid Cleansing Gel for Meibomian Glands Dysfunction Management.
Protocol ID	ID18-17/ HPCLIDM012018002
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 gel on: i. Symptomatology; ii. Meibomian gland status. The secondary objective of the study was to quantify the effects of the eyelid cleansing gel 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® Hydraclean Cleansing Gel hyaluronic acid 0.2% and allantoin, CE marked cleansing gel for eyelid hygiene used as per its CE marking indication and modality of use. The eyelid cleansing gel 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	30 symptomatic dry eye participants were enrolled and completed the study. 17 (57%) were female and 13 (43%) were male. The average age was 54.5 ± 16.1years, median 57.5 years, ranged between 19 and 75 years
Statistical Methods	The efficacy of the eyelid cleansing gel 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).

ISRCTN12394408 Basic Results

18/LO/0810, IRAS 246160

Sample Size Justification	This was an exploratory study and no formal sample size calculation was performed.
Results	<p>Following one month use of the eyelid cleansing gel, the main study findings are summarized below:</p> <ul style="list-style-type: none">i. OSDI score was 39.2 ± 18.9 (mean \pm std) at baseline. After one-month use of the eyelid cleansing gel, the OSDI score decreased significantly to 24.3 ± 18.3 ($p < 0.001$).ii. MGD mean score was 11.5 ± 4.8 at baseline. After one-month use of the eyelid cleansing gel, the MGD score decreased significantly to 8.5 ± 4.9 ($p < 0.001$).iii. Eyelash contamination (grade 0=clear lashes) was slightly better after one month use of eyelid cleansing gel compared with the baseline, but not statistically significant (72% vs 55%, $p = 0.322$).iv. Oxford ocular surface staining score showed slightly less staining after one-month use of the eyelid cleansing gel compared with baseline (median 2.0 vs.3.0, mode 8.0 vs 0.0, $p = 0.283$).v. Lissamine green lid margin staining was unchanged by the one-month of use of the eyelid cleansing gel (upper lid $p = 0.456$; lower lid $p = 0.713$).vi. There was no significant difference in palpebral redness after one month use of the eyelid cleansing gel compared to baseline ($p = 0.495$).vii. Overall comfort rating at baseline was 44.6 ± 21.7. After one-month use of the eyelid cleansing gel, the overall comfort rating increased significantly to 55.7 ± 20.7 ($p = 0.004$).viii. Overall dryness rating at baseline was 58.1 ± 20.1. After one-month use of the eyelid cleansing gel, the overall dryness rating decreased significantly to 44.5 ± 21.9 ($p = 0.003$).
Adverse Events	Two subjects (ID#6 mild, eyelid irritation with headache and ID#7 mild, non-device related AEs). Both events resolved, and the subjects 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® Hydraclean Cleansing Gel in managing lid margin anomalies and producing improvement in the ocular comfort of dry eye sufferers with eyelid anomalies supporting the rationale of the study.