Contact Lens Update
CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

A nonrandomized, open-label study to evaluate the effect of nasal stimulation on tear production in subjects with dry eye disease

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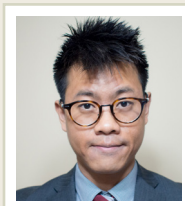

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Dry eye disease is a highly prevalent condition, affecting up to 50% of individuals within certain populations.[1] This condition may cause significant ocular discomfort and has the potential to cause damage to the ocular surface.[2] The management of dry eye disease typically involves a variety of options, ranging from over-the-counter tear supplementation to specially prepared amniotic membranes.[3] Recently, a new type of treatment based on stimulating the nasolacrimal reflex to induce tearing has emerged.[4] This therapy works by inserting a device with into the nasal passages to gently stimulate the anterior ethmoidal nerve.[4] Stimulation of the anterior ethmoidal nerve activates the nasolacrimal reflex pathway and stimulates the lacrimal gland to promote tearing. The purpose of this study was to determine the efficacy and safety of this device in reducing signs and symptoms of dry eye disease.

Friedman NJ, Butron K, Robledo N, Loudin J, Baba SN, Chayet A. A nonrandomized, open-label study to evaluate the effect of nasal stimulation on tear production in subjects with dry eye disease. Clin Ophthalmol. 2016;10:795-804.

Methods

This was a prospective, open-label, single-arm study with 40 participants (who were at least 18) with mild to moderate dry eye disease. To be eligible for the study, participant symptoms were required to be at least 13 on the Ocular Surface Disease Index (OSDI). They also needed to have a repeatable unstimulated Schirmer's score of less than 15mm/5 minutes, or a stimulated (using a Q-tip) Schirmer's score of 10mm/5 minutes higher than unstimulated values. Additional criteria for entry was that they needed to have normal lid anatomy and blinking function in each eye.

The device is described as a handheld battery-powered, current-controlled, neurostimulator attached to an intranasal lead. Participants were trained on how to use the device and were provided one for use four times daily. The device was inserted into the nasal passage to stimulate the anterior nasal mucosa. The level of stimulation was customizable, and participants were instructed to apply stimulation until they felt a tickling sensation or an urge to sneeze.

The outcome variables of interest were:

1. difference in stimulated versus unstimulated anesthetized Schirmer's scores,
2. tear breakup time,

3. corneal staining,
4. conjunctival staining,
5. dry eye symptoms (visual analog scale) and severity (OSDI), and
6. patient satisfaction.

In addition to baseline measurements, safety measurements were obtained (visual acuity, adverse events tracking, nasal endoscopic examination, slit lamp biomicroscopy with dilated fundus examination, and IOP). Participants returned at various intervals over a six-month period for follow-up assessments.

Results

At baseline, there was a 138% and 114% increase in Schirmer's scores in the right and left eye, respectively. These values stabilized to a 57% and 55% increase in the right and left eye, respectively after using the stimulator for six months.

Corneal staining was significantly reduced from baseline in both eyes after day 7. Likewise, conjunctival staining was also significantly reduced from baseline in both eyes after day 30.

Both symptom and severity scores were significantly lower than baseline at each of the follow-up visits. The average duration of symptom relief when using the device was approximately three hours. There was no significant change in tear breakup time over the study. Overall, at least 72% of the respondents indicated that they were moderately to highly satisfied, would use the device again, and would highly recommend this therapy to others with dry eye disease.

The adverse events related to the device included one case of migraine lasting one day in a participant who had a history of migraines, and one case of nasal discomfort lasting two days. Both cases were resolved without medical intervention. No clinically significant changes were detected with slit lamp biomicroscopy and indirect ophthalmoscopy. There were also no changes to the mucosal tissues on nasal endoscopy between baseline and study exit.

Discussion

Overall, the application of gentle electrical stimulation to the anterior ethmoidal nerve within the nasal cavity dramatically increased tearing. This device was found to relieve dry eye symptoms for approximately three hours, and improved ocular surface staining over the course of 180 days. This device was also found to be safe to use, and well-received by the participants in the study.

REFERENCES

1. Stapleton F, Alves M, Bunya VY, et al. TFOS DEWS II Epidemiology Report. *Ocul Surf.* 2017;15(3): 334-65.
2. Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II Definition and Classification Report. *Ocul Surf.* 2017;15(3): 276-83.
3. Jones L, Downie LE, Korb D, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf.* 2017;15(3): 575-628.
4. Friedman NJ, Butron K, Robledo N, et al. A nonrandomized, open-label study to evaluate the effect of nasal stimulation on tear production in subjects with dry eye disease. *Clin Ophthalmol.* 2016;10: 795-804.