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Randomized, controlled, crossover trial comparing the impact of sham or intranasal neurostimulation on conjunctival goblet cell degranulation

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Purpose: The aim of the study was to investigate the effects of the Oculeve Intranasal Lacrimal Neurostimulator (ILN) on conjunctival goblet cell degranulation.

Design: A randomized, double-masked, placebo-controlled crossover trial

Methods: A total of 15 subjects (5 normal and 10 dry eye) were enrolled in a three-visit study consisting of one screening and two separate randomized-masked ILN treatments (sham extranasal or intranasal). Tear meniscus height (TMH) was measured by AS-OCT before and after applications. Impression cytology (IC) was taken from the bulbar conjunctiva of the right eye for PAS staining and from the left eye for MUC5AC mucin immunostaining at baseline and after each treatment. The ratio of degranulated to non-degranulated GCs was measured as a marker of secretion.

Results: In all participants, both IB and TB cytology specimens stained for MUC5AC revealed a significantly higher ratio of degranulated to non-degranulated GCs after the ILN (IB: 2.28 ± 1.27 and TB: 1.81 ± 1.01) compared to baseline (IB: 0.56 ± 0.55 , $p=0.015$) (TB: 0.56 ± 0.32 , $p=0.003$) and extranasal sham application (IB: 0.37 ± 0.29 , $p=0.001$) (TB: 0.39 ± 0.33 , $p=0.001$). When the same analysis was repeated in the dry eye or control groups, the ratio was significantly higher after ILN than the baseline ratio and ratio after extranasal application in both groups ($p < 0.05$).

Moreover, while control subjects had higher ratio of degranulated to non-degranulated GCs at baseline (0.75 ± 0.52) compared to the dry eye group (0.41 ± 0.27); the ratio became slightly higher in dry eye (2.04 ± 1.12 vs. 1.99 ± 1.21 in control) after the ILN application. There was no significant difference between the IB or TB conjunctiva locations in terms of the effectiveness of the ILN application on conjunctival goblet cell secretory response.

Conclusions: These preliminary results document that the Oculeve ILN can stimulate degranulation of goblet cells in the conjunctiva, which is a promising new approach for the management of dry eye.

- This study protocol was registered on ClinicalTrials.gov (#NCT02385292)

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