Thermal Pulsation Therapy with Dextenza Versus Prednisolone Acetate or Sham for Meibomian Gland Dysfunction with Inflammation

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American Society of Cataract and Refractive Surgeons | San Diego, CA | 2023

Disclosures

Relevant Financial Disclosures (Lisa M. Nijm)

- Research Grant: Ocular Therapeutix

Study Disclosures

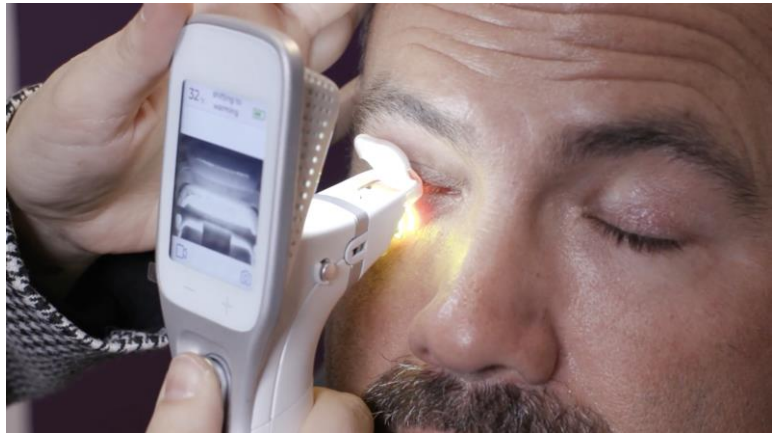
- This study was funded by Ocular Therapeutix, Inc.
- This presentation discusses an off-label use of DEXTENZA. DEXTENZA is approved by the U.S. Food and Drug Administration (FDA) for the treatment of ocular inflammation and pain following ophthalmic surgery, and the treatment of ocular itching associated with allergic conjunctivitis.

Introduction

- Meibomian gland dysfunction is defined as

  > "a chronic, diffuse abnormality of the meibomian glands, …[that] may result in alteration of the tear film, symptoms of eye irritation, clinically apparent **inflammation**, and ocular surface disease"[1]

- Thermal pulsation therapy softens then expresses inspissated meibum from impacted meibomian glands[2]
- Steroid therapy has been shown in several MGD studies to **improve tear film inflammatory mediators, gland expressibility, and/or clinical symptoms**[3-5]
- The **dexamethasone intracanalicular insert** (DEXTENZA [DEX], Ocular Therapeutix, Bedford, MA) is a rod-shaped hydrogel matrix incorporating dexamethasone 0.4 mg that elutes a tapering concentration of preservative-free steroid to the ocular surface for up to 30 days[6,7]



Thermal pulsation therapy (Systane iLux, Alcon Laboratories, Fort Worth, TX)

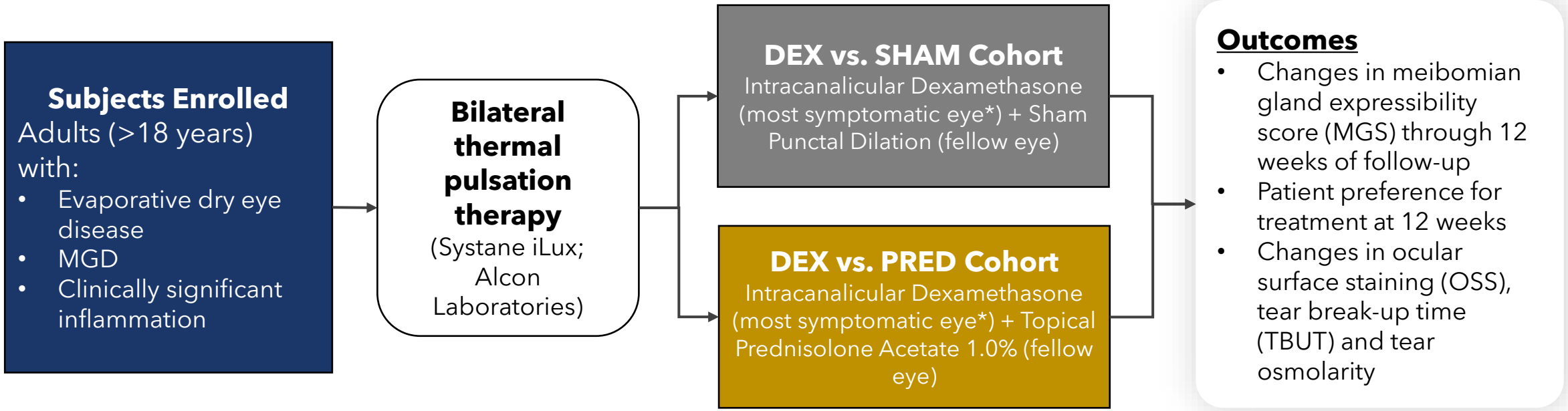
Intracanalicular dexamethasone insert placed into the lower canaliculus at the slit lamp

Top image courtesy of Alcon Laboratories. Bottom image courtesy of Ocular Therapeutix, Inc.

References: 1. Nichols KK, et al. *Invest Ophthalmol Vis Sci.* 2011;52(4):1922-1929. **2.** Wesley G, et al. *Optom Vis Sci*. 2022;99(4):323-332. **3.** Ko JS, et al. *Eye (Lond).* 2018;32(2):439-445. **4.** Lee H, et al. *Am J Ophthalmol.* 2014;158(6):1172-1183. **5.** Akyol-Salman I, et al. *J Ocul Pharmacol Ther*. 2012;28(1):49-52. **6.** Tyson SL, et al. *J Cataract Refract Surg*. 2019;45(2):204-212. **7.** Walters T, et al. *J Clin Exp Ophthalmol*. 2016;7:1-11.

Study Design: A Prospective, Open-label Comparative Study

Purpose: To characterize the added benefit of dexamethasone intracanalicular insert in eyes with meibomian gland dysfunction (MGD) undergoing thermal pulsation therapy



* by patient report or the right eye if equal

Baseline Characteristics

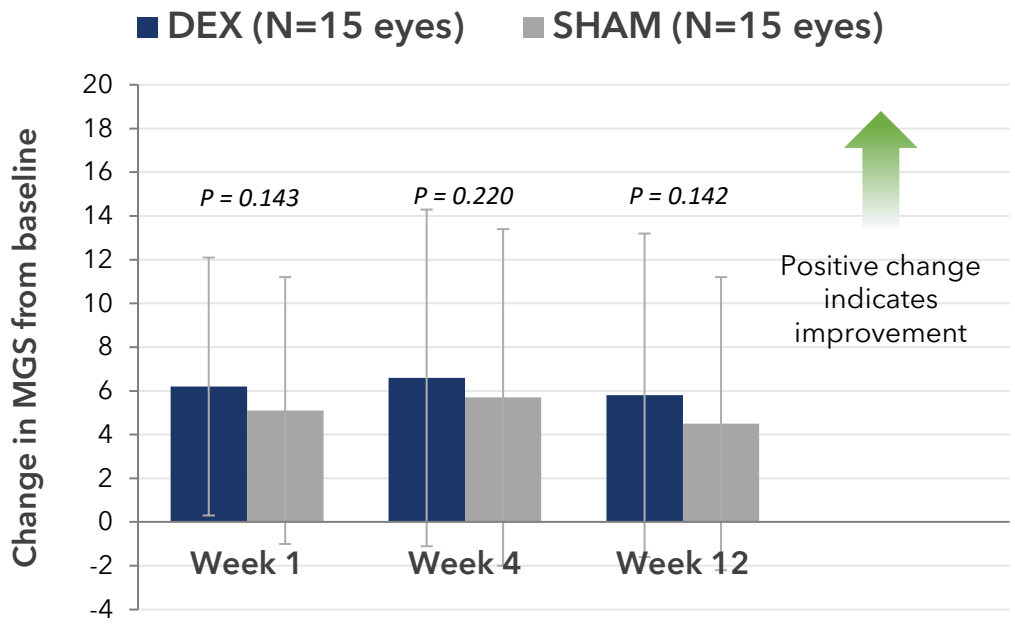
- 30 patients participated in this study. Mean (SD) age was 63.3 (20.8) years, roughly half were female (46.7%), and most (93.3%) were White.
- **DEX vs. SHAM** cohort: two groups were well-matched at baseline for MGS, TBUT, tear osmolarity, while DEX eyes had worse OSS scores
- **DEX vs PRED** cohort: both groups were well-matched at baseline for all parameters

Parameter	DEX vs. SHAM Cohort (N=15 patients)			DEX vs. PRED Cohort (N=15 patients)		
	DEX (N=15 eyes)	**SHAM** (N=15 eyes)	P value	**DEX** (N=15 eyes)	**PRED** (N=15 eyes)	P value
Meibomian Gland Expressibility Score, mean (SD)	20.0 (6.7)	20.7 (6.7)	0.263	14.7 (5.6)	15.7 (5.4)	0.114
Ocular surface staining score, mean (SD)	9.5 (4.8)	7.6 (5.2)	**0.030**	10.3 (6.6)	9.3 (4.3)	0.359
Tear break-up time (sec), mean (SD)	5.7 (1.6)	5.1 (2.1)	0.333	4.8 (1.9)	5.3 (2.3)	0.399
Tear osmolarity (mOsm/L), mean (SD)	312.5 (12.7)	307.3 (13.8)	0.171	309.1 (11.0)	308.9 (13.9)	0.957

DEX vs. SHAM Results

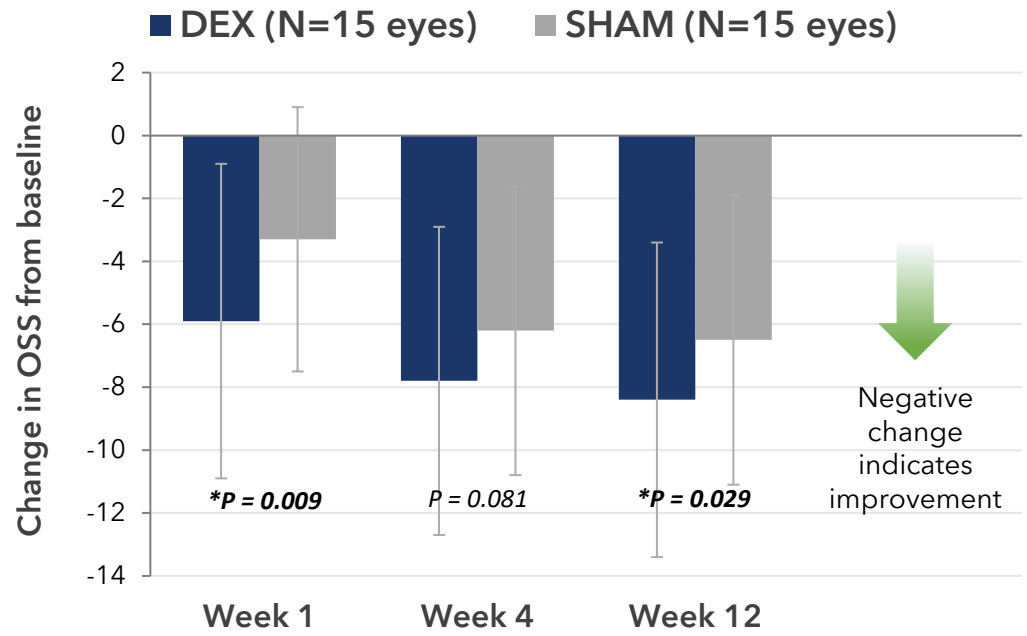
- **Thermal pulsation therapy with DEX or SHAM improved MGS at all time points**
- **OSS scores improved in both groups at all time points with similar changes from baseline except at week 1 and 12 – mean OSS scores improved more in DEX than SHAM eyes (P<0.05)**

Meibomian Gland Score (MGS)



Error bars represent standard deviation (SD)
P values characterize differences between DEX eyes and SHAM eyes

Ocular Surface Staining Score (OSS)

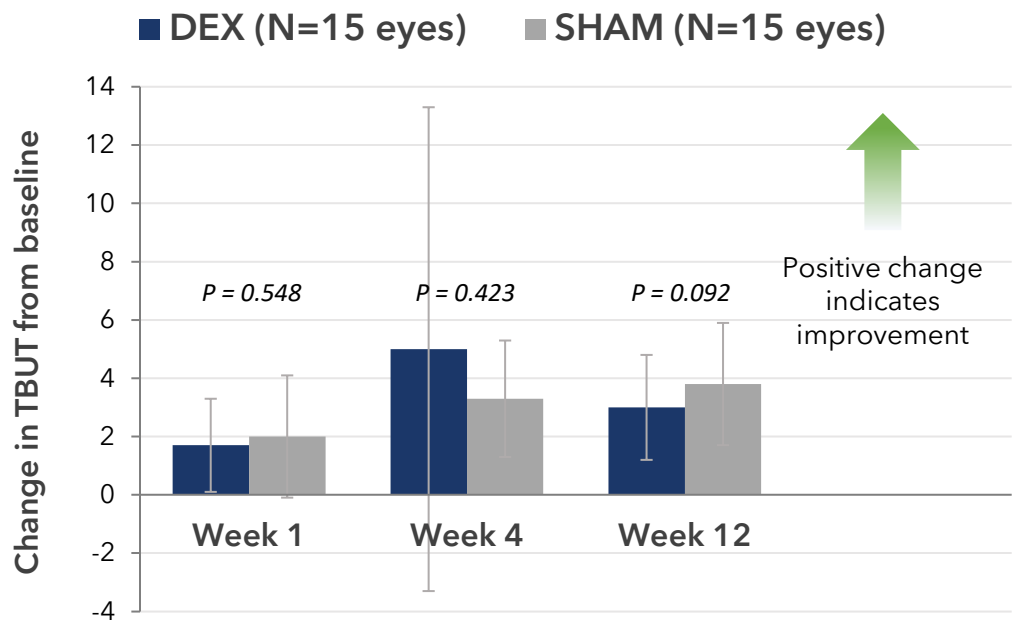


Error bars represent standard deviation (SD)
P values characterize differences between DEX eyes and SHAM eyes
*P<0.05

DEX vs. SHAM Results (Con't)

- **Thermal pulsation with DEX or SHAM improved TBUT similarly all time points**
- **Tear osmolarity at week 12 had improved more in DEX eyes compared to SHAM eyes (P=0.035).**

Tear Break-Up Time (TBUT)



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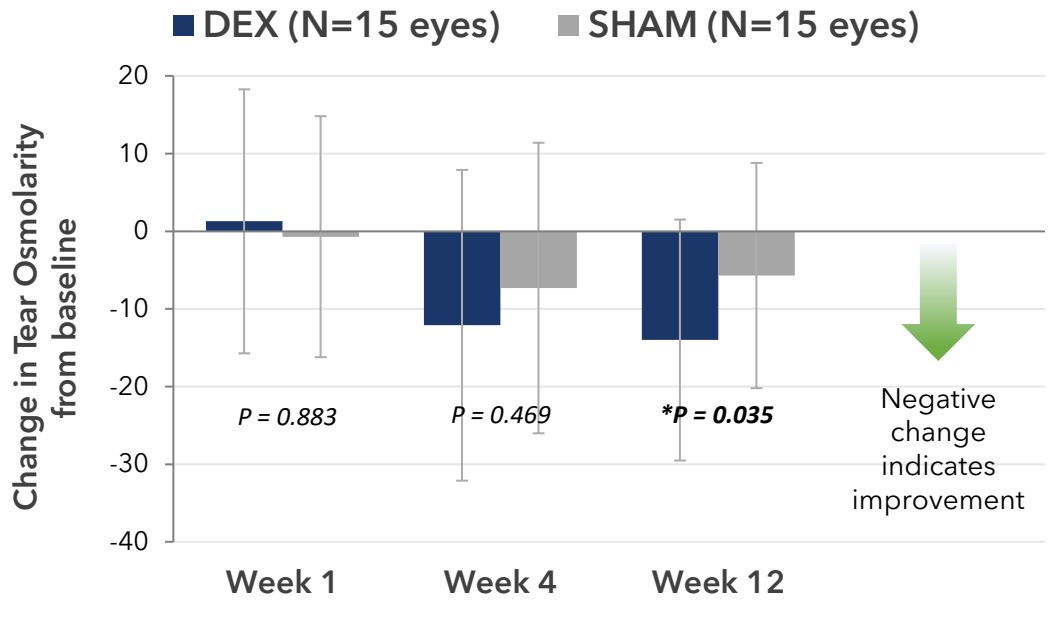
P values characterize differences between DEX eyes and SHAM eyes

Tear Osmolarity

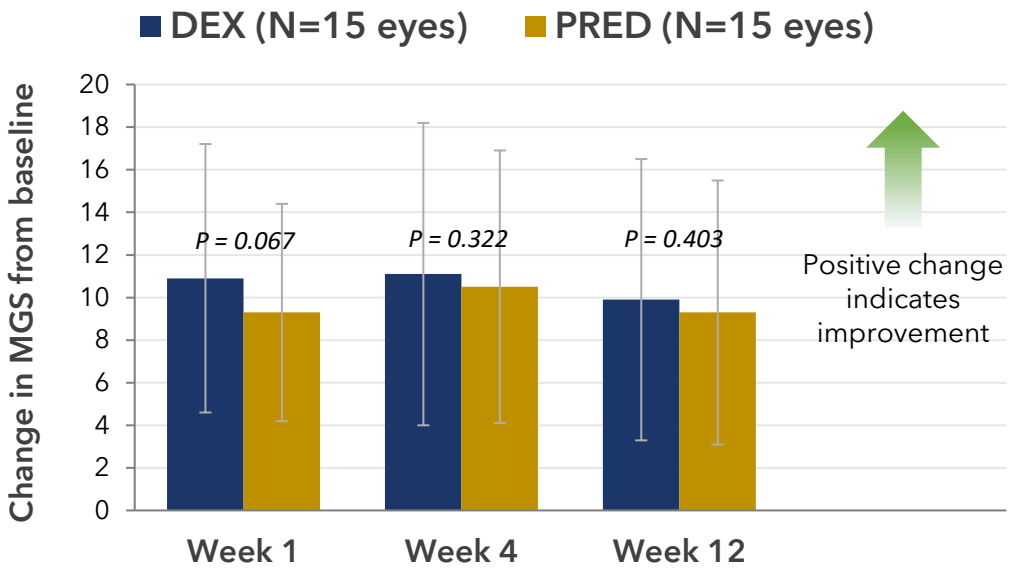


Error bars represent standard deviation (SD)
P values characterize differences between DEX eyes and SHAM eyes
*P<0.05

DEX vs. PRED Results

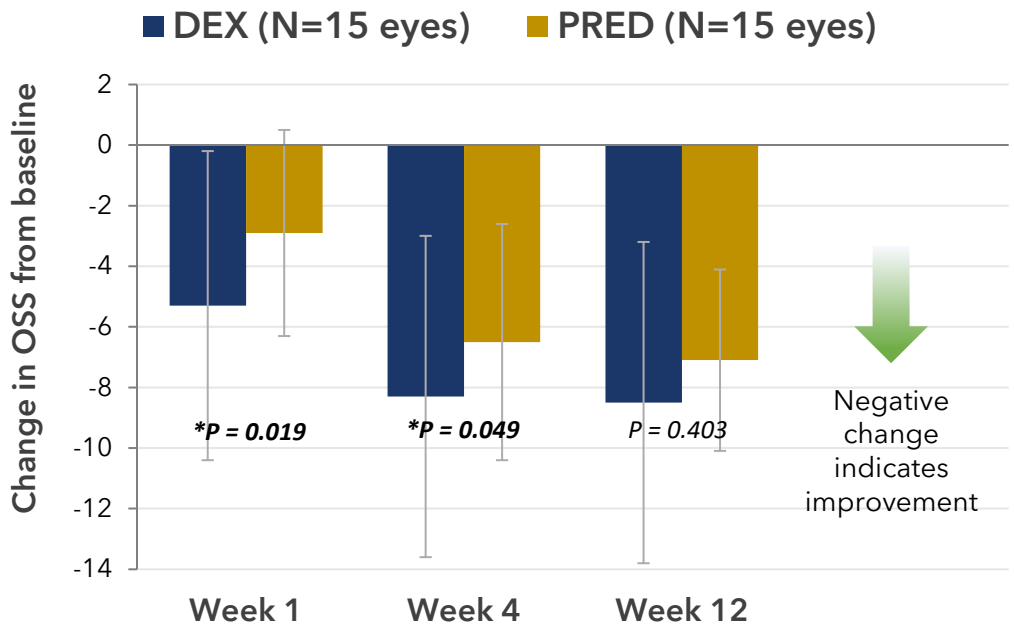
- **Mean MGS improved in both DEX and PRED eyes at all time points; changes from baseline were similar between groups at all time points.**
- **DEX demonstrated fast and greater improvements in OSS scores at weeks 1 and 4 (P<0.05) possibly due to the punctal occlusive effects from the insert**

Meibomian Gland Score (MGS)



Error bars represent standard deviation (SD)
P values characterize differences between DEX eyes and PRED eyes

Ocular Surface Staining (OSS) Score

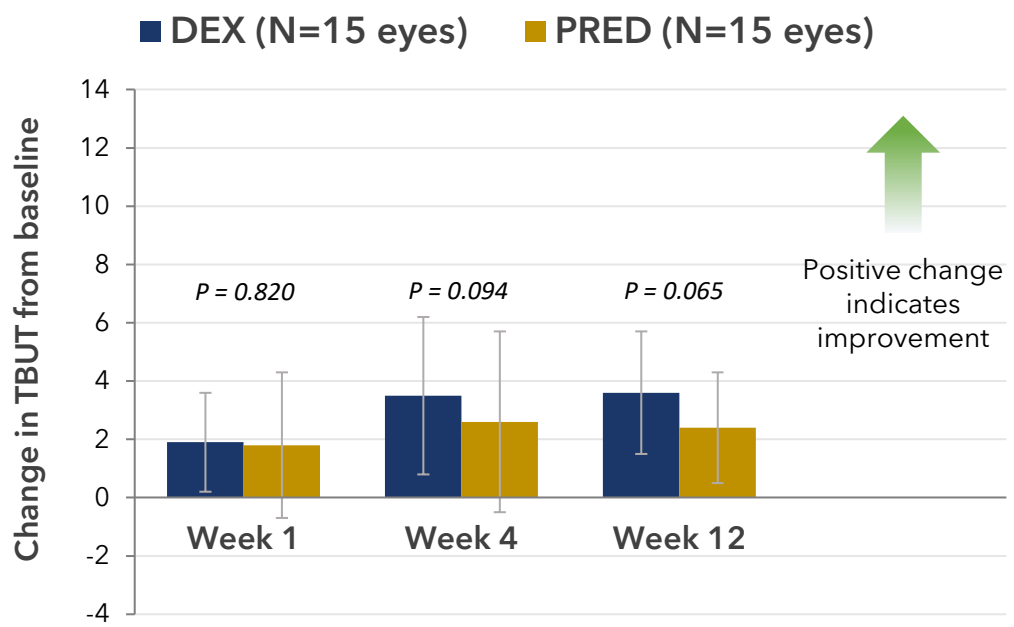


Error bars represent standard deviation (SD)
P values characterize differences between DEX eyes and PRED eyes
*P<0.05

DEX vs. PRED Results (Con't)

- **TBUT improved in DEX and PRED eyes at all time points with similar changes from baseline at each time point**
- **Tear osmolarity was improved from baseline in both groups by week 12, with similar changes from baseline between groups**

Tear Break Up Time (TBUT)



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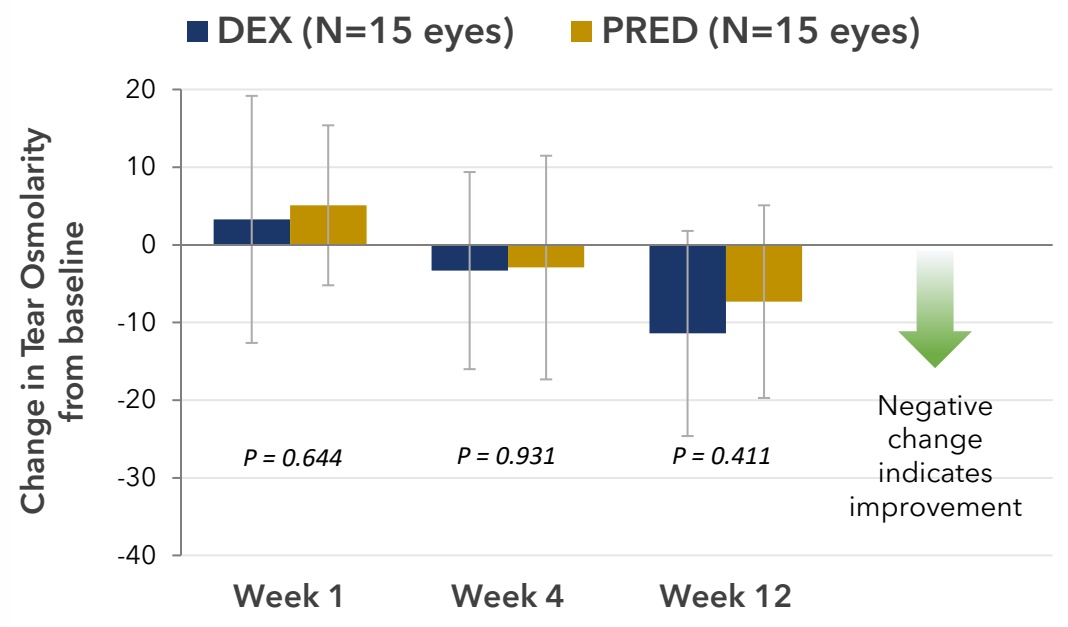
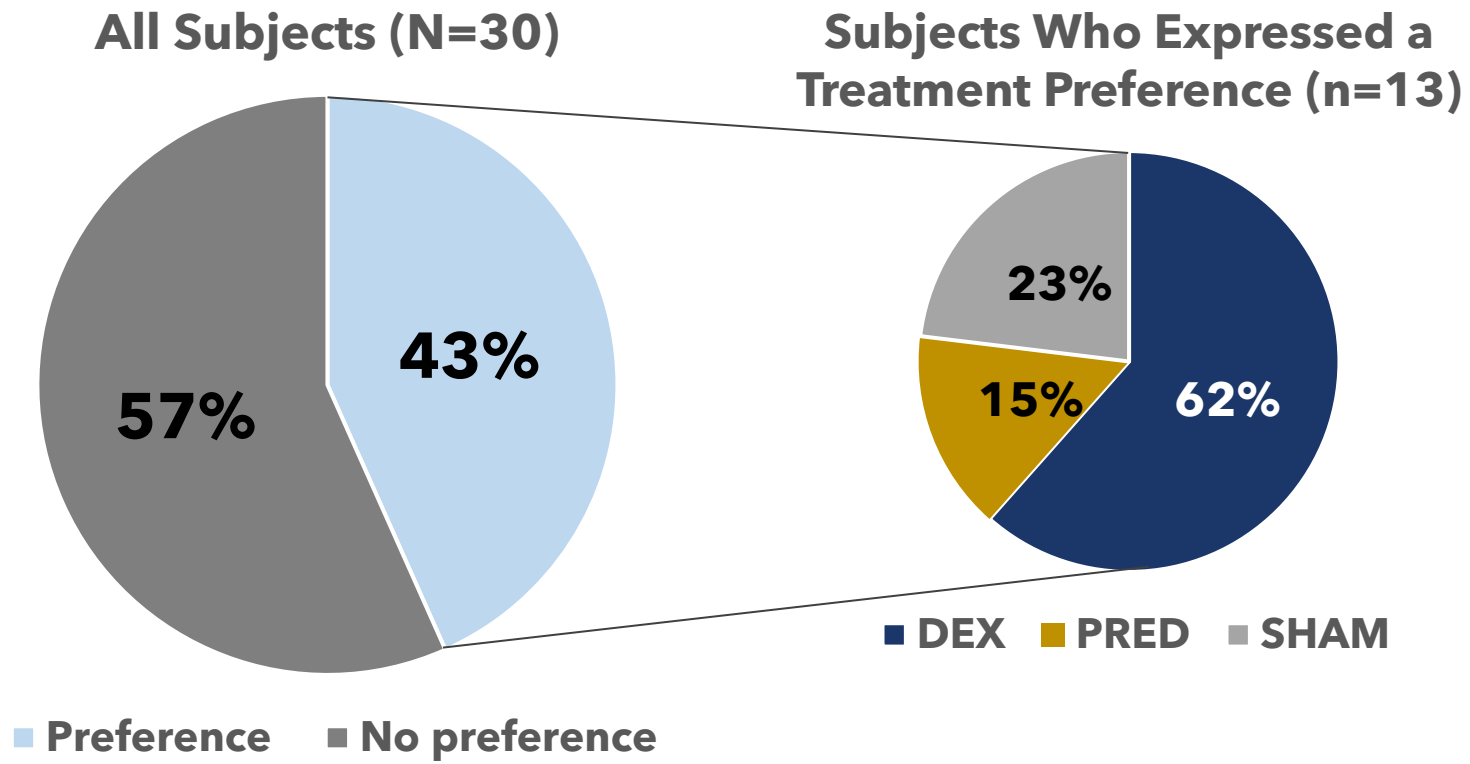
Tear Osmolarity



Error bars represent standard deviation (SD)
P values characterize differences between DEX eyes and PRED eyes

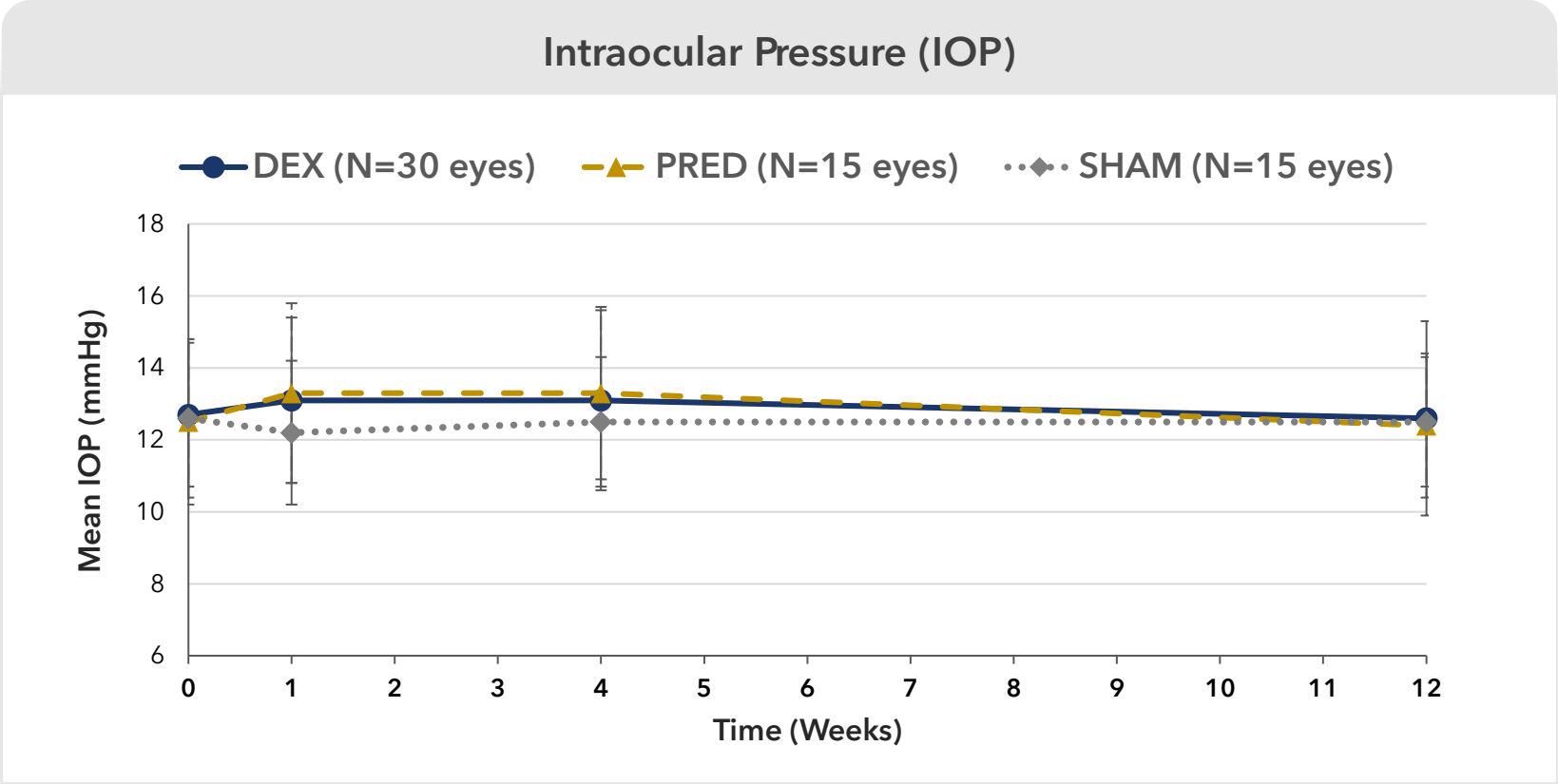
Treatment Preference

- Overall, 17/30 patients (56.7%) expressed no preference for therapy.
- Of patients who expressed a treatment preference (n=13), 61.5% preferred DEX over PRED (15.3%) or SHAM (23.1%)



Safety Analysis

- No adverse events related to any study procedures were reported
- No clinically significant changes in mean IOP at each follow-up visit were observed in DEX, PRED, and SHAM eyes



Conclusions

- Thermal pulsation therapy safely and effectively improved MGS, OSS, TBUT, and tear osmolarity in eyes with MGD as seen from improvements in all groups, including SHAM
- The addition of DEX produced additional improvements in OSS and osmolarity possibly due to the insert's punctal occlusive and/or sustained-release effects.
- DEX was at least as effective as prednisolone acetate in improving outcomes of thermal pulsation therapy
  - DEX demonstrated greater improvements in ocular surface staining early on at 1 and 4 weeks following treatment
- Of the two steroid therapies, patients preferred DEX over PRED by more than a 2:1 margin (61.5% vs. 15.3%)