# Novel Deep Learning Algorithm for Suprachoroidal Space Segmentation and Measurement in Optical Coherence Tomography

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Presentation
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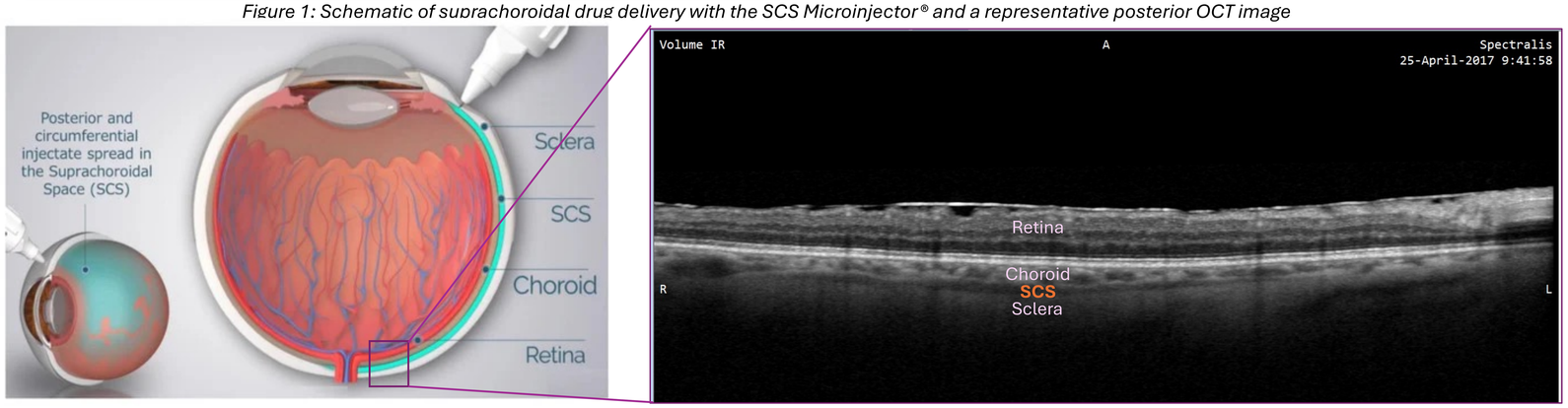
## PURPOSE

- To develop a deep learning model, specifically built for identifying, segmenting and measuring the thickness and area of the suprachoroidal space (SCS), imaged through optical coherence tomography (OCT).
  - **SCS Drug Delivery is becoming increasingly common, with XIPERE® as the first FDA-approved combination product for suprachoroidal administration**

Clearside has developed the first ever machine learning algorithm for imaging the opening of the **Suprachoroidal Space** after drug delivery, for evaluating patient data.

*Figure 1: Schematic of suprachoroidal drug delivery with the SCS Microinjector® and a representative posterior OCT image*




## BACKGROUND

- Suprachoroidal injection delivers drug to the potential space between the sclera and choroid.
- With an approved treatment in the US, Australia and Singapore and multiple clinical trials utilizing the SCS Microinjector to administer therapeutic agents, SCS injection is a proven approach and becoming standardized.
- OCT is a common imaging modality to evaluate the ocular anatomical structures, including the retina and the choroid. Most OCT studies of the posterior segment focus on the retinal tissue and few studies focus on the SCS. (Figure 1).
- Machine learning (ML) with U-Net is a new tool to automatically and rapidly perform image analysis.

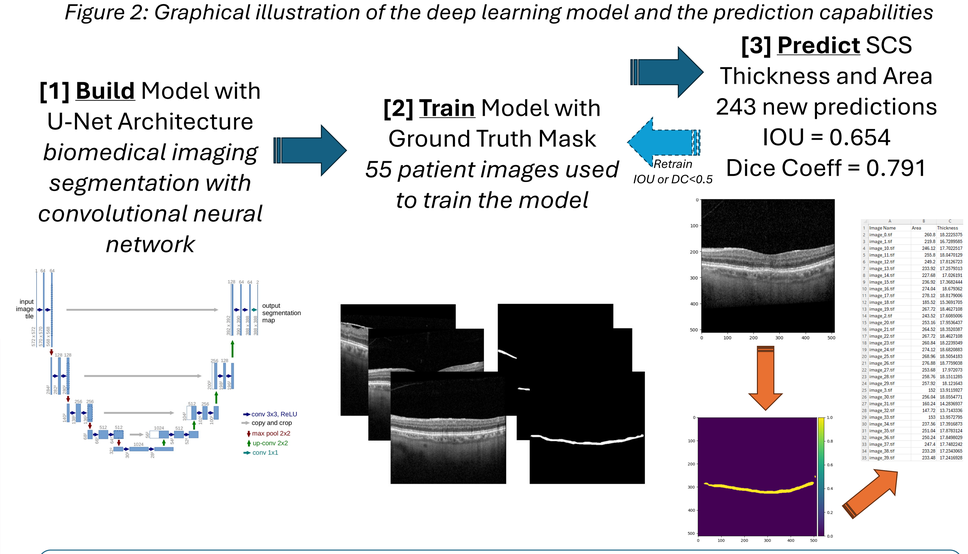
The combination of precise suprachoroidal drug delivery mechanism (such as Clearside's SCS Microinjector®), reproducible high-quality OCT imaging and reliable ML algorithms may hold the key to improved understanding of drug delivery into the SCS, SCS opening dynamics and effects on patient outcomes.

## METHODS

- A U-Net deep learning architecture was constructed in Python for fast and precise segmentation and measurement of the SCS.
- OCT B-scan images from 3 clinical trials with suprachoroidal injections (OASIS, Phase 1/2a, NCT04626128; ODYSSEY, Phase 2, NCT05891548; PEACHTREE, Phase 3, NCT02595398) were obtained. Fifty-five (55) images from Heidelberg Spectralis were included based on image quality in the training model set (Figure 2).
- Ground truth binary mask segmentations were manually produced. The images and their binary masks were utilized to train the U-Net model to detect the SCS and calculate thickness and area.
- Model segmentations were evaluated by measuring the Dice similarity coefficient and Intersection Over Union (IOU) in separate test images.

**Disclosure:** CW and RA are employees of Clearside Biomedical, Inc. *OA was an engineering intern at Clearside Biomedical, Inc. leading the project. She is currently a PhD student at Georgia Institute of Technology

*Figure 2: Graphical illustration of the deep learning model and the prediction capabilities*




## RESULTS

- The algorithm accurately segmented the SCS in 0.515 seconds per image on a standard laptop CPU while achieving a Dice similarity coefficient of 0.791 and Mean IOU of 0.654.
- The algorithm displayed good predictions for 243 new OCT images from clinical trials in 2 different indications (uveitis macular edema and neovascular AMD).
- The segmented SCS thickness and area calculations were similar to those reported in literature.
  - The thickness of the SCS opening was observed to be on the order of 18-20 µm. Some SCS opening was observed at baseline, prior to the suprachoroidal injections.

AI can be used to accurately monitor the suprachoroidal space using standard OCT imaging.

## CONCLUSIONS & DISCUSSIONS

- To our knowledge, this is **the first ML algorithm** specifically targeting the segmentation of the SCS.
- The algorithm accurately segmented the SCS and effectively measured thickness and area of the SCS.
- It provides a reproducible and unbiased platform to characterize drug spread over time and across different drug products with disparate formulation characteristics.
- As OCTs are routinely taken for patients with retinal diseases, this algorithm may also be applied to monitor patients over time.

Other groups developing AI monitoring for OCT should consider including an SCS feature.

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