

Safety and Effectiveness Comparison of Hydrogel-Based Intracanalicular Dexamethasone Insert Placement in the Lower Versus Upper Punctum: The SPENCER Study

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Disclosures

Financial Disclosures (Patrick Spencer)

- Patrick Spencer (presenting author) was an investigator in this trial

Study Disclosures

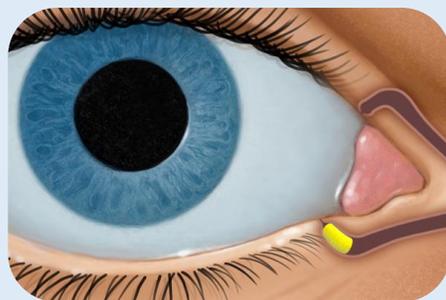
- The study was sponsored by Ocular Therapeutix, Inc.

Purpose

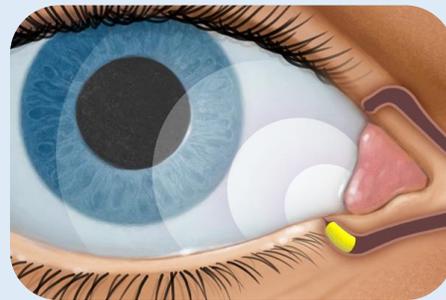
To evaluate the safety and effectiveness of intracanalicular dexamethasone insert (DEX) following cataract surgery with or without MIGS when placed in the lower or upper punctum

Intracanalicular Dexamethasone Insert (DEX)¹

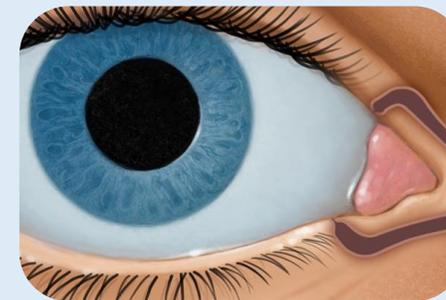
- FDA-approved for the treatment of post-op ocular inflammation and pain, and the treatment of ocular itching associated with allergic conjunctivitis
- Demonstrated to be safe and effective in three Phase 3 clinical trials when inserted into the lower canaliculus following cataract surgery



Insert into the vertical canaliculus



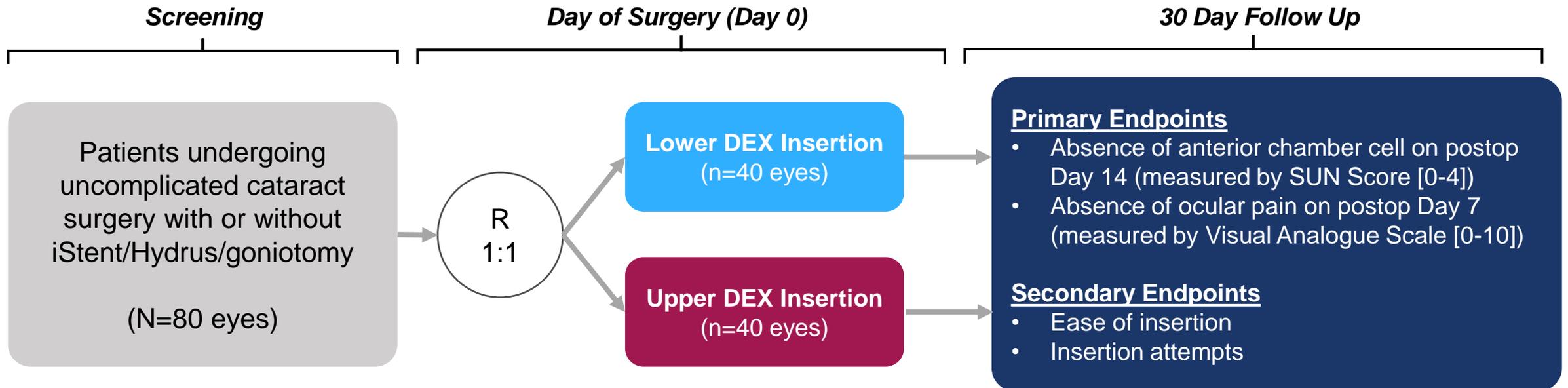
Releases dexamethasone for up to 30 days



Resorbs with no need for removal

The SPENCER Study Investigated Upper versus Lower Insertion of Intracanalicular Dexamethasone Insert

Trial Design: randomized, controlled, open-label study



Baseline Demographics Were Well-Balanced Between Treatment Groups

	Lower DEX Insertion (N=39 eyes)*	Upper DEX Insertion (N=40 eyes)	P-value
Age , years, mean (SD)	68.5 (8.1)	68.3 (9.1)	>0.05
Sex , n (%)			>0.05
Male	16 (41.0%)	14 (35.0%)	
Female	23 (59.0%)	26 (65.0%)	
Race , n (%)			>0.05
White	4 (10.3%)	6 (15.0%)	
African American	35 (89.7%)	34 (85.0%)	
American	0 (0.0%)	0 (0.0%)	
Surgical Procedure , n (%)			>0.05
Cataract Surgery Only	35 (89.7%)	35 (87.5%)	
Cataract-MIGS	4 (10.3%)	5 (12.5%)	
Cataract Type , n (%)			>0.05
Nuclear	26 (66.7%)	25 (62.5%)	
Sclerosis	1 (2.6%)	1 (2.5%)	
Cortical	12 (30.8%)	14 (35.0%)	

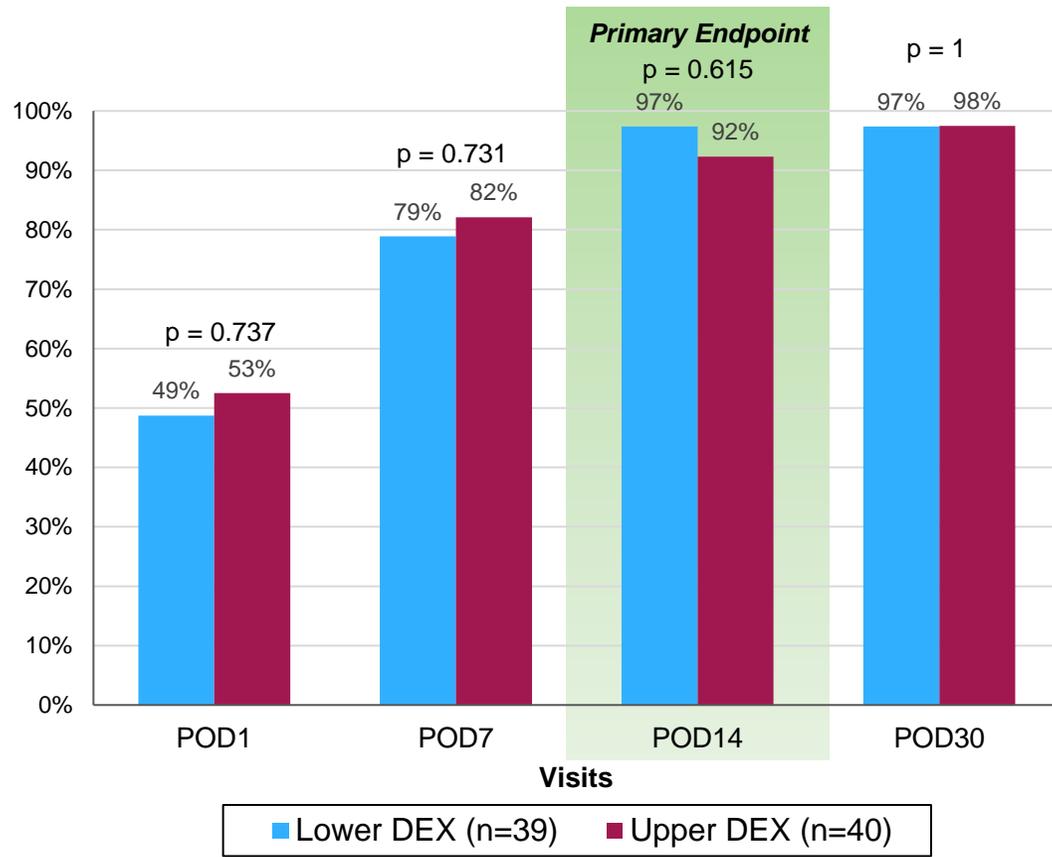
MIGS=minimally invasive glaucoma surgery; SD=standard deviation

*One subject in the Lower DEX Insertion group withdrew from the study

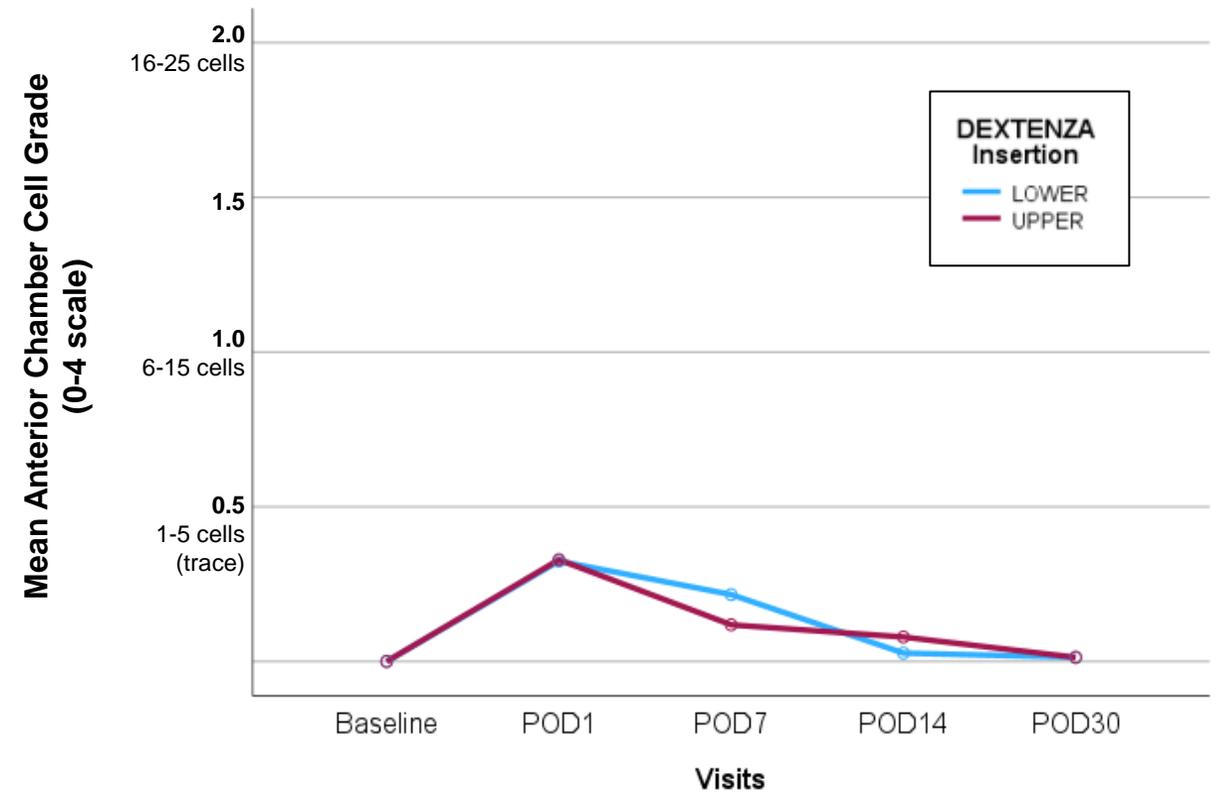
There were no statistically significant differences in baseline demographics and characteristics between groups (P>0.05 for all).

Incidence of Postop Inflammation on Day 14 was Similar Between Upper DEX and Lower DEX Insertions

Proportion of Subjects with Complete Absence of Anterior Chamber Cell

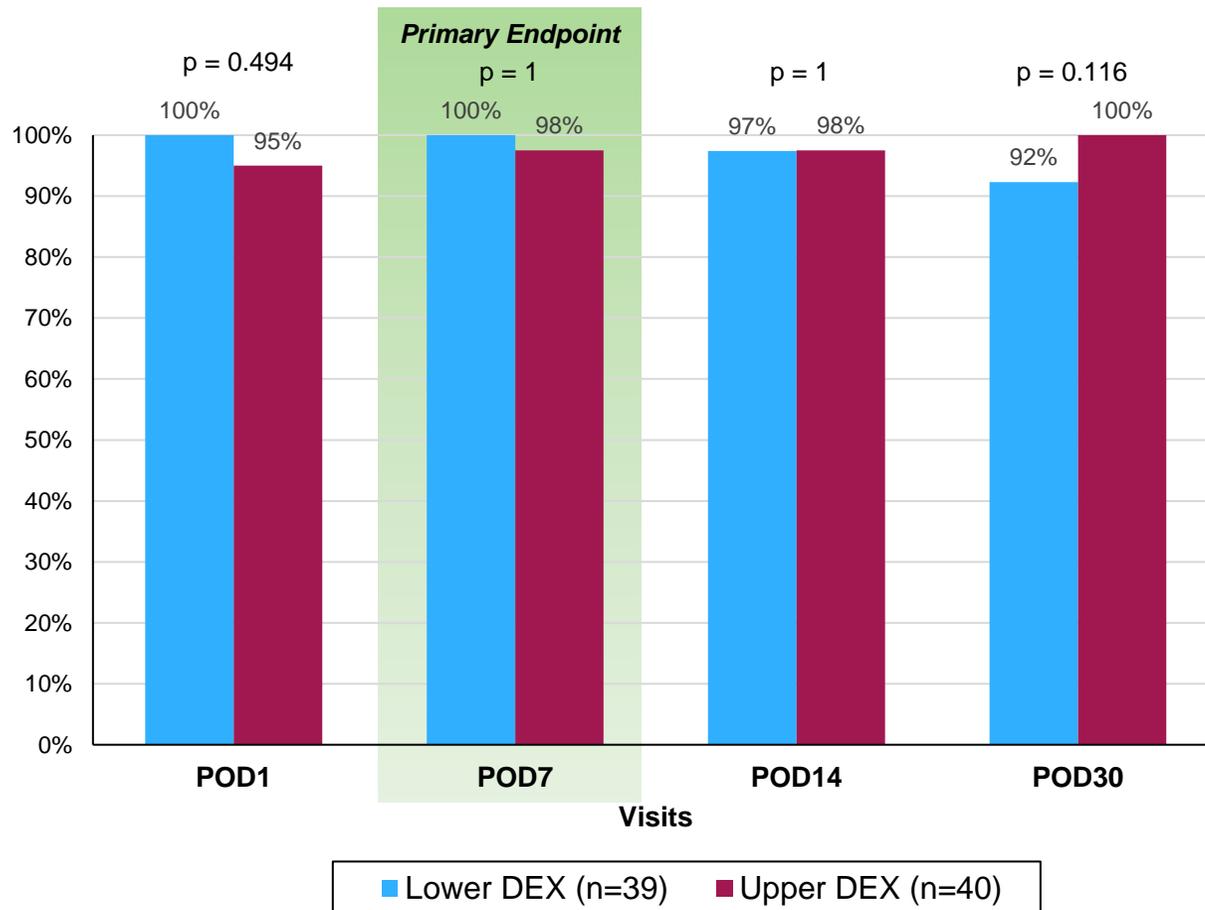


Mean Anterior Chamber Cell Grade in Upper DEX and Lower DEX Groups



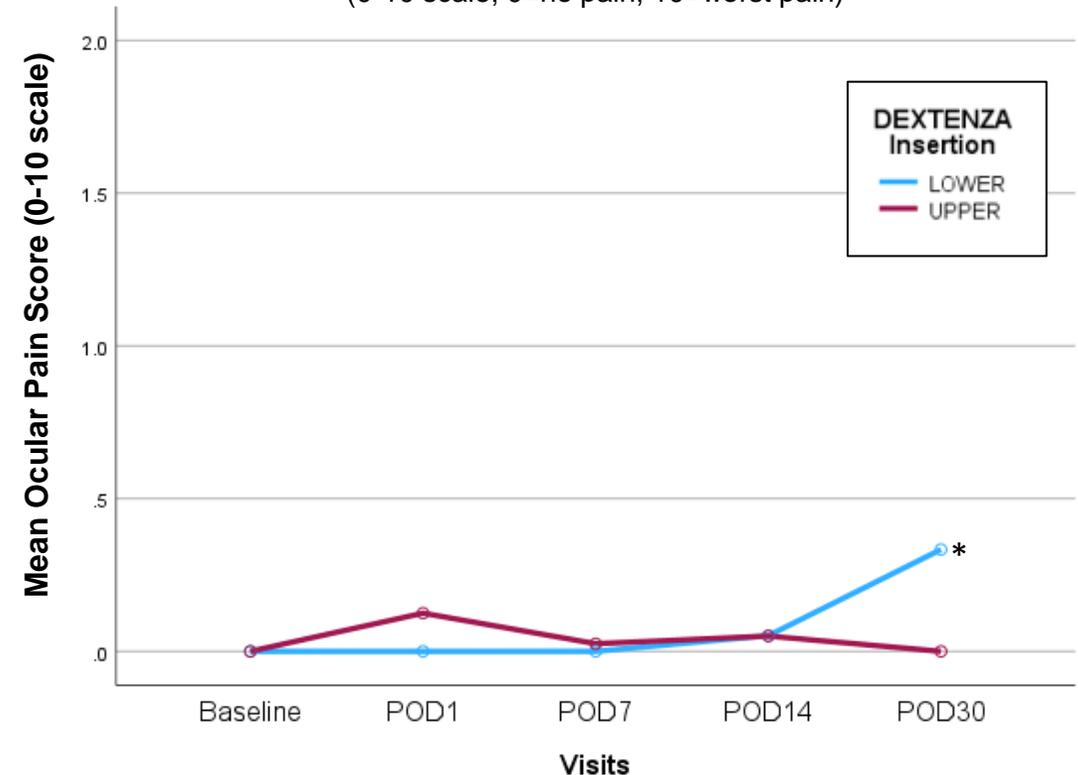
Proportion of Eyes with Postop Pain on Day 7 were Comparable Between Upper DEX and Lower DEX Insertions

Proportion of Subjects with Complete Absence of Pain



Mean Ocular Pain Score in Upper DEX and Lower DEX Groups

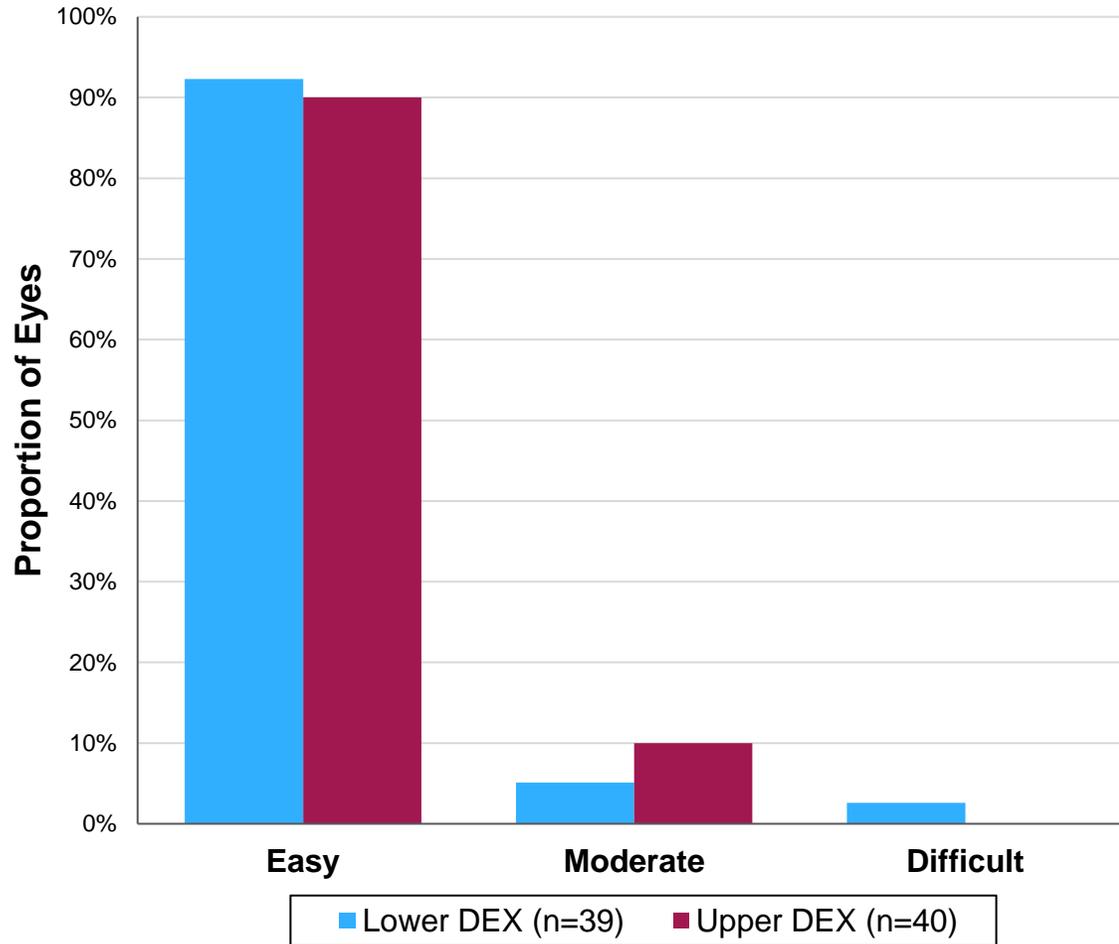
(0-10 scale; 0=no pain, 10=worst pain)



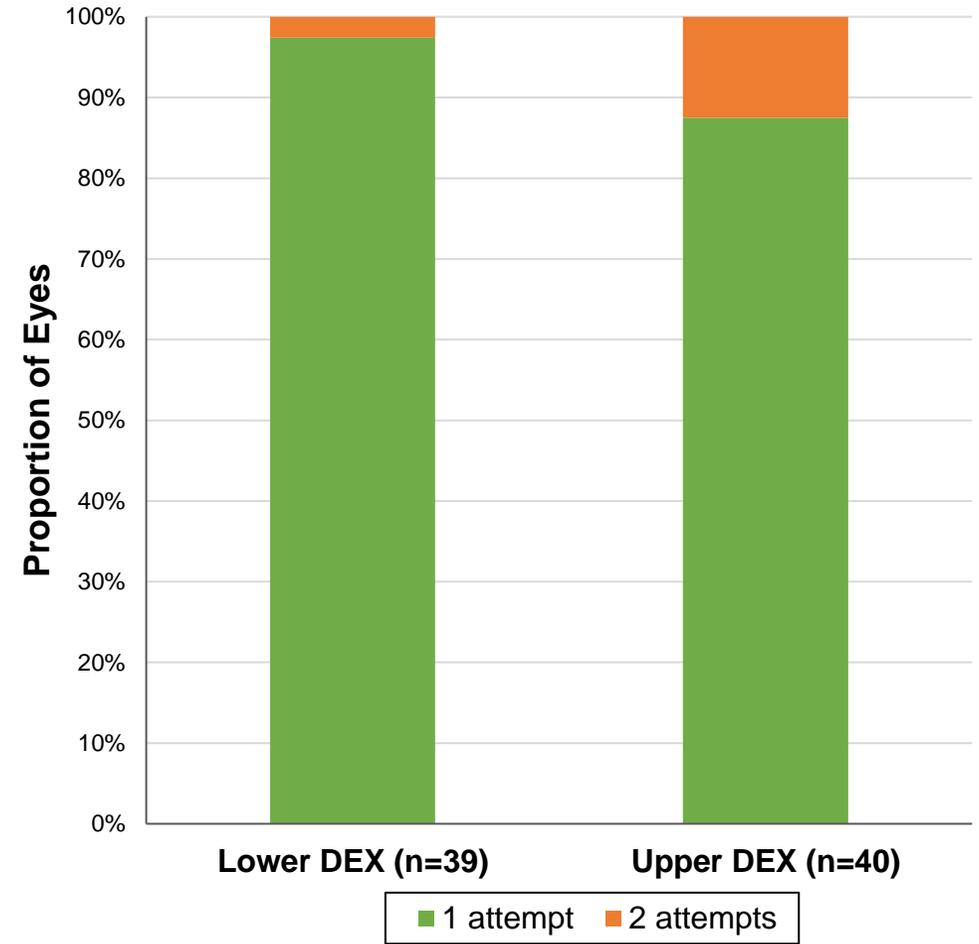
*One patient in the LOWER group experienced corneal edema at Day 30. The adverse event was considered unrelated to DEX

Majority of Insertions (~90%) in Upper and Lower DEX Groups were Rated Easy and Achieved in One Attempt

Ease of Insertion



Attempts to Achieve Successful Insertion



Upper DEX Insertion Safety Profile Similar to Lower DEX Insertion

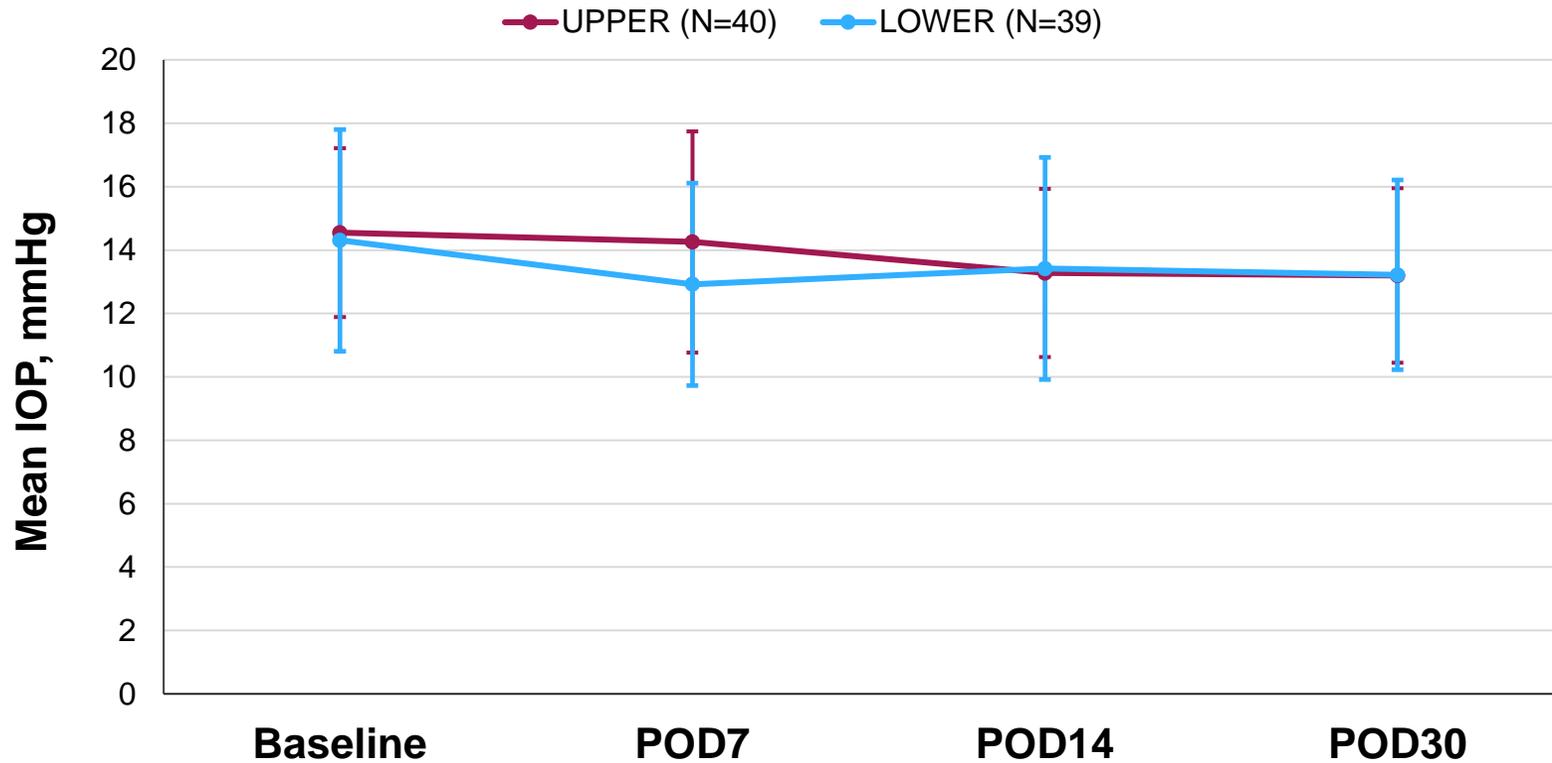
- All reported ocular adverse events were mild or moderate in severity
- One increased IOP event (7 mmHg increase from baseline) was reported in the Upper DEX Insertion group which was attributed to the cataract surgery procedure and deemed unrelated to the DEX insert
- One treatment-related AE was reported: Insert Fell Out in the Lower DEX Insertion group

	Lower DEX Insertion (N=39 eyes)	Upper DEX Insertion (N=40 eyes)
Ocular Adverse Events (AEs), n (%)	4 (10.3%)	4 (10.0%)
Increased IOP	0 (0.0%)	1 (2.5%)
CME	1 (2.6%)	1 (2.5%)
Blurred Vision	0 (0.0%)	1 (2.5%)
Anterior Chamber Inflammation	1 (2.6%)	1 (2.5%)
Corneal Edema	1 (2.6%)	0 (0.0%)
Insert Fell Out	1 (2.6%)	0 (0.0%)
Ocular AEs by Maximum Severity, n (%)		
Mild	3 (7.7%)	2 (5.0%)
Moderate	1 (2.6%)	2 (5.0%)
Severe	0 (0.0%)	0 (0.0%)
Serious AE, n (%)	0 (0.0%)	0 (0.0%)

AE=adverse event; CME=cystoid macular edema; IOP=intraocular pressure

No Clinically Significant Changes in Mean IOP Observed in Either DEX Upper or Lower Insertion Groups

Mean Intraocular Pressure in Upper DEX and Lower DEX Groups



Conclusions

- Upper DEX insertion demonstrated reduction in postop ocular inflammation and pain outcomes comparable to lower DEX insertion for up to 30 days
- Upper DEX insertion was generally well tolerated with no serious or severe ocular AEs reported and no clinically significant differences in mean IOP compared to lower DEX insertion.
- Ease of insertion and attempts to insert DEX successfully were similar between upper- and lower-canalculus insertion groups
- Our data provide evidence for clinicians to decide which punctum to insert DEX in based on the patient's specific needs and/or conditions.