

# Effects of Punctal Occlusion on Ocular Itching and Conjunctival Redness in Subjects with Allergic Conjunctivitis

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ASCRS Annual Meeting | April 22-26, 2022 | Washington, DC

# Disclosures

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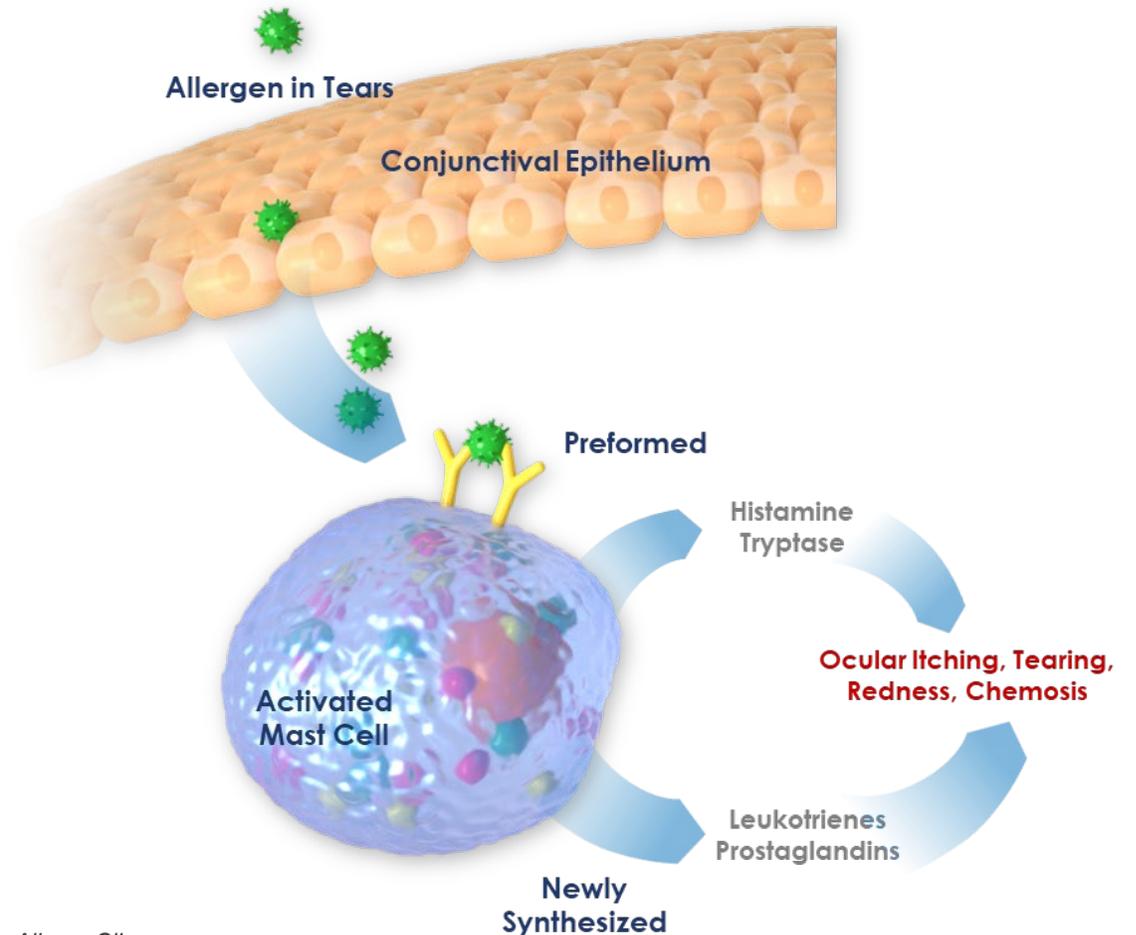
- **Presenter:** Steven Silverstein was an investigator in the current study.
- **Co-authors:** Michelle A Sato and Edward J. Meier were investigators in the current study. Srilatha Vantipalli and Michael H. Goldstein are employees of Ocular Therapeutix. Stella Dai was a former employee of Ocular Therapeutix.
- **Funding:** This study was supported by Ocular Therapeutix.

# Background

- Seasonal and perennial allergic conjunctivitis (AC) represent the most common form of ocular allergy<sup>1,2</sup>
- Exposure to an allergen causes release of histamine and results in ocular itching and hyperemia<sup>3-5</sup>
- There is limited evidence on the effect punctal occlusion has on signs and symptoms of AC

**Research Question: Does punctal occlusion using a hydrogel insert worsen signs and symptoms of AC?**

## Inflammatory Mechanism of Allergic Conjunctivitis



**References:** 1. Rosario N, et al. *Curr Opin Allergy Clin Immunol*. 2011;11(5):471–476. 2. Gomes PJ. *Curr Opin Allergy Clin Immunol*. 2014;14(5):451-456. 3. Leonardi A, et al. *Curr Opin Allergy Clin Immunol*. 2007;7(5):429-435. 4. Leonardi A, et al. *Acta Ophthalmol Scand*. 1999;77(s228):21-23. 5. Leonardi A, et al. *Curr Allergy Asthma Rep*. 2002;2:325-331.

# Study Design

**Objective: To investigate the effect of punctal occlusion on ocular itching and conjunctival redness associated with allergic conjunctivitis**



## Study Design

- Three randomized, double-masked, vehicle-controlled, multicenter Phase 3 clinical trials



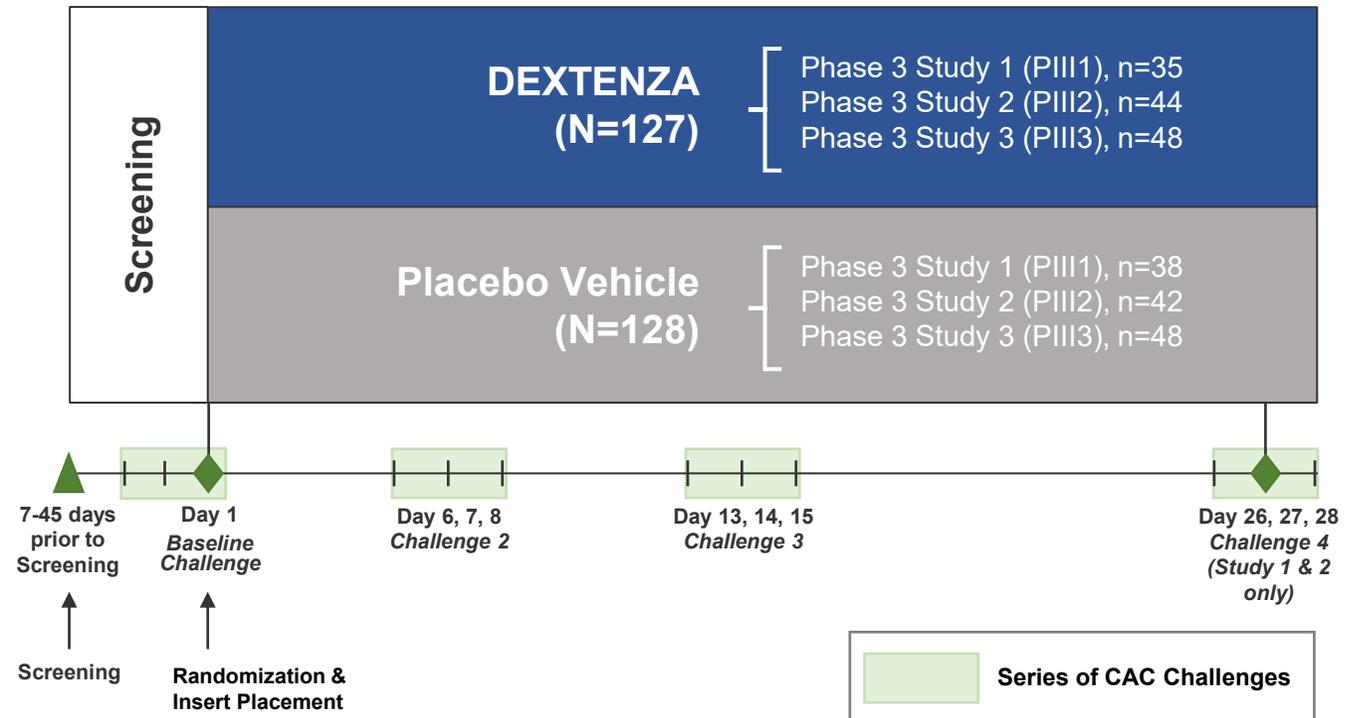
## Key Inclusion Criteria

- History of allergic conjunctivitis
- Positive skin test to seasonal and perennial allergen
- Bilateral CAC reaction



## Study Outcomes

- Post-CAC ocular itching (0-4 scale)
- Post-CAC conjunctival hyperemia (0-4 scale)

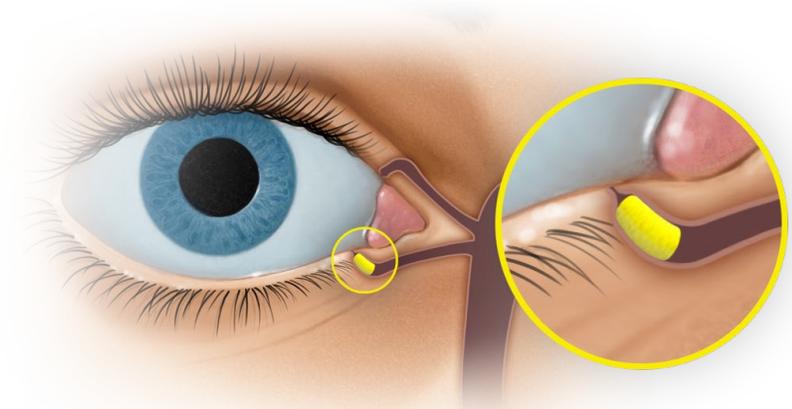


**Only data from subjects who received placebo-vehicle insert was included in this analysis**

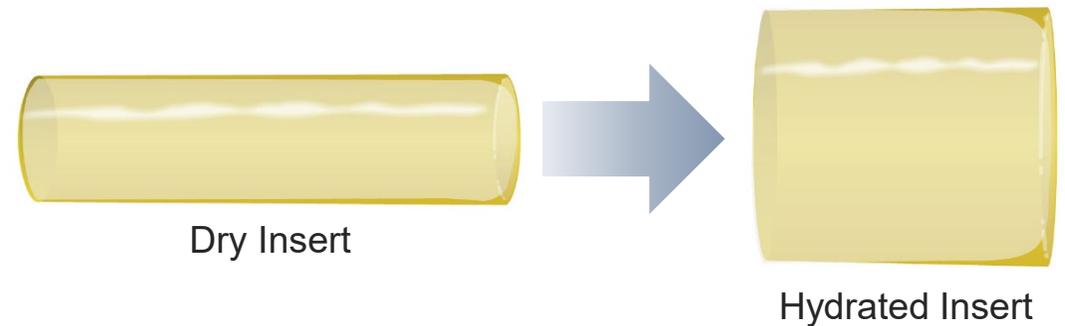
# Placebo-Vehicle Intracanalicular Insert

- Polyethylene glycol (PEG) hydrogel
- No active ingredient
- Hydrates and swells to fit the canaliculus
- Occludes the punctum
- Degrades and clears the nasolacrimal tract after 30 days

## Insert in the Canaliculus



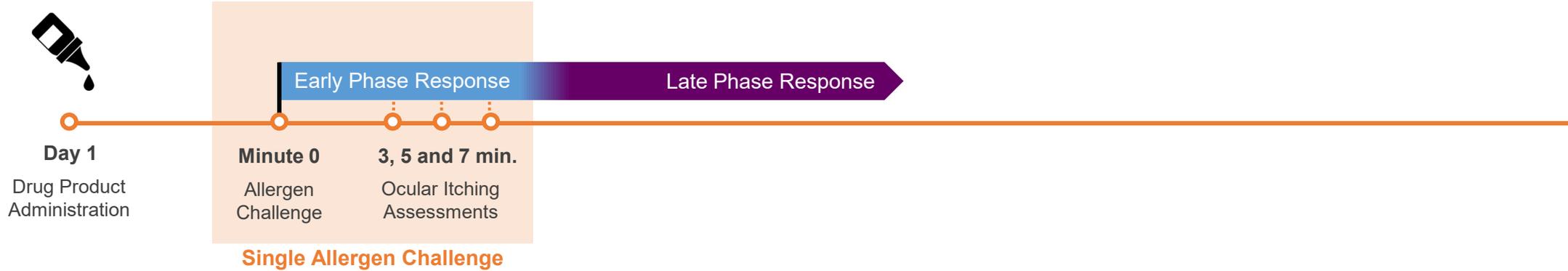
## Insert Swelling After Hydration



# Standard vs. Modified CAC Model

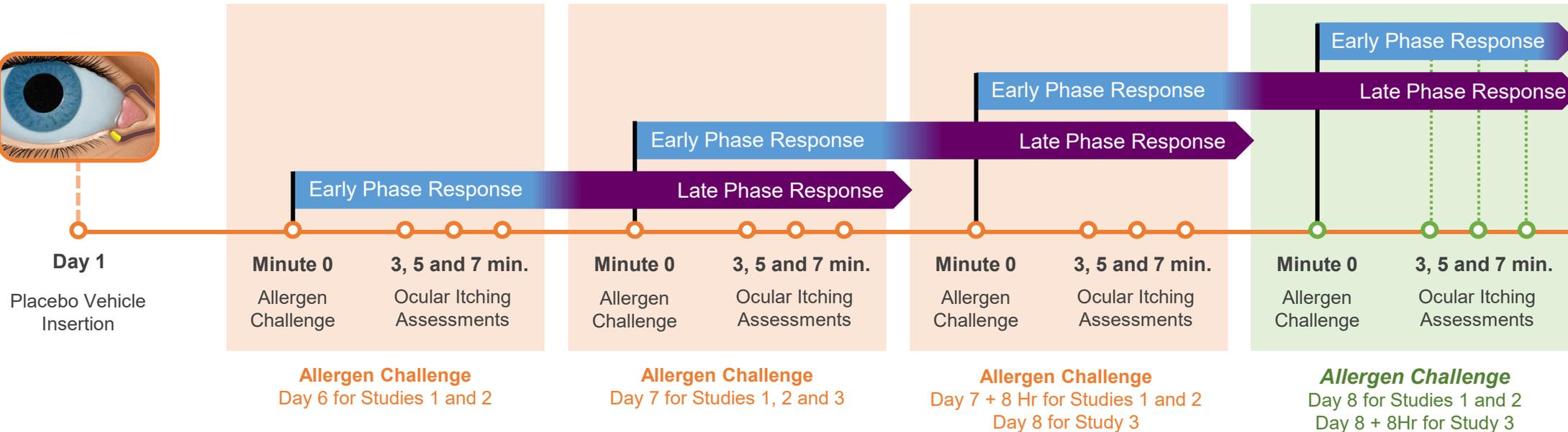
## Standard CAC Model<sup>1</sup>

A Single Allergen Challenge Following Test Article Administration



## Modified CAC Model<sup>2-4</sup>

Multiple Repeated Allergen Challenges Following Test Article Administration

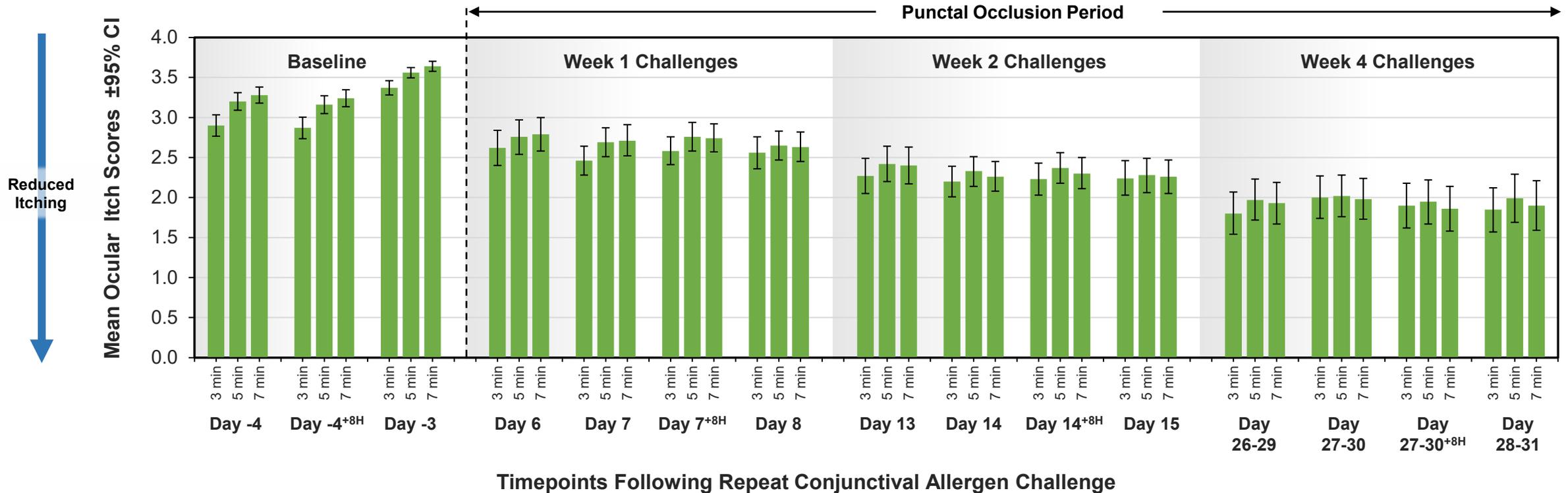


**References:** 1. Abelson M, et al. *Curr Allergy Asthma Rep.* 2003;3(4):363-368. 2. McLaurin EB, et al. *Am J Ophthalmol.* 2021;229:288-300. 3. McLaurin E, et al. Evaluating the Safety and Efficacy of DEXTENZA, a Dexamethasone Insert (0.4 mg) for the Treatment of Ocular Itching: Results from Three Clinical Trials. Presented at the American Society of Cataract and Refractive Surgeons Annual Meeting. San Diego, CA. May 6, 2019. 4. Kenyon KR, et al. Phase 3 Trial Evaluating an Intracanalicular Dexamethasone Insert (0.4 mg) for the Treatment of Patients with Allergic Conjunctivitis. Presented at the American Society of Cataract and Refractive Surgeons Annual Meeting. Boston, MA. May 16, 2020.

# Ocular Itching Over Time

Ocular itch scores decreased over a 1-month period following punctal occlusion

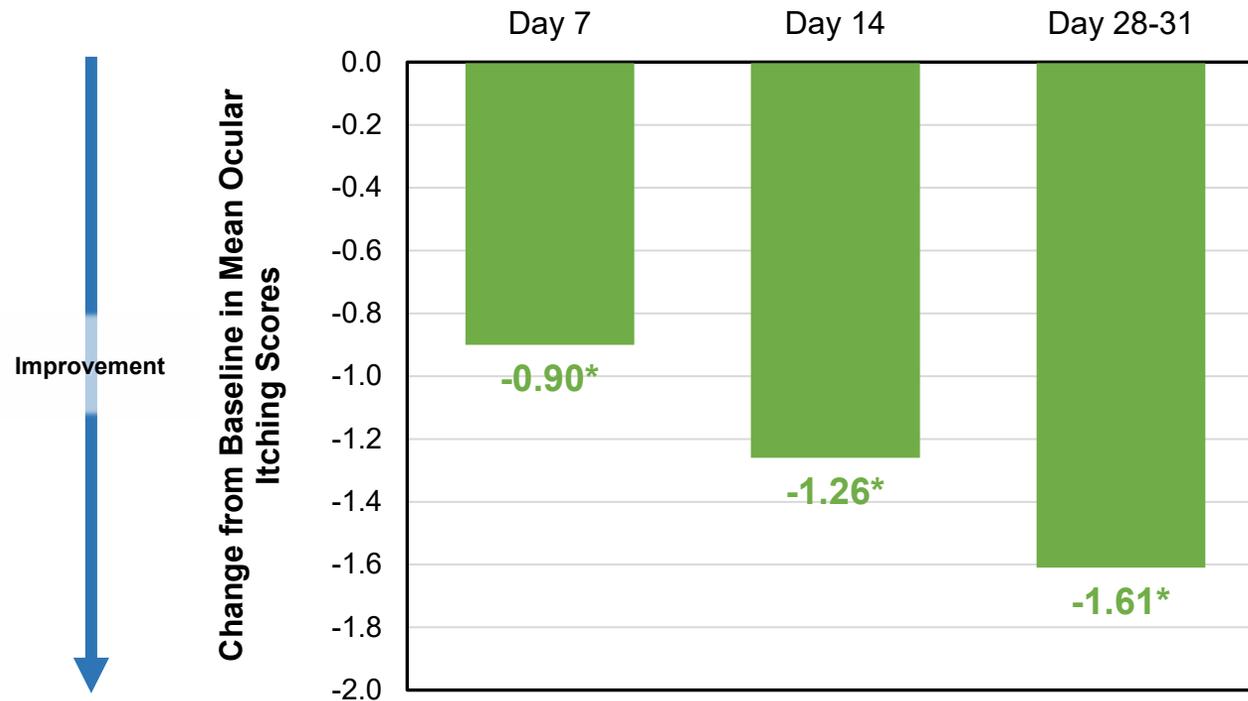
POOLED OCULAR ITCHING SCORES FOLLOWING PUNCTAL OCCLUSION (N=128)



# Ocular Itching Change from Baseline

On Days 7, 14 and 28, ocular itching scores were statistically significantly reduced from baseline ( $P < 0.05$ )

## CHANGE FROM BASELINE IN POST-CAC OCULAR ITCHING SCORES (N=128)



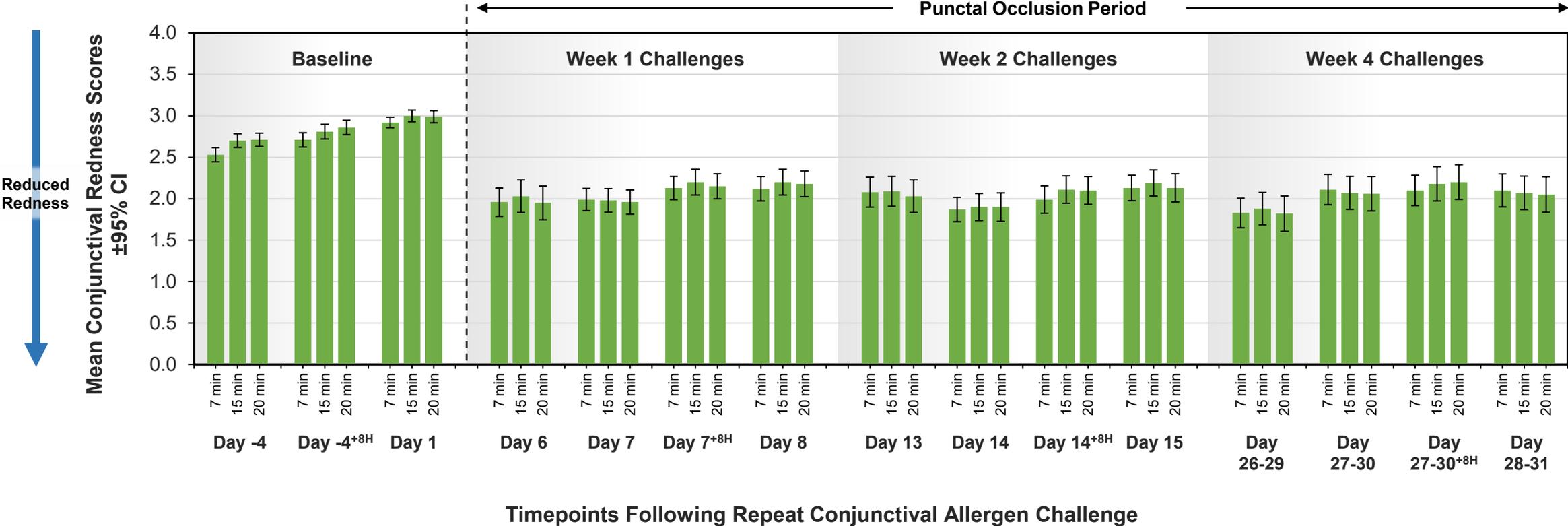
\*  $P < 0.001$

Change from baseline was calculated as the difference between the mean of 3, 5 & 7 min post-CAC ocular itching scores on Day -3 and Day 7, 14 & 28-31. Mean (SD) baseline ocular itching score was 3.52 (0.44)

# Conjunctival Redness Over Time

Following punctal occlusion, post-CAC conjunctival redness scores decreased from baseline for 1 month

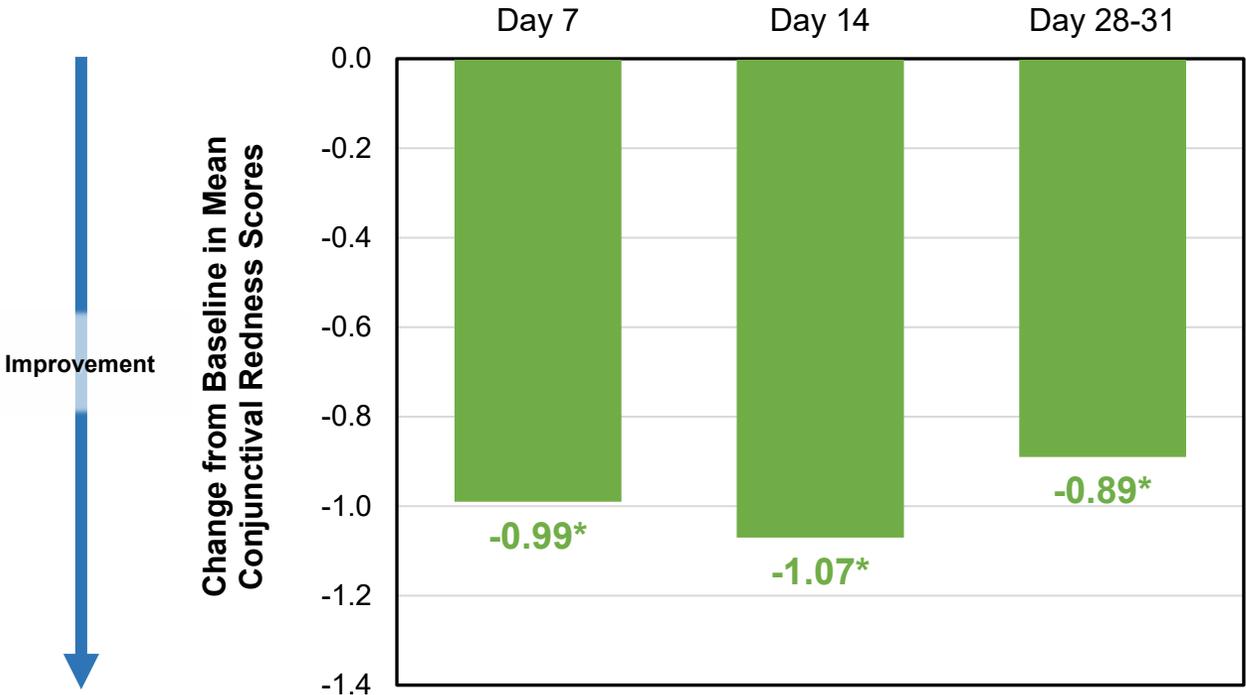
POOLED CONJUNCTIVAL REDNESS SCORES FOLLOWING PUNCTAL OCCLUSION (N=128)



# Conjunctival Redness Change from Baseline

On Days 7, 14 and 28, conjunctival redness scores were statistically significantly reduced from baseline ( $P < 0.05$ )

CHANGE FROM BASELINE IN POST-CAC CONJUNCTIVAL REDNESS SCORES (N=128)



\*  $P < 0.001$   
Change from baseline was calculated as the difference between the mean of 7, 15 & 20 min post-CAC conjunctival redness scores on Day 1 and Day 7, 14 & 28-31. Mean (SD) baseline conjunctival redness score was 2.97 (0.39)

# Conclusions

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- Post-hoc, pooled analysis of placebo-vehicle subject data (N=128) from three randomized, masked clinical trials using a modified, repeat CAC model
- Following punctal occlusion with a hydrogel insert, ocular itching and conjunctival redness decreased from baseline at week 1 and remained reduced through week 4
- Reductions in mean ocular itching and redness scores at Day 7, 14 and 28 were statistically significant compared to baseline ( $P < 0.001$ )
- **Punctal occlusion did not worsen ocular itching and conjunctival redness associated with allergic conjunctivitis**