

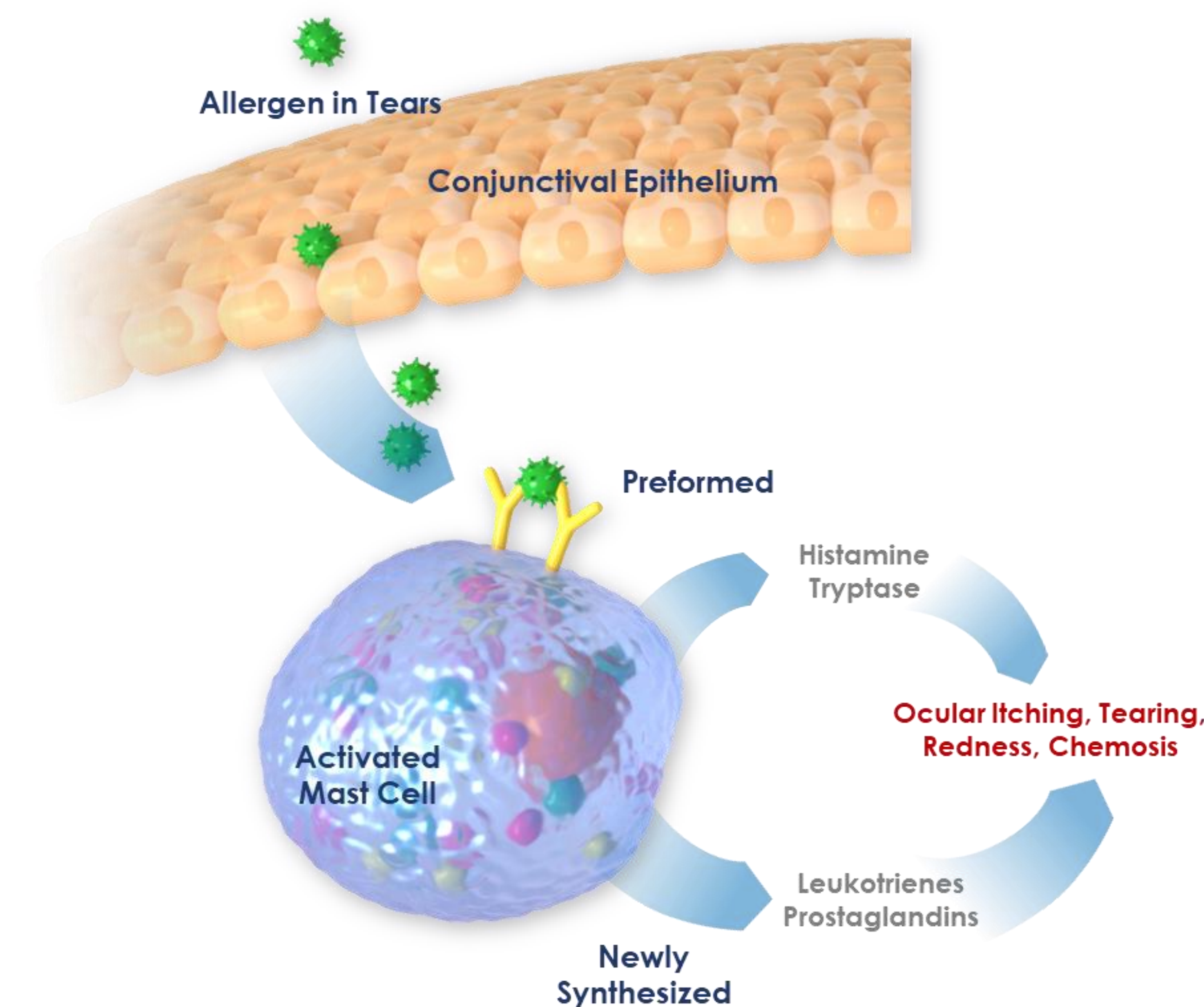
# Effects of Punctal Occlusion on Ocular Itching and Conjunctival Redness Associated with Allergic Conjunctivitis

Nysha Blender, OD<sup>1</sup>; Fabiana Q. Silva, MD<sup>1</sup>; Trung Tran, OD<sup>1</sup>; Stella Dai, MS<sup>1</sup>; Srilatha Vantipalli, PhD<sup>1</sup>; Mitra Sehi, OD, PhD<sup>1</sup>; Michael Goldstein, MD<sup>1</sup>  
<sup>1</sup>Ocular Therapeutix Inc., Bedford, MA

## BACKGROUND

- Seasonal and perennial allergic conjunctivitis (AC) represent the most common form of ocular allergy and affect up to 40% of the US population<sup>1,2</sup>
- Ocular itching and hyperemia often seen with AC are a result of allergen exposure which causes mast cell degranulation and release of histamine soon after<sup>3-5</sup> (Figure 1)

Figure 1. Early Phase Response in Allergic Conjunctivitis



- The effects of punctal occlusion on the signs and symptoms of other ocular surface diseases such as dry eye disease have been reported, however, there is limited evidence on the effect of punctal occlusion in AC
- Here we evaluate the effect of punctal occlusion in allergic conjunctivitis

## STUDY OBJECTIVES

To investigate changes in ocular itching and conjunctival redness associated with allergic conjunctivitis following punctal occlusion with a resorbable, hydrogel intracanalicular insert

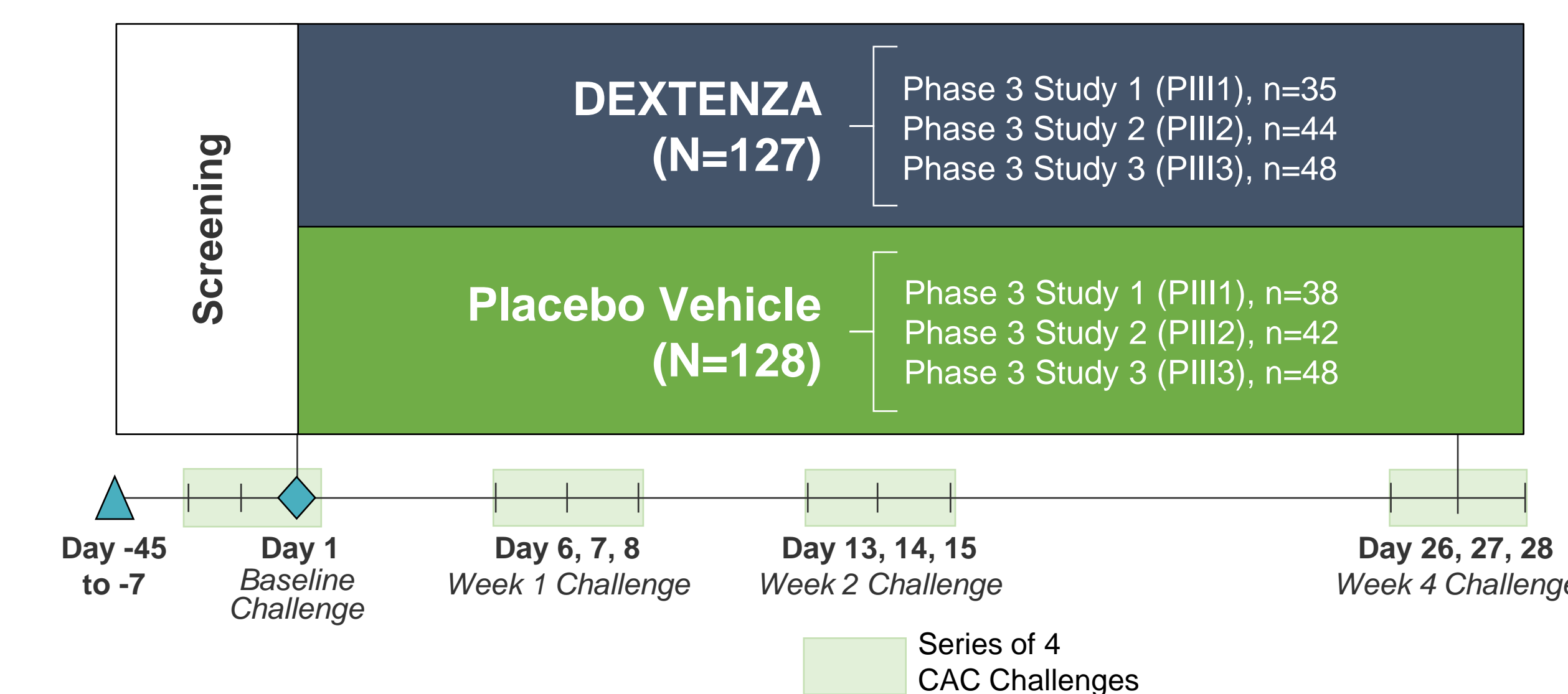
## METHODS

### Study Design

Post-hoc pooled analysis of three randomized, multicenter, double-masked, vehicle-controlled Phase III clinical trials in subjects with AC (Figure 2):

- Evaluated the efficacy and safety of DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg compared to placebo-vehicle (PV) insert (only data from PV subjects were included in this study)
- PV insert was made of a PEG-based hydrogel and did not contain an active ingredient. Once inserted into the puncta, inserts swelled to fit the canaliculus and were designed to last throughout Day 30 following insertion
- Used a modified Ora-CAC Model with repeated allergen challenges (Ora Inc., Andover, MA, USA)

Figure 2: Study Design of Four Clinical Trials Evaluating DEXTENZA in Allergic Conjunctivitis Subjects



### Assessments

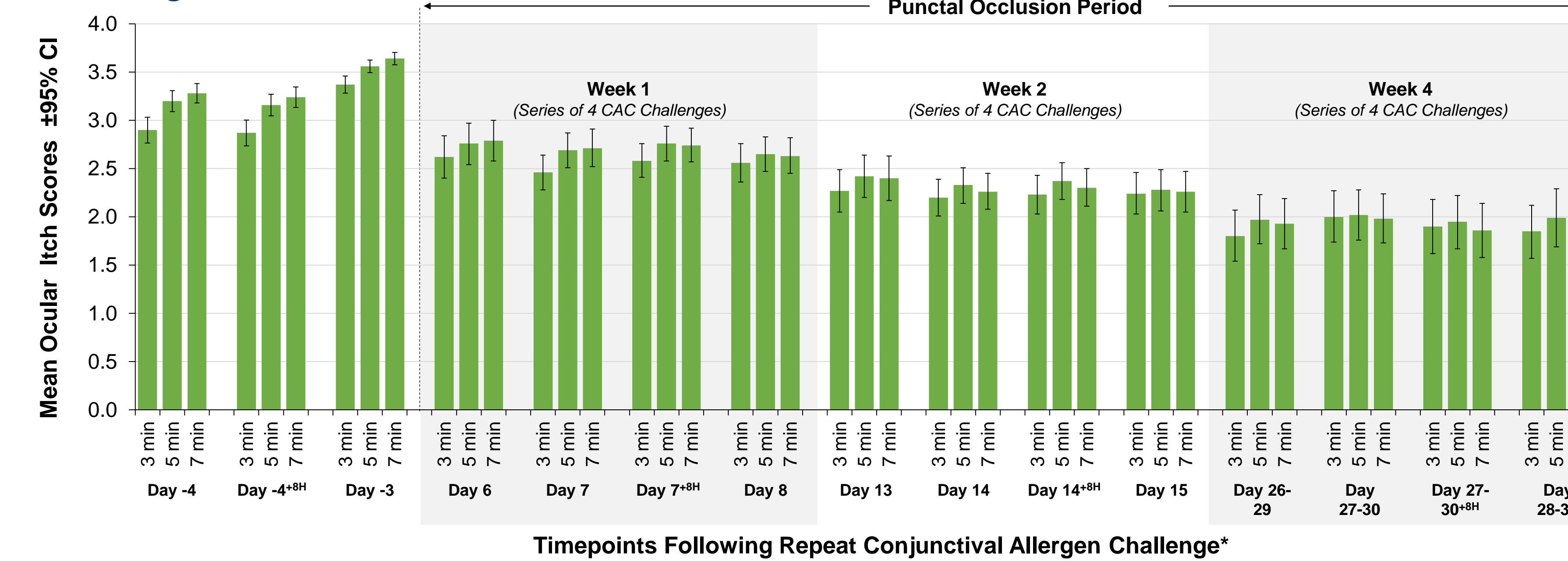
- Subject-evaluated ocular itching score 3, 5 and 7 minutes following allergen challenge on Week 1, 2 and 4 post-insertion
  - Ora Calibra itch scale (0-4 scale where 0 = none and 4 = incapacitating itch; 0.5 unit increments allowed)
- Investigator-evaluated conjunctival redness score 7, 15 and 20 minutes following allergen challenge on Week 1, 2 and 4 post-insertion
  - Ora Calibra conjunctival redness scale (0-4 scale where 0 = none and 4 = extremely severe; 0.5 unit increments allowed)

## RESULTS

### Ocular Itching

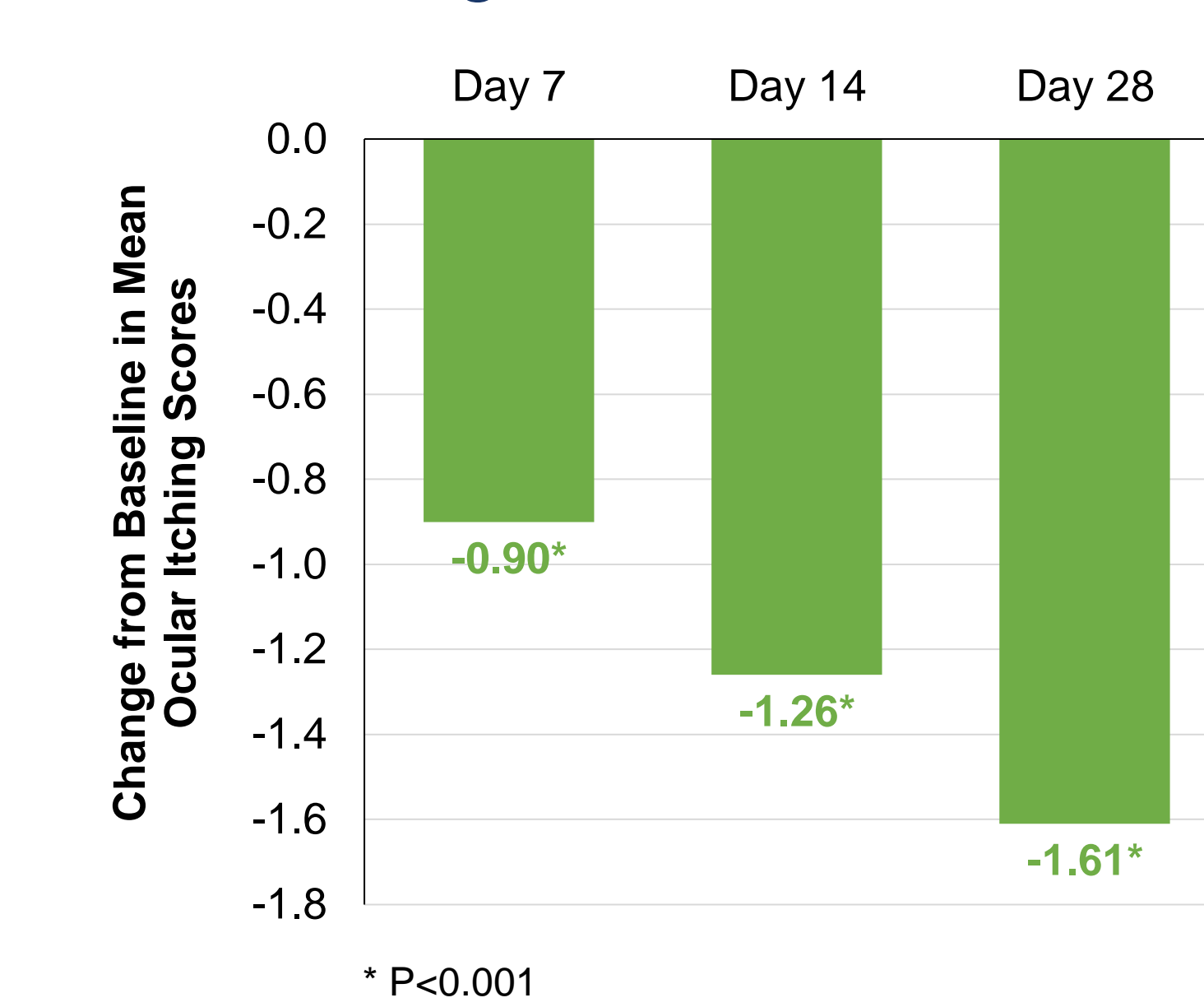
- Compared to baseline, subjects reported numerically lower mean ocular itching scores at 3, 5 and 7 minutes following repeat allergen challenges at all timepoints after insertion of a hydrogel intracanalicular insert (Figure 3A)
- At baseline, mean (SD) ocular itching score was 3.52 (0.44). On Days 7, 14 and 28 post-insertion, mean ocular itching scores were statistically significantly reduced to 2.62, 2.26, and 1.91, respectively (P<0.001) (Figure 3B)

Figure 3A. Effect of Punctal Occlusion on Ocular Itching Scores Following Repeat Allergen Challenges



\*The modified CAC model used a series of 4 successive CACs conducted over 3 days. The first CAC was performed, then the second and third CACs were on the next day (8 hours apart), and the fourth CAC was 24 hours after the third CAC. Subjects reported ocular itching 3, 5 and 7 minutes after each CAC.

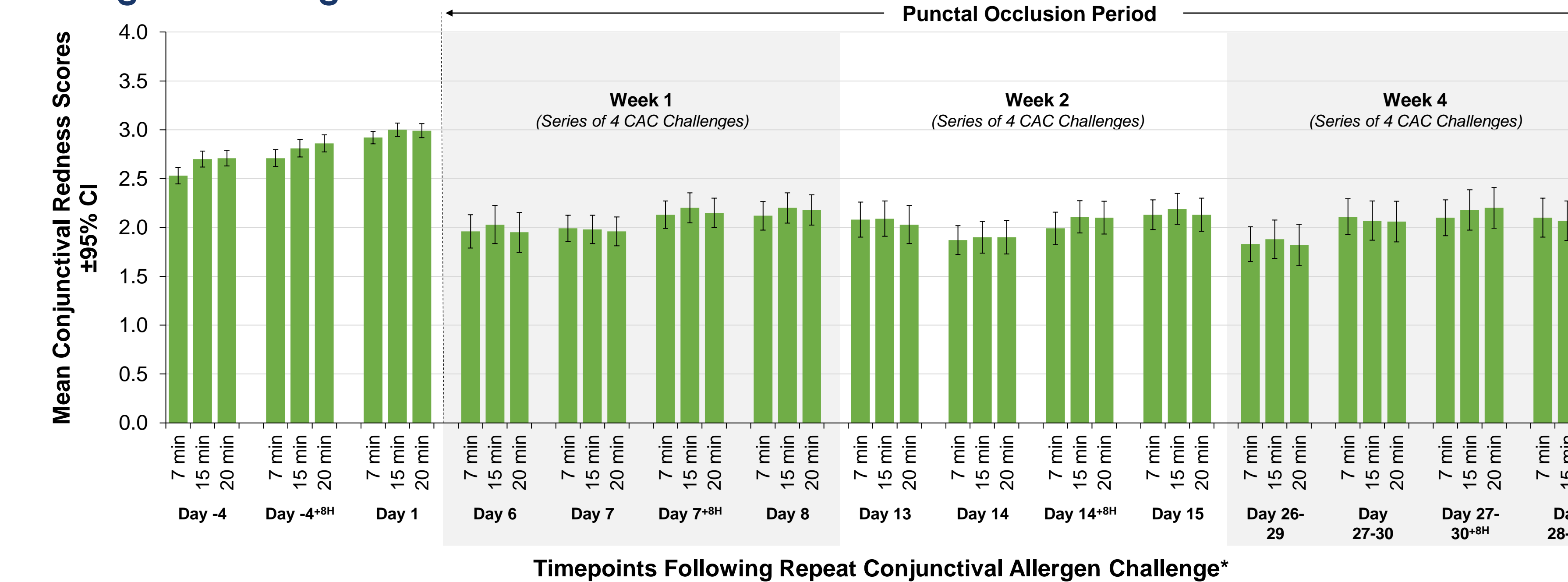
Figure 3B. Change from Baseline in Ocular Itching Score



### Conjunctival Redness

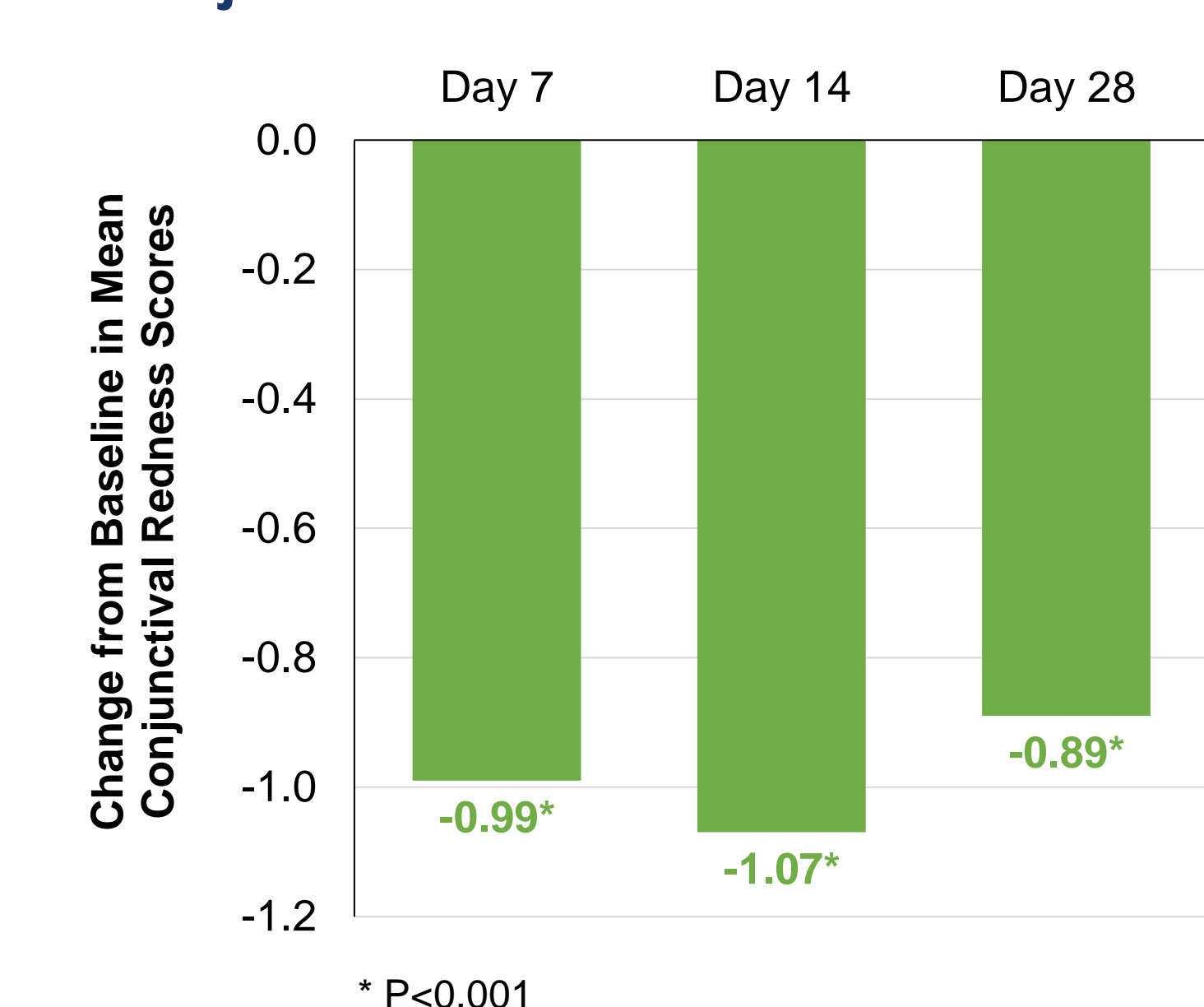
- Following insertion of a hydrogel intracanalicular insert, mean conjunctival redness scores at 7, 15 and 20 minutes after repeat allergen challenge were numerically lower compared to baseline (Figure 4A)
- At baseline, mean (SD) conjunctival redness score was 2.97 (0.39). On Days 7, 14 and 28 post-insertion, mean conjunctival redness scores were statistically significantly reduced to 1.98, 1.90, and 2.08, respectively (P<0.001) (Figure 4B)

Figure 4A. Effect of Punctal Occlusion on Conjunctival Redness Scores Following Repeat Allergen Challenges



\*The modified CAC model used a series of 4 successive CACs conducted over 3 days. The first CAC was performed, then the second and third CACs were on the next day (8 hours apart), and the fourth CAC was 24 hours after the third CAC. Investigators evaluated conjunctival redness 7, 15 and 20 minutes after each CAC.

Figure 4B. Change from Baseline in Conjunctival Redness Score



## CONCLUSIONS

Punctal occlusion with a resorbable hydrogel intracanalicular insert did not worsen ocular itching and conjunctival redness in subjects with allergic conjunctivitis.

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**Abbreviations:** CAC, conjunctival allergen challenge; CI, confidence interval; H, hour; PEG, polyethylene glycol; SD, standard deviation

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