

Post Hoc Analysis of Clinical Suprachoroidal Injection Experience for Non-infectious Uveitis

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The American Society of Retina Specialists

2020 Annual Virtual Meeting

July 24 – 26, 2020

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1. Clearside Biomedical, Inc.

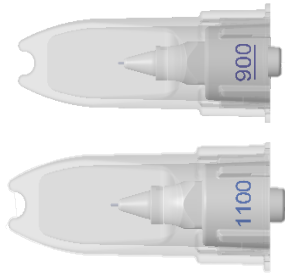
Financial Disclosures

- S Kurup:
 - Allergan (Consultant)
 - Clearside (this talk, no other compensation)
 - Alimera (Consultant)
 - Regeneron (Grant)
 - I CROWD (Consultant)
- C Wan:
 - Clearside Biomedical, Inc.
 - Employee, stockholder
 - Salary, stock, stock options
- B Kapik:
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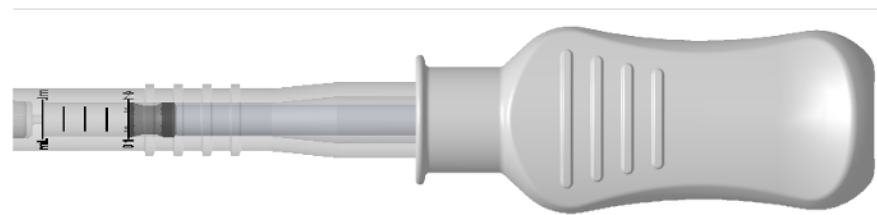
Suprachoroidal Injection (SCI) with microinjector and microneedle

- SCI performed 1,000+ times in clinical trials to date
- Emerging as an effective drug delivery route to the back of the eye
- Two needle lengths included to accommodate variation in patient anatomy

**900 μ m and 1100 μ m Needles
(capped)**



SCS Microinjector[®] Syringe

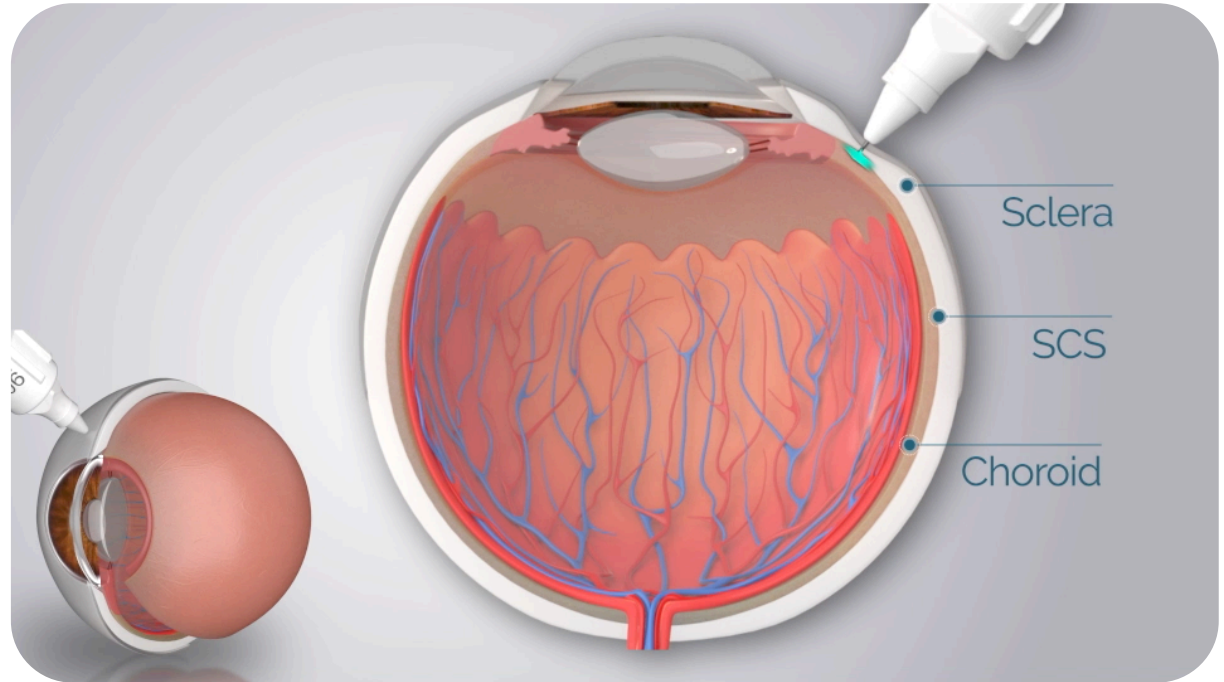


SCI with a Microinjector and microneedle

SCS Microinjector®
Prepared for procedure

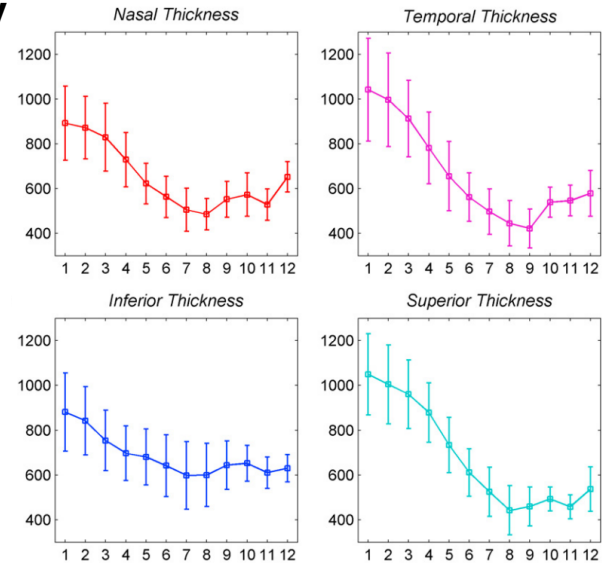
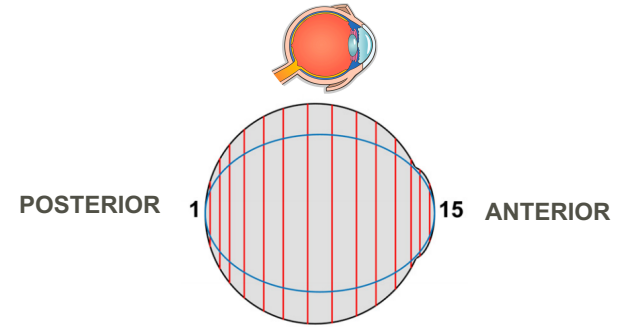
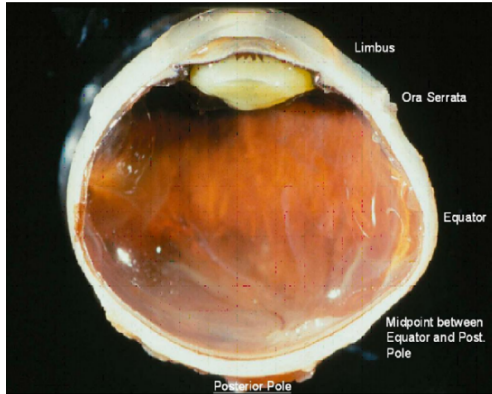


Free length of
900 μm or 1100 μm



Scleral Thickness

- Sclera is **thickest posteriorly** and **thinnest equatorially**
- **Inferior quadrant appears thicker** than other quadrants
- Scleral thickness is relatively **consistent circumferentially** in the pars plana region



Norman et al. "Dimensions of the human sclera: Thickness Measurement and Regional Changes with Axial Length" *Exp. Eye Res*, 2010
 Taban M, Lowder CY, Ventura AA, et al. Scleral thickness following fluocinolone acetonide implant (Retisert). *Ocul Immunol Inflamm*. 2010;18(4):305-313.
 doi:10.3109/09273941003658292

Methods

- Retrospective evaluation of correlation between usage of 900 μm / 1100 μm needle in SCIs and demographics and ocular characteristic data
 - Included baseline injections to minimize experience bias
 - Included SCIs where the investigator determined CLS-TA was administered
- Two non-infectious uveitis trials: PEACHTREE and AZALEA
- A user experience survey was completed to evaluate the injection experience in one trial.

Results

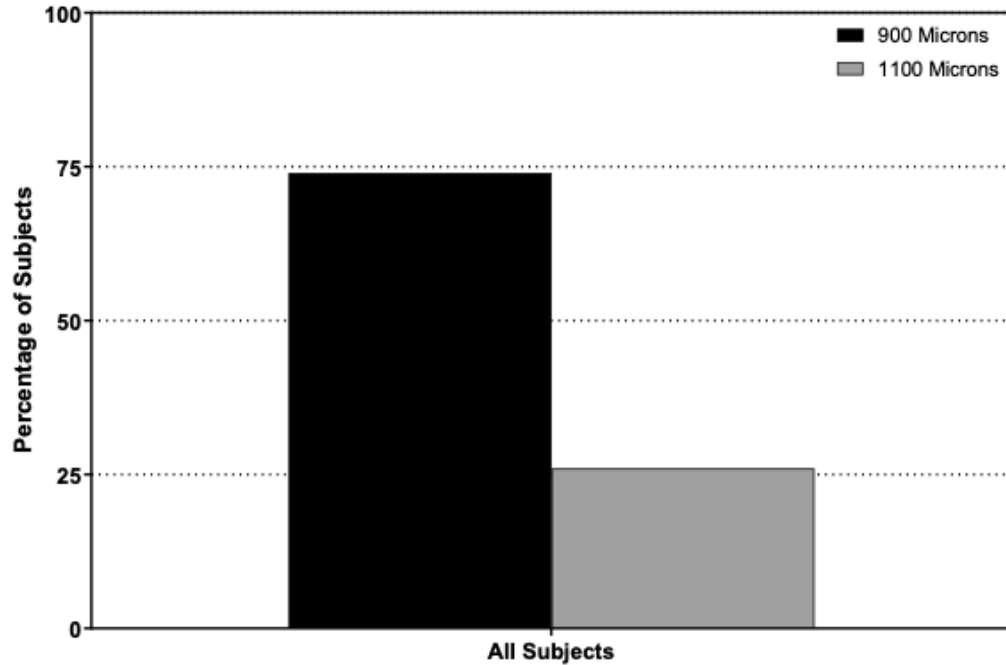
- Baseline SCIs in 133 total patients in PEACTHREE and AZALEA
 - 74% were completed with the 900 μm needle

Demographic & ocular characteristics grouped by correlation to needle length used

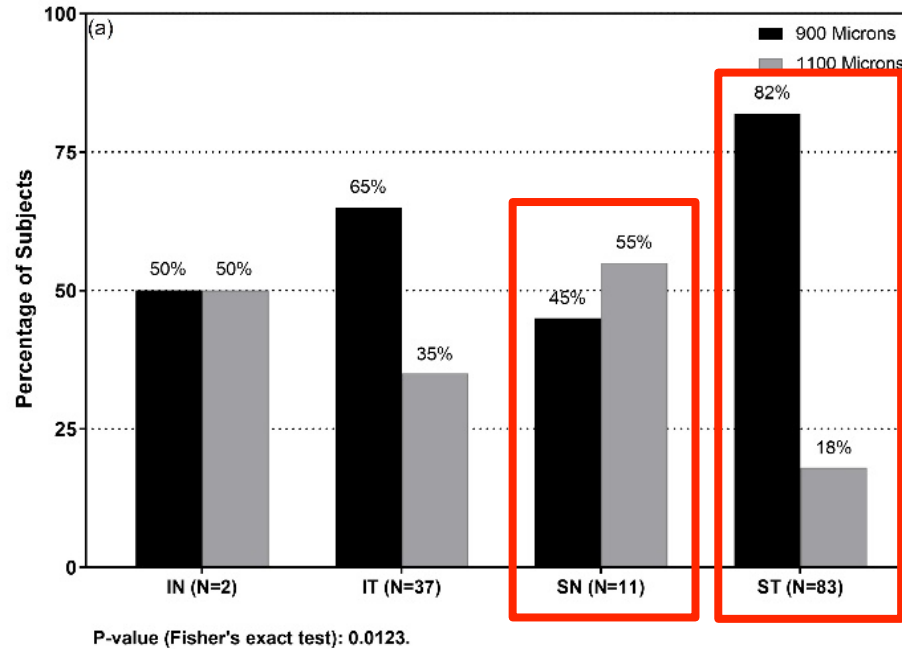
CORRELATION		
Significant $p < 0.001$ ¹	Moderate $p < 0.05$ ¹	None $p \geq 0.05$ ¹
Disease duration	Administration quadrant Age	Gender Lens status Uveitis location Disease course Disease onset

¹. Without Bonferroni correction

74% of 133 total baseline injections were completed with the 900 μm needle

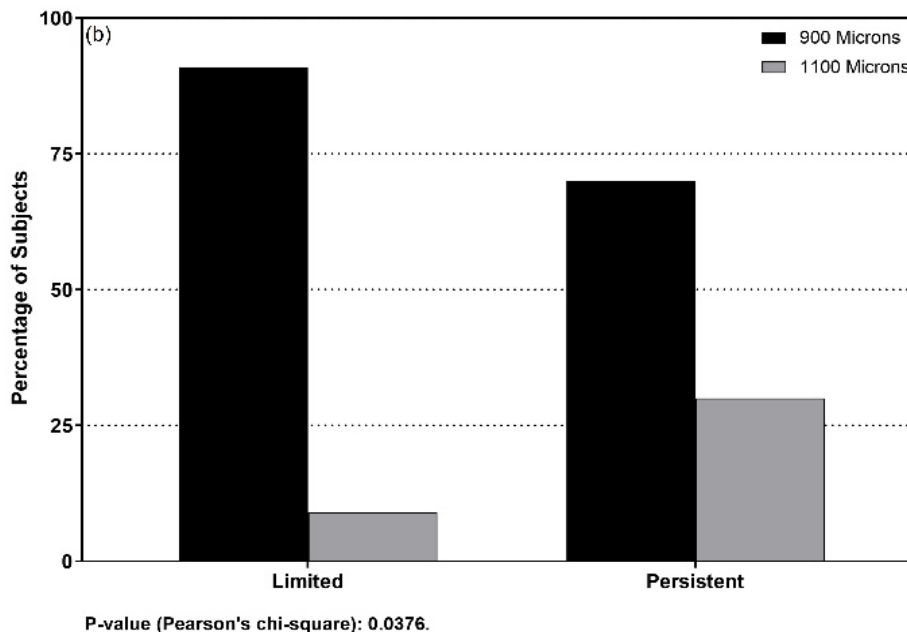


Administration quadrant was statistically related to needle usage



82% of injections administered superotemporally were completed with the 900 μm needle compared to 45% of injections administered superonasally

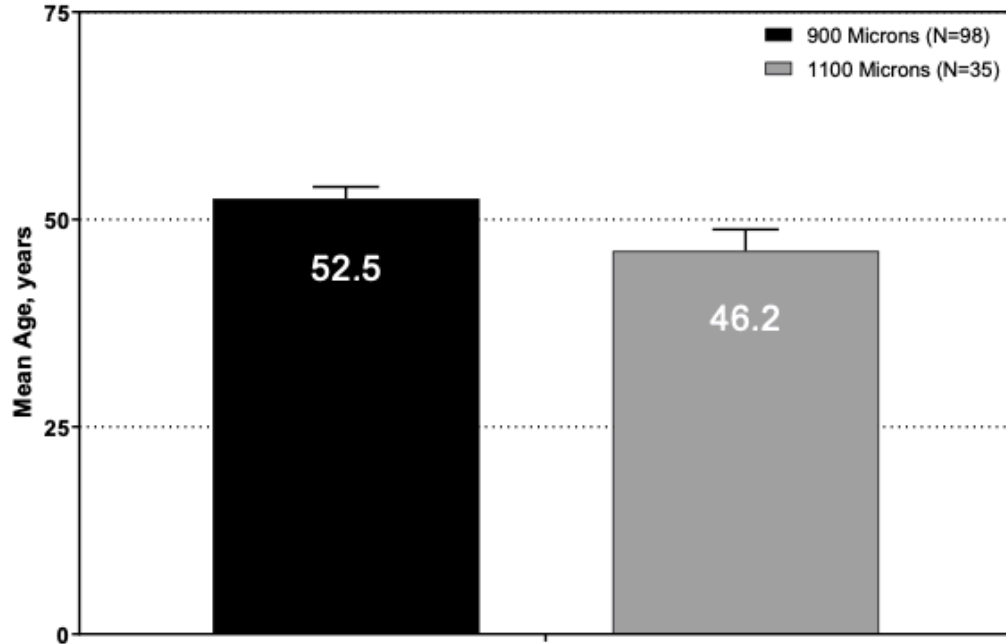
Disease duration statistically correlated with needle length



Limited: ≤ 3 months duration
Persistent: > 3 months duration

91% of injections were completed with the 900μm needle for Limited (≤ 3 months) and 70% for Persistent (> 3 months)

Age moderately correlated with needle length



A mean age of difference of approximately 6 years in patients who required use of the 1100 μm needle

No statistical relationship between needle length and

- gender
- lens status
- uveitis location
- disease course
- disease onset

User experience survey

- Over 80% of the physicians responded that SCIs presented no new challenges compared to other types of injections.

Conclusion

- Overall, the two needles provided in the kit accommodated patient ocular anatomic and demographic variation
- SCIs showed consistency across demographics and ocular characteristics
- Small correlations exist between needle length used and age, injection quadrant, disease duration
 - ST injection quadrants correlations are particularly consistent with previously reported anatomic variation by quadrant

Note: These correlations should not be used to inform clinical decisions