

Clinical Experience with the SCS Microinjector™ for Suprachoroidal Injections by Ophthalmologists



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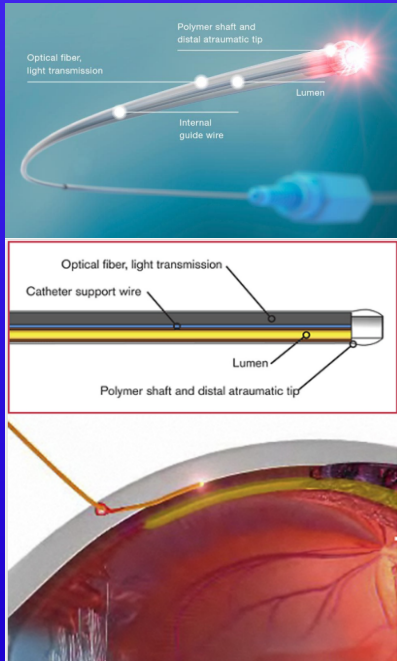
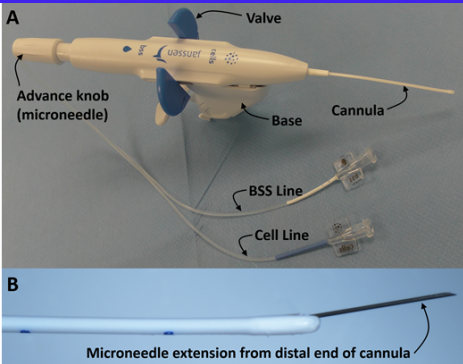
Pertinent Financial Disclosures

- Milan Shah, MD
 - Research funding (Clearside Biomedical)

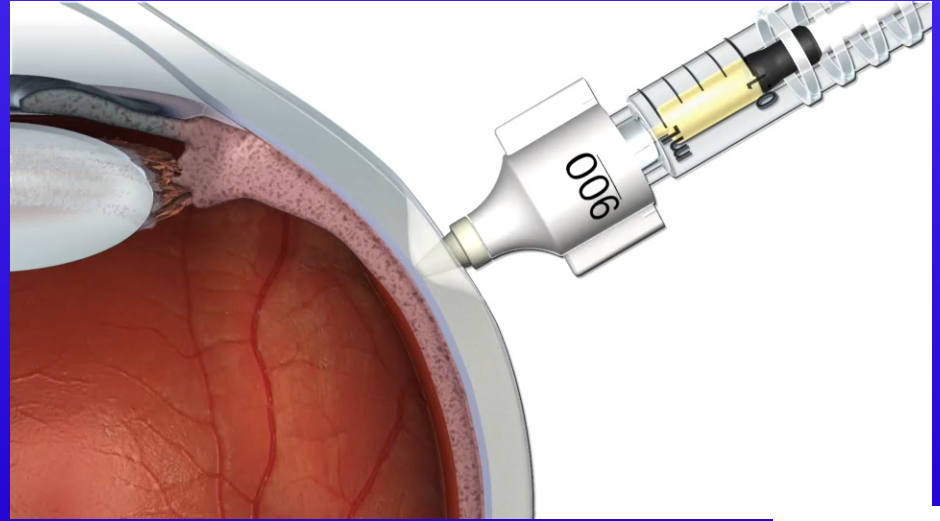


Suprachoroidal Space (SCS)

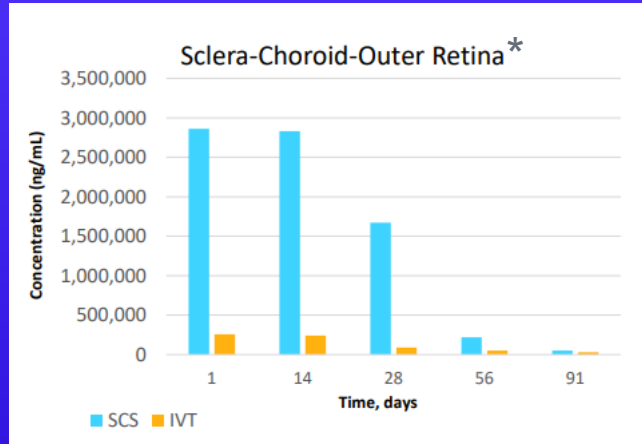
Historically-approached via
cannulation in the OR



SCS Microinjector™
in the office

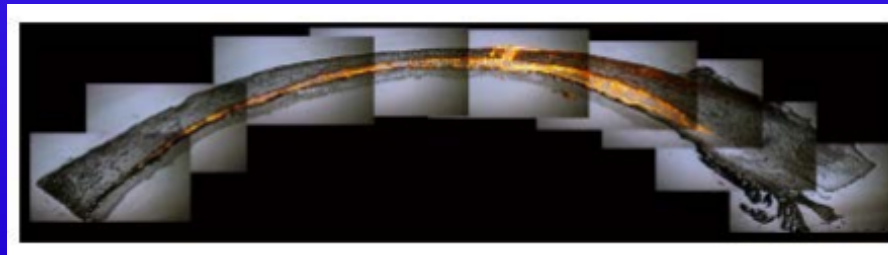


Suprachoroidal Space (SCS): Targeted Delivery



Efficacy

- Over 10x drug in choroid and RPE with SCS[®] injection, compared to IVT
- A potentially useful ocular distribution of drug to target posterior segment pathologies



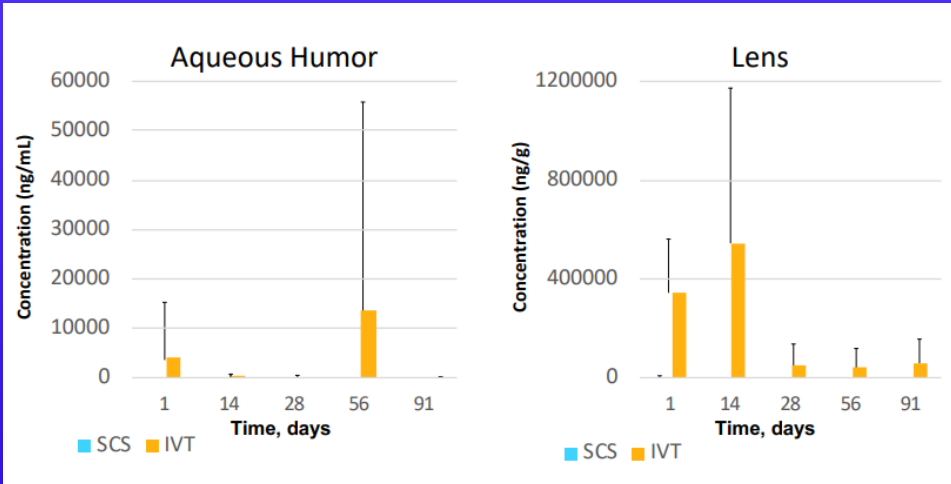
SC Injection of Fluorescent Particles
Posterior Spread

* Based on preclinical study conducted at Clearside

Kurup et al. 2016

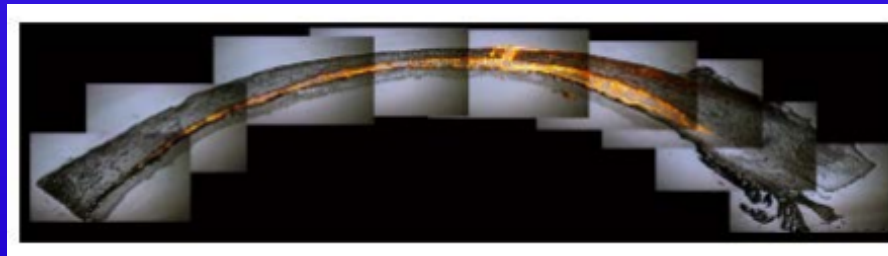


Suprachoroidal Space (SCS): Targeted Delivery



Safety

- Lower exposure to the anterior segment for SCS injection, compared to IVT



SC Injection of Fluorescent Particles
Posterior Spread

* Based on preclinical study
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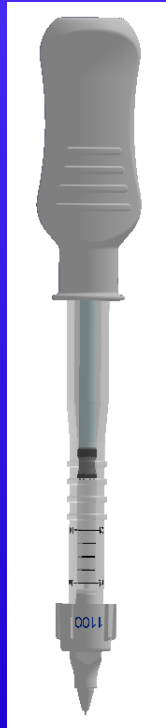
Kurup et al. 2016



Suprachoroidal Injections with Novel SCS Microinjector™

Injection Tool

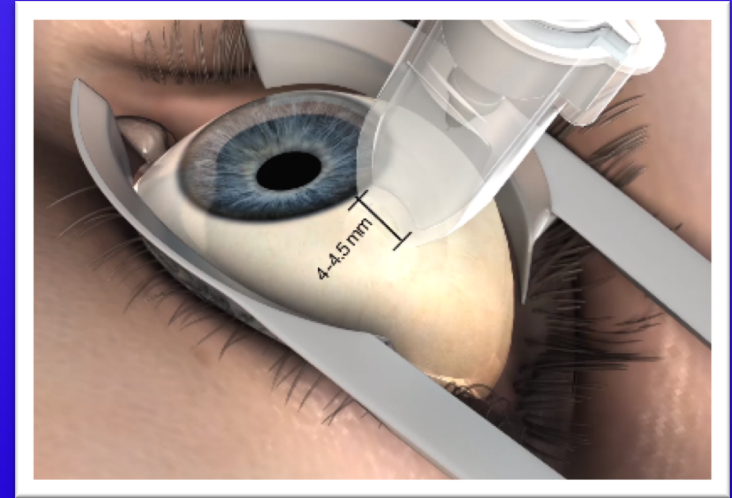
SCS Microinjector



Two needle lengths for
anatomic variability

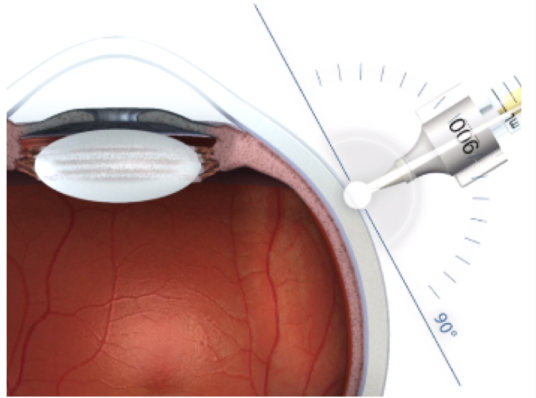
Injection Location

4-5 mm post-limbus
ST quadrant

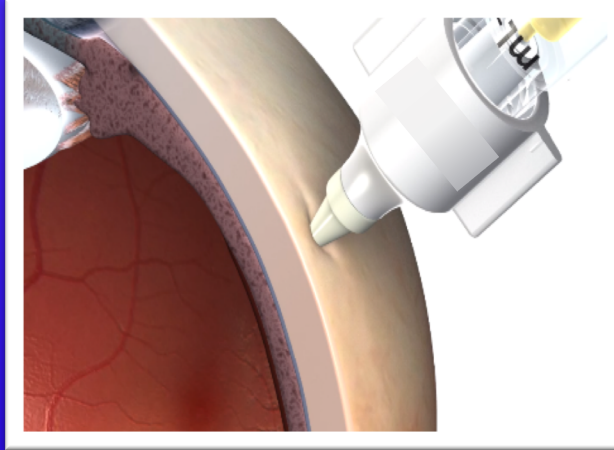


Suprachoroidal Injections with Novel SCS Microinjector™

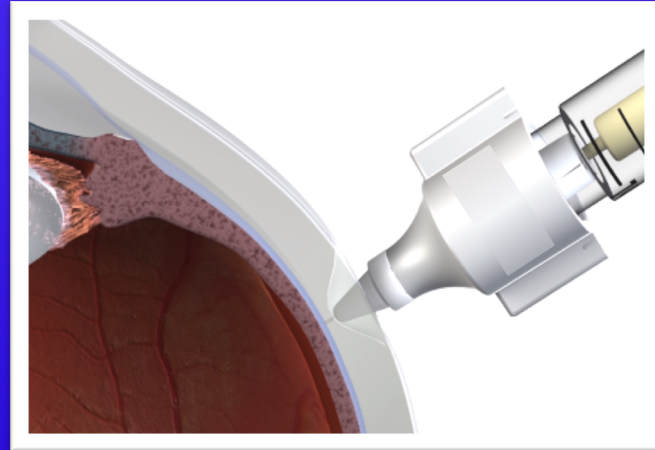
Perpendicularity



Dimple



Inject Slowly



Study Objective and Methods

- **Objective**
 - to describe clinical experience for SC injection with the SCS Microinjector
 - evaluate usage frequency of the two needle lengths (900 and 1100 μm)
- **Methods**
 - Post-hoc analysis of two clinical trials for treatment of non-infectious uveitis¹
 - 252 injections; 134 subjects
 - 2 SC injections of CLS-TA per subject at Day 0 and Week 12
 - Standardized training prior to injections
 - Survey of injection experience



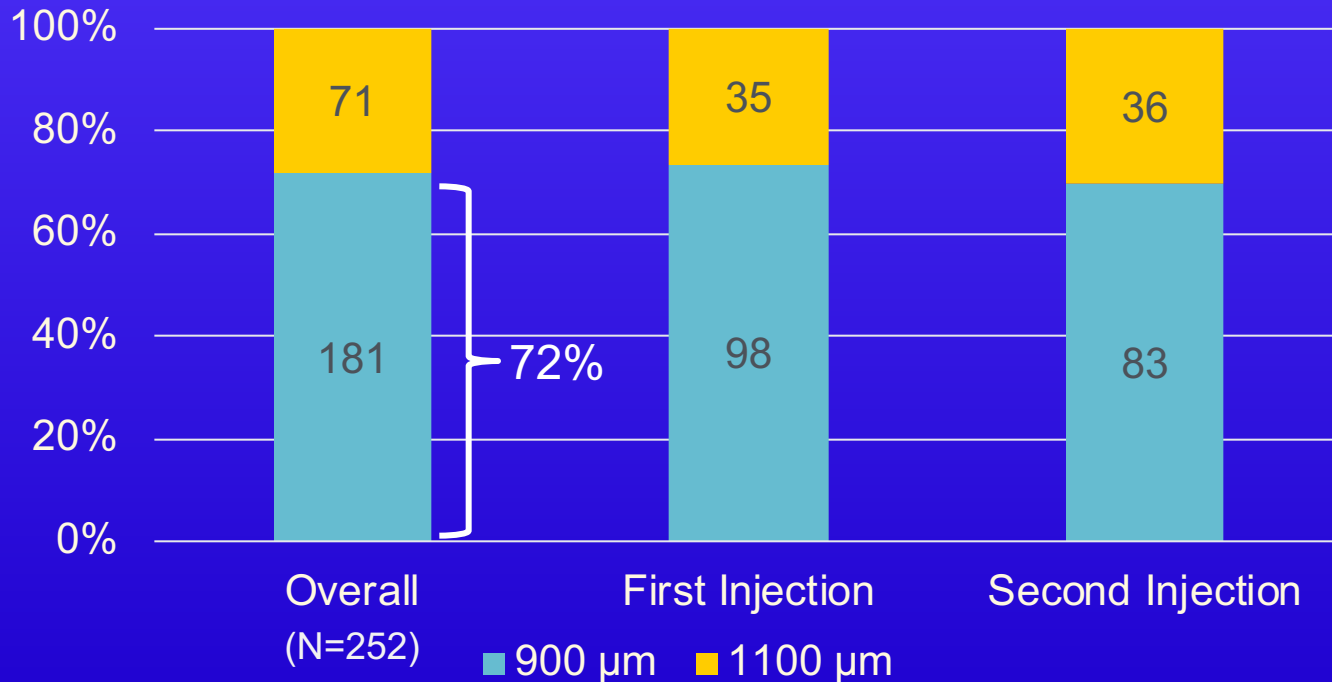
Outcome Measures – Needle Usage Frequencies

- Primary Outcome Measures
 - % injection with 900 μm needle;
 - % injection with 1100 μm needle (requiring switch)
- Additional Measures
 - Needle length **consistency** between injections per patient;
 - Needle use relative to **injection quadrant**;
 - Needle use relative to **uveitis subtype**;
 - Needle use relative to various **uveitis disease state**
- Clinical injection experience survey



Injection Usage Frequency with 900 μ m vs 1100 μ m Needle

Needle Usage Breakdown

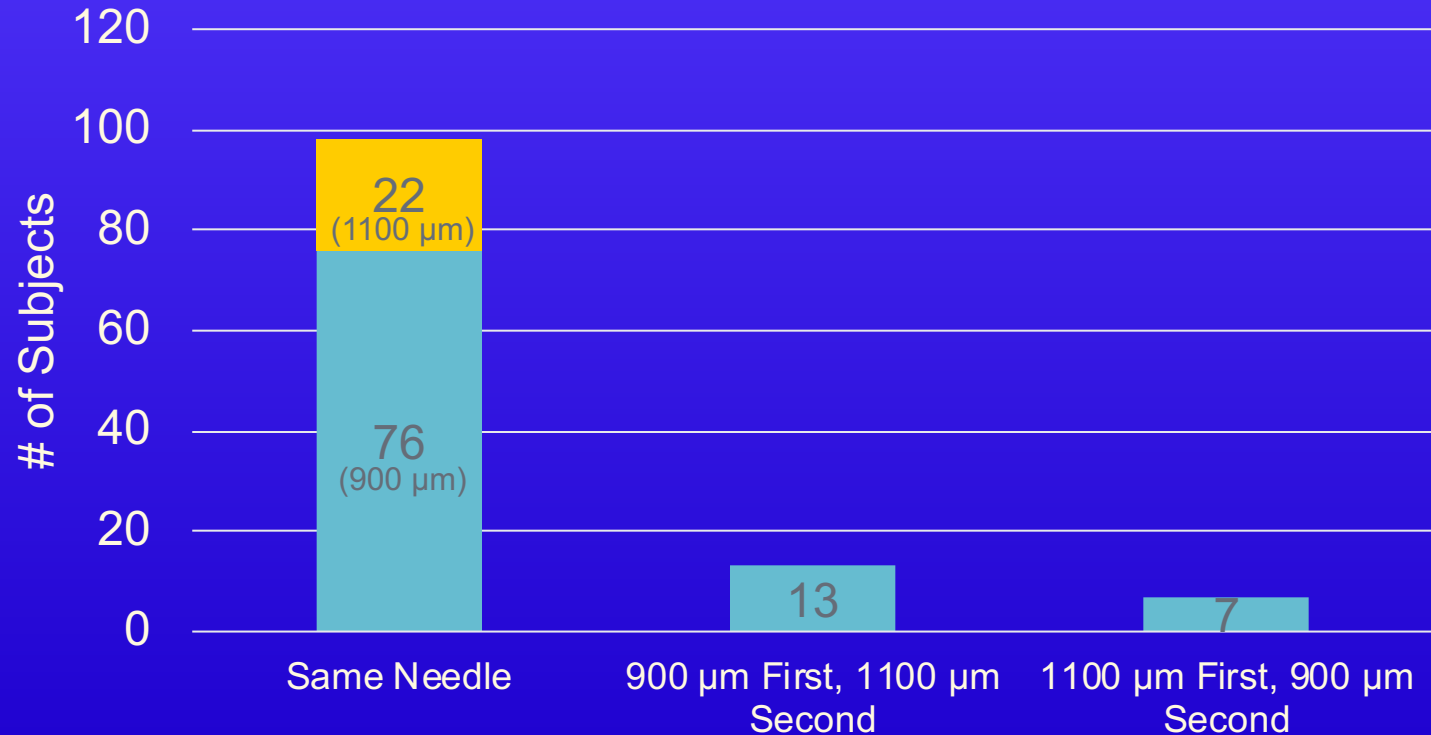


*No statistical difference among the three groups

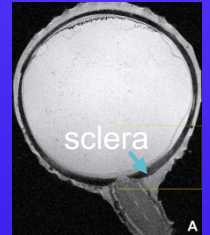
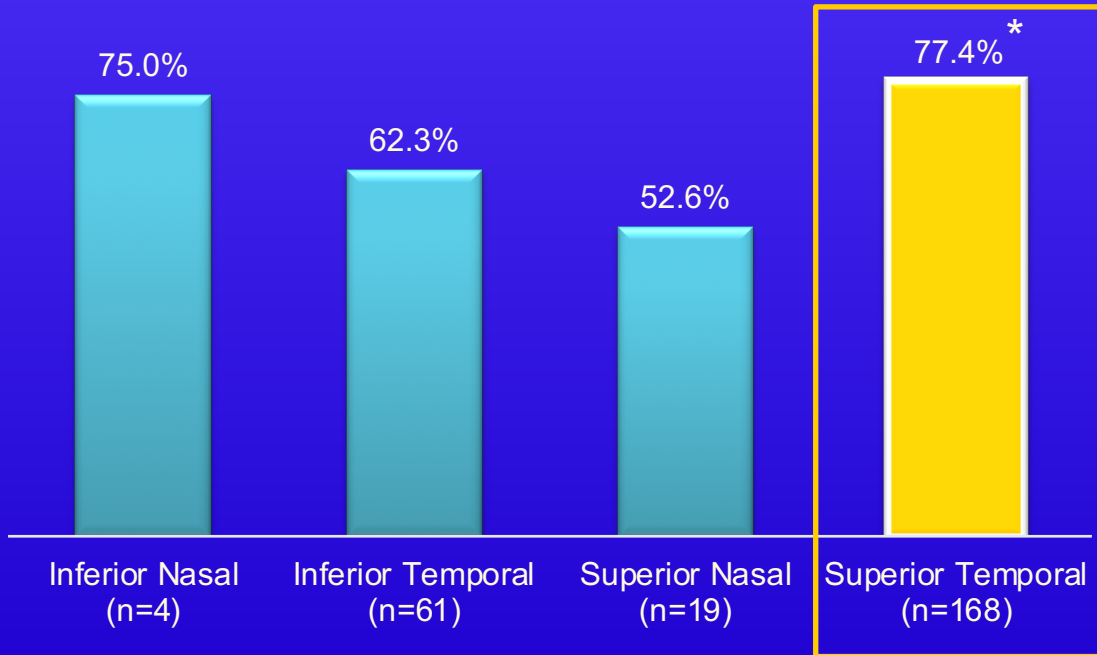


83% Subjects Injected with Same Length Needle for Both Injections

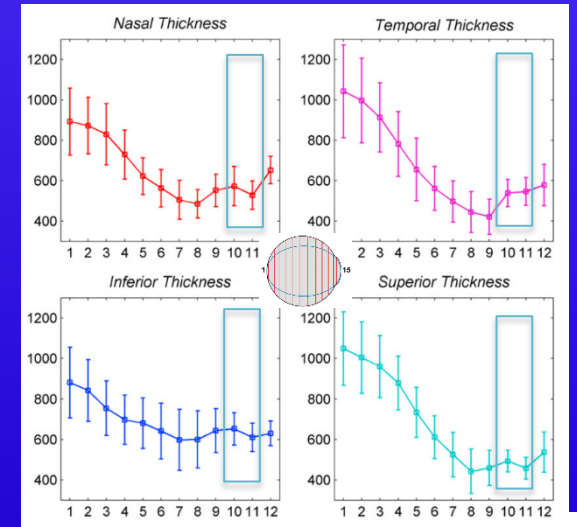
Inter-Injection Needle Length Variability



Usage Frequency of 900 μm Needle by Quadrant



MicroMRI revealed variations in scleral quadrant thickness ◊

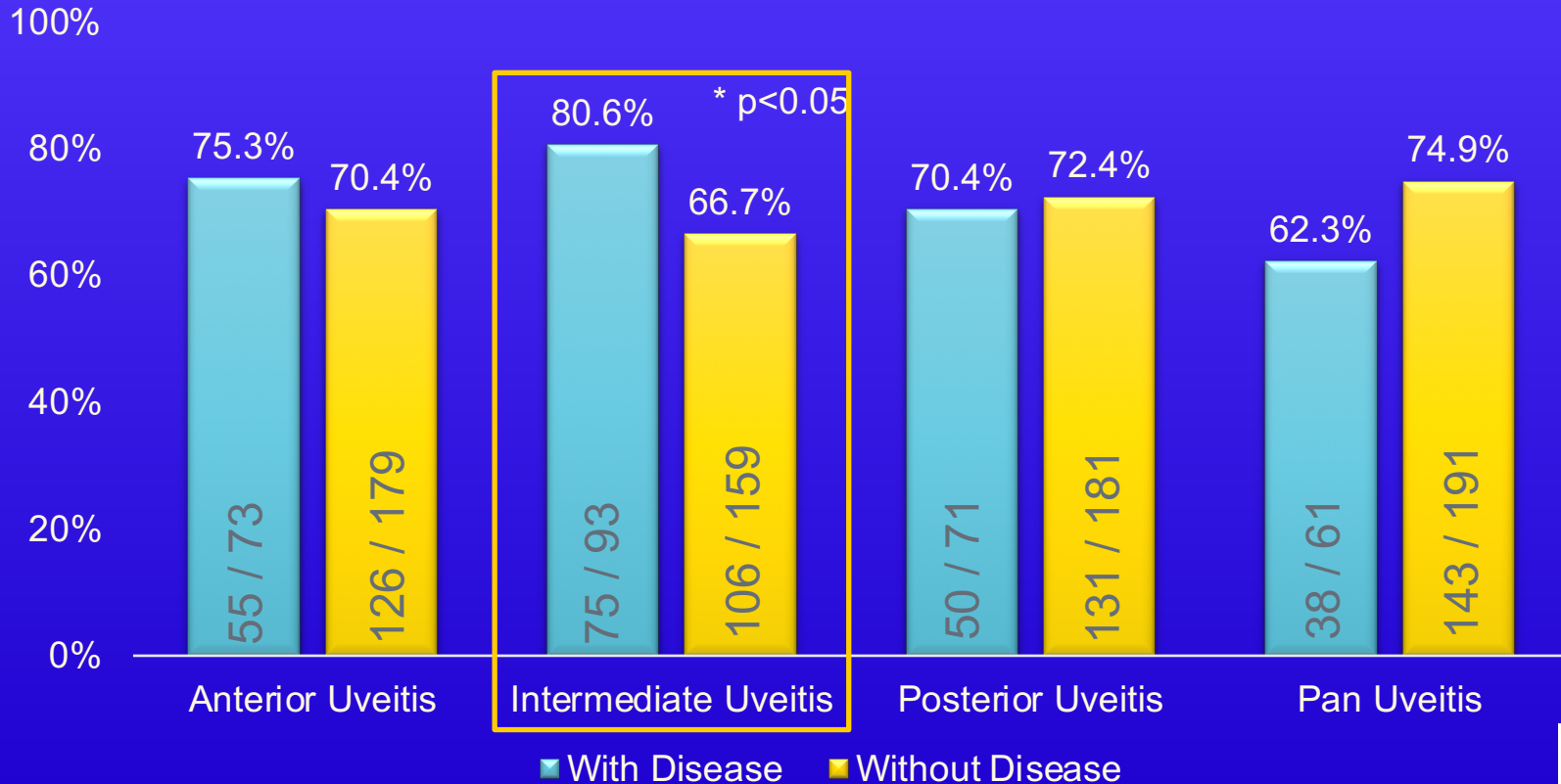


* $p < 0.05$

◊ Norman et al. 2010



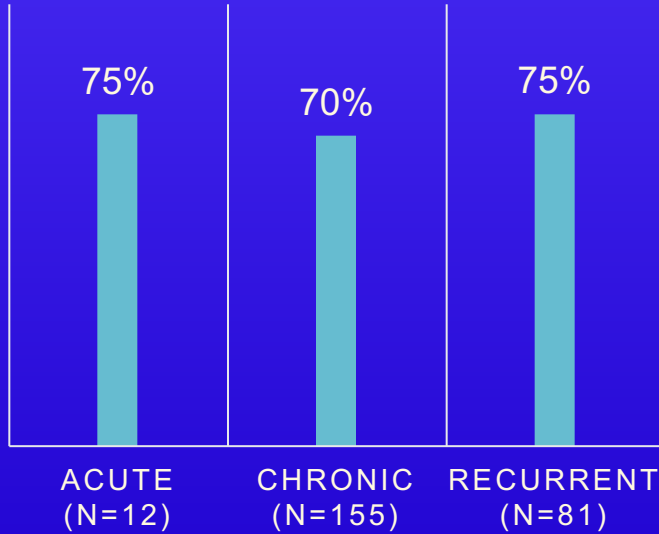
Usage Frequency of 900 μm Needle by Uveitis Subtypes



Needle Usage Frequency by Disease Variation Subtypes

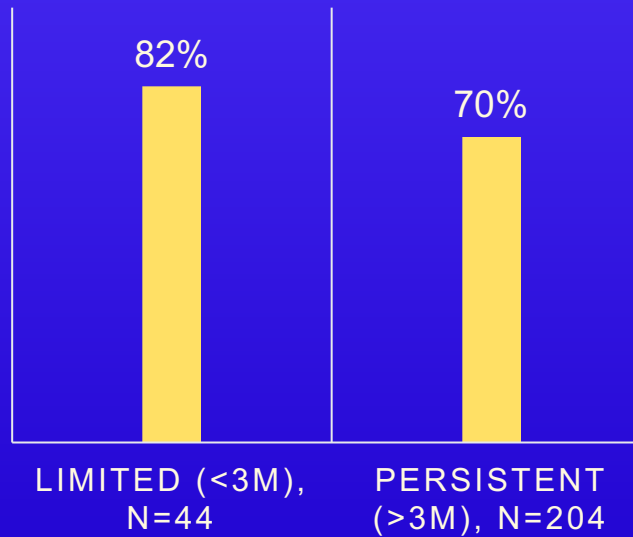
900 μ m Needle Injection

DISEASE COURSE



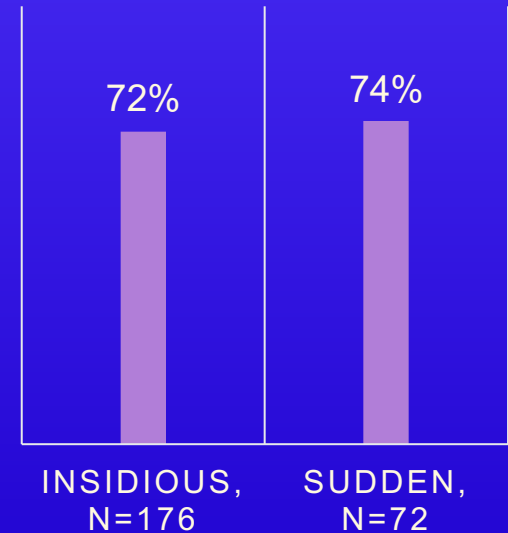
p=0.70

DISEASE DURATION



p=0.10

DISEASE ONSET

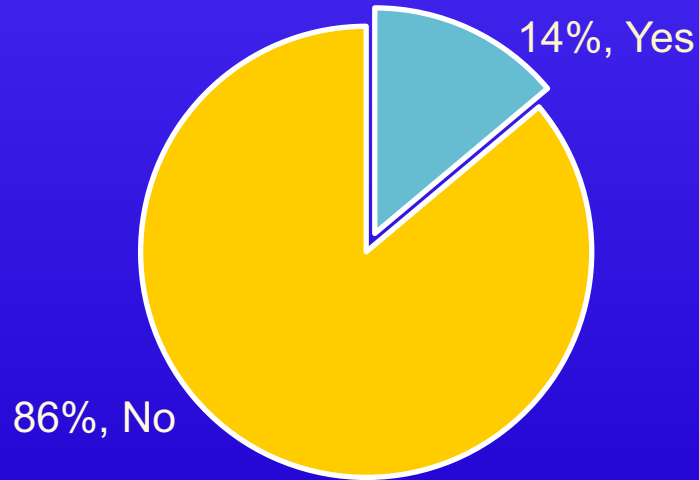


p=0.75

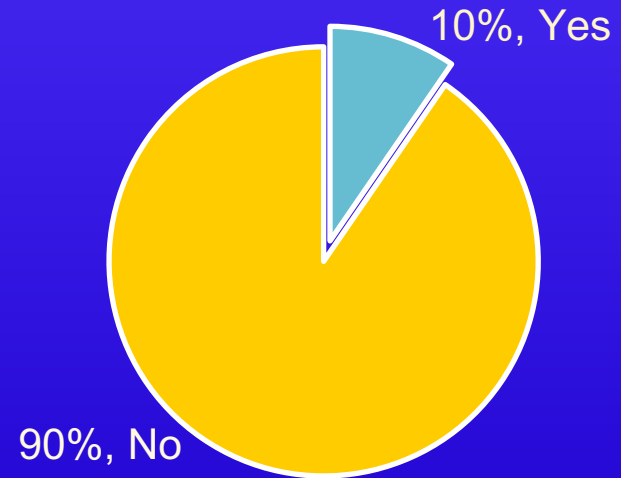


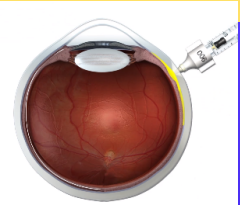
Survey Revealed Little Difficulty in Performing SC injections

Did the SC injection present any new challenges as compared to other ocular injections? (n=73)



Did you have difficulty with any of the steps in the procedure? (n=73)





Take Home Points

- SCS injections can be easily conducted in the office.
 - Proper techniques is critical.
 - Retinal surgeons got this! 😊
- 72% of injections completed without a needle switch
 - ST quadrant injections required least amount of needle switching
- Survey results show that the SC injection technique is easily learned and adapted in the clinic setting
- Future platform for gene therapy , tumors, etc.



Thank You

