Post Hoc Analysis of Clinical Suprachoroidal Injection Experience Across Retinal Disease Indications

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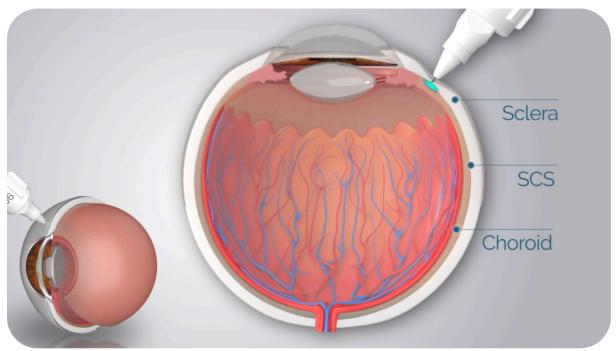


Financial Disclosures

- CH: Clearside Biomedical (C), Bausch and Lomb (C)
- CW: Clearside Biomedical (E, I)
- BK: Clearside Biomedical (E, I)

Suprachoroidal Injection (SCI) with the SCS Microinjector®





Suprachoroidal Injection (SCI) with the SCS Microinjector®

- SCI performed 1,000+ times in clinical trials to date
- Two needle lengths included to accommodate variation in patient anatomy when starting with 900 µm needle



Methods

- Data acquired from 6 prospective controlled trials across 3 disease states:
 - Noninfectious Uveitis (AZALEA, PEACHTREE)
 - Diabetic Macular Edema (TYBEE)
 - Retinal Vein Occlusion (TANZANITE, SAPPHIRE, TOPAZ)
- Post-hoc evaluation of correlation between needle usage, 900 μm vs 1100 μm, in SCIs and demographics and ocular characteristic data
 - Included <u>baseline</u> injections to minimize experience bias
 - Included SCIs where the investigator determined CLS-TA was administered

Results

- Suprachoroidal injections were performed in 133, 36, and 412 patients with NIU, DME, and RVO, respectively
- Across these trials, in response to the prompt: "Was the suprachoroidal injection administered?" 98.1% of injecting physicians reported "Yes"

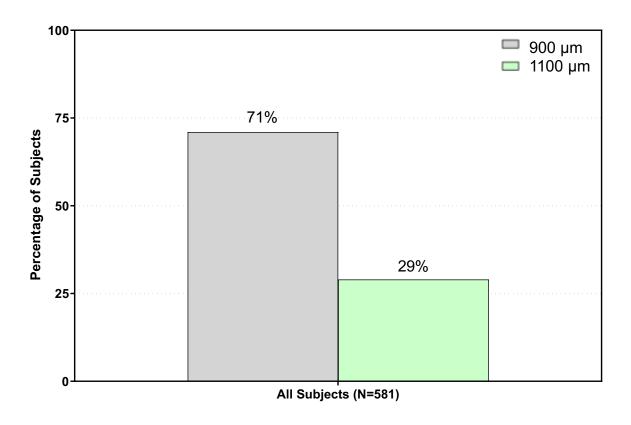
Demographic & ocular characteristics grouped by correlation to needle length used

CORRELATION		
Significant p<0.001 ¹	Moderate p<0.01 ¹	None <i>p</i> ≥0.01 ¹
Administration quadrant	Gender ²	Disease indication Visual acuity Intraocular pressure Retinal central subfield thickness Lens status Age Race

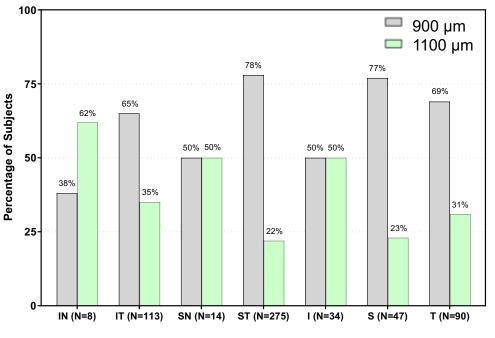
Without Bonferroni correction

^{2.} The variations by gender could be confounded by other factors, such as height or weight differences between male and female study subjects, which were not assessed.

Overall, 71% of Baseline SCIs Completed with the 900 µm Needle



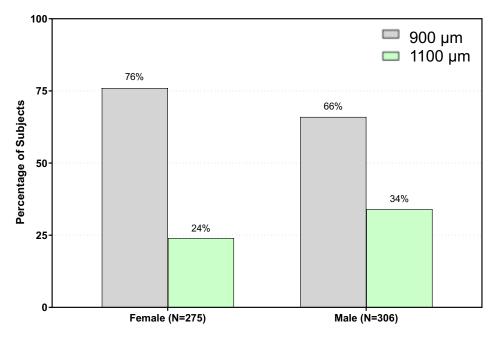
Administration quadrant correlated with needle length used



P-value (Pearson's chi-square): 0.0005.

The variations in administration quadrant corroborates literature reports of thinner sclera in the superior hemisphere, compared to the inferior hemisphere, at the level of the pars plana

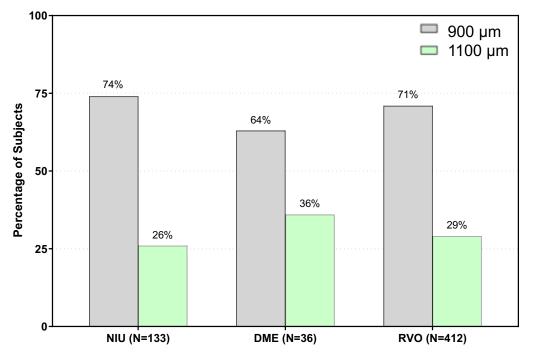
Gender moderately correlated with needle length used



P-value (Pearson chi-square): 0.0061.

The variations by gender could be confounded by other factors, such as height or weight differences between male and female study subjects, which were not assessed.

Disease indication did not correlate with needle length used



P-value (Pearson's chi-square): 0.5035.

64 – 74% of injections were completed with the 900 μm needle for NIU, DME, and RVO indications

Conclusion

- To date, this is the largest aggregate dataset of clinical SCI with mounting evidence pointing to the reliability and consistency of the procedure.
- The two needle length options successfully accommodate for anatomical variations across patients and retinal disease states.
- Correlations were found between needle length and gender and injection quadrant.