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

Milan Shah, M.D.
Midwest Eye Institute
Indianapolis, IN

Cherry Wan, Ph.D.
Clearside Biomedical
Alpharetta, GA
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

https://www.ellex.com/products/ittrack/
De Smet et al. 2018
Peden et al. 2011
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

* Based on preclinical study conducted at Clearside
Kurup et al. 2016

SC Injection of Fluorescent Particles
Posterior Spread
Suprachoroidal Space (SCS): Targeted Delivery

Safety

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

Based on preclinical study conducted at Clearside
Kurup et al. 2016
Suprachoroidal Injections with Novel SCS Microinjector™

**Injection Tool**
SCS Microinjector

**Injection Location**
4-5 mm post-limbus
ST quadrant

Two needle lengths for anatomic variability:
- 900 µm
- 1100 µm
Suprachoroidal Injections with Novel SCS Microinjector™

Perpendicularly

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 uveitis\(^1\)
    - 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

1. Peachtree and Azalea, Clearside Biomedical
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 900µm vs 1100µm Needle

Needle Usage Breakdown

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=252)</th>
<th>First Injection</th>
<th>Second Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>900 µm</td>
<td>181</td>
<td>98</td>
<td>83</td>
</tr>
<tr>
<td>1100 µm</td>
<td>71</td>
<td>35</td>
<td>36</td>
</tr>
</tbody>
</table>

72% of Overall

*No statistical difference among the three groups
83% Subjects Injected with Same Length Needle for Both Injections

Inter-Injection Needle Length Variability

- Same Needle: 76 (900 µm), 22 (1100 µm)
- 900 µm First, 1100 µm Second: 13
- 1100 µm First, 900 µm Second: 7
Usage Frequency of 900 µm Needle by Quadrant

<table>
<thead>
<tr>
<th>Quadrant</th>
<th>Count (n)</th>
<th>Usage Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inferior Nasal</td>
<td>4</td>
<td>75.0%</td>
</tr>
<tr>
<td>Inferior Temporal</td>
<td>61</td>
<td>62.3%</td>
</tr>
<tr>
<td>Superior Nasal</td>
<td>19</td>
<td>52.6%</td>
</tr>
<tr>
<td>Superior Temporal</td>
<td>168</td>
<td>77.4% *</td>
</tr>
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</table>

MicroMRI revealed variations in scleral quadrant thickness.

* p<0.05

◊ Norman et al. 2010
Usage Frequency of 900 μm Needle by Uveitis Subtypes

- Anterior Uveitis: 75.3% (55/73) with disease, 70.4% (126/179) without disease
- Intermediate Uveitis: 80.6% (75/93) with disease, 66.7% (106/159) without disease
- Posterior Uveitis: 70.4% (50/71) with disease, 72.4% (131/181) without disease
- Pan Uveitis: 62.3% (38/61) with disease, 74.9% (143/191) without disease

* p<0.05
### Needle Usage Frequency by Disease Variation Subtypes

**900 \( \mu \text{m} \) Needle Injection**

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<tr>
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<th>DISEASE ONSET</th>
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<tr>
<td>ACUTE (N=12)</td>
<td>LIMITED (&lt;3M), N=44</td>
<td>INSIDIOUS, N=176</td>
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<td>CHRONIC (N=155)</td>
<td>PERSISTENT (&gt;3M), N=204</td>
<td>SUDDEN, N=72</td>
</tr>
<tr>
<td>RECURRENT (N=81)</td>
<td>82%</td>
<td>72%</td>
</tr>
<tr>
<td></td>
<td>70%</td>
<td>74%</td>
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p-values:
- 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)
- 14%, Yes
- 86%, No

Did you have difficulty with any of the steps in the procedure? (n=73)
- 10%, Yes
- 90%, No
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