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**Important Safety Information**  
In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia.

**Ophthalmology Times**  
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# Novel neurostimulator device uses nasal cavities to stimulate tears

Intranasal electrical stimulation offers new pathway to upregulate body's tearing system

March 15, 2017

By Michelle Dalton

Editor's note: Since the time of these presentations, Allergan submitted a de novo application for the Oculeve Intranasal Tear Neurostimulator device. According to the FDA, this process provides a pathway for medical devices for which general and/or special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

Chronic dry eye disease (DED) affects more than 25 million people and to date the only pharmacologic therapies are topical or involve punctal plugs.

Results from two studies with a neurostimulator indicate there may be a new pathway to upregulate the body's tear system.

The device (Oculeve Intranasal Tear Neurostimulator, Allergan) comprises a disposable tip with hydrogel that tops a durable, rechargeable stimulator unit, said John Berdahl, MD, Vance Thompson Vision, Sioux Falls, SD. Five levels of patient-adjusted stimulation are part of the device as well.

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Stephen C. Pflugfelder, MD, chair and professor of ophthalmology, Baylor College of Medicine, Houston, said clinicians now know tear secretion is regulated by the lacrimal functional unit, and that the nasal cavities play a role.

“Schirmer with nasal stimulation with a cotton-tip applicator is recognized to induce reflex tearing,” Dr. Pflugfelder said, “Nasal anesthesia decreases tear production by 34% in normal subjects.”

Goblet cells secrete mucin in response to neural stimulation, he added.

Several publications confirm dry eye may disrupt neural signaling of tear secretion by decreased corneal sensitivity, anticholinergic medications, autoantibodies to acetylcholine receptors, or inflammatory cytokines, Dr. Pflugfelder said.

[Pathway advantage](#)

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Cheryl Guttman Krader et al., Ophthalmology Times, 2017
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Colleen E. McCarthy et al., Optometry Times, 2016

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Caroline Cassels et al., Medscape, 2015
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PracticeUpdate, 2017
- Dry Eye Syndrome: Diagnostic and Treatment Tips**   
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


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