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

ASRS 2020 Annual Meeting

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Financial Disclosures

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

C = Consultant; E = Employment; R = Recipient; I = Personal Financial Interest
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 baseline 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

<table>
<thead>
<tr>
<th>CORRELATION</th>
<th>Significant $p&lt;0.001$</th>
<th>Moderate $p&lt;0.01$</th>
<th>None $p\geq0.01$</th>
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</table>
| Administration quadrant | Gender$^2$ | Disease indication  
Visual acuity  
Intraocular pressure  
Retinal central subfield thickness  
Lens status  
Age  
Race |
Overall, 71% of Baseline SCIs Completed with the 900 µm Needle
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

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

- NIU: 74% (N=133) vs. 26% (N=1100 µm)
- DME: 64% (N=36) vs. 36% (1100 µm)
- RVO: 71% (N=412) vs. 29% (1100 µm)

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.

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