Treatment response analysis of visual acuity and central subfield retinal thickness following suprachoroidal CLS-TA

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Disclosures: F (Financial Support); I (Personal Financial Interest); E (Employment); C (Consultant); P (Patent); R (Recipient)

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Purpose

❖ To provide model-based evidence of a relationship between CLS-TA treatment and best corrected visual acuity (BCVA).

Methods

❖ Data from two Phase 3 trials, PEACHTREE and AZALEA, evaluating suprachoroidal CLS-TA, a proprietary triamcinolone acetonide injectable suspension for the treatment of uveitis, were used to develop model-based treatment response longitudinal models.

❖ A covariate analysis was conducted to identify clinically relevant and statistically significant intrinsic and extrinsic factors affecting changes in BCVA response to CLS-TA treatment.

❖ Covariates evaluated included race, age, sex, country, baseline BCVA, baseline central subfield retinal thickness (CST) and anatomic location of ocular inflammation.
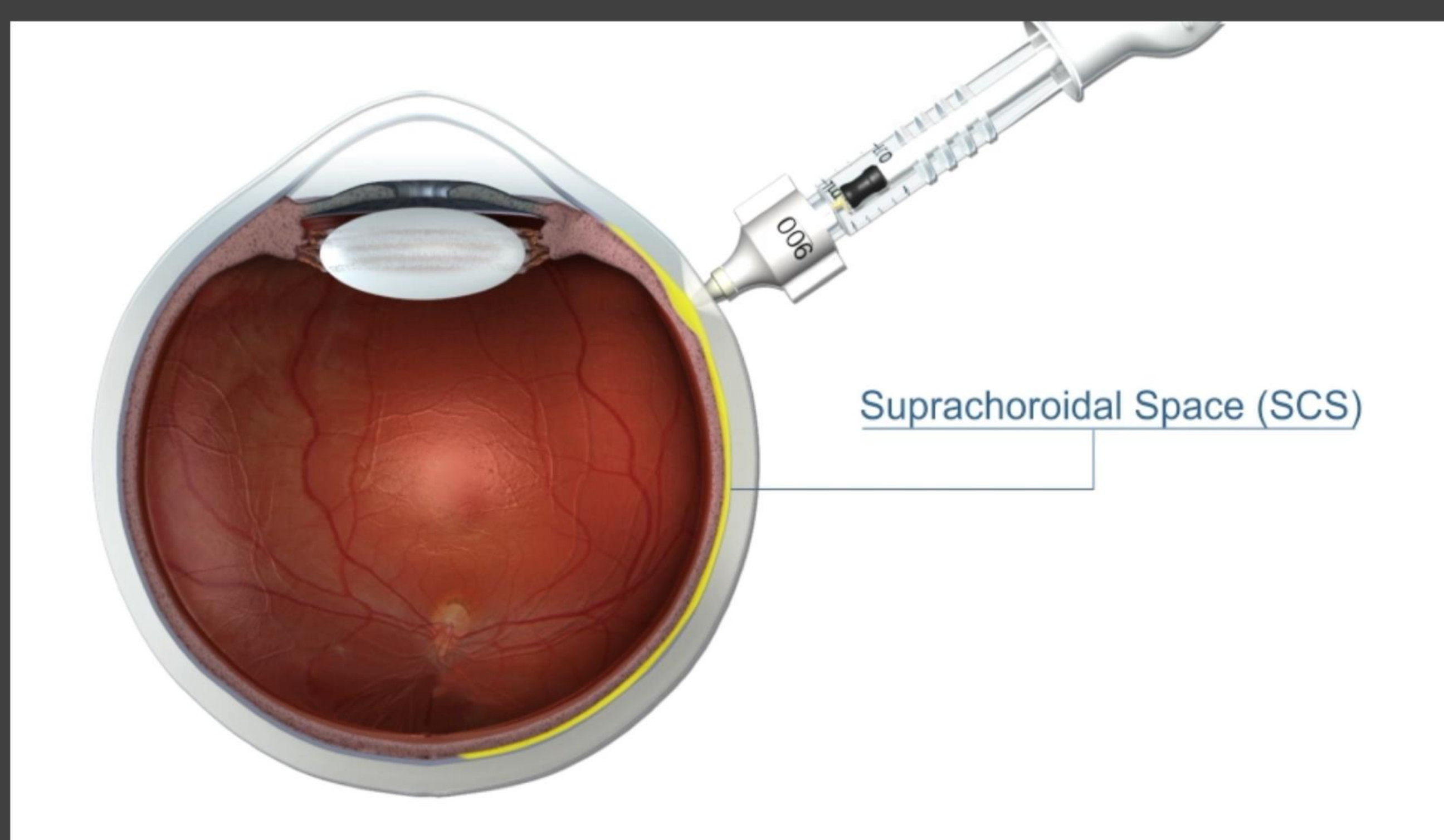

Figure 1: Schematic representation of suprachoroidal CLS-TA delivery

Results

Best Corrected Visual Acuity (BCVA)
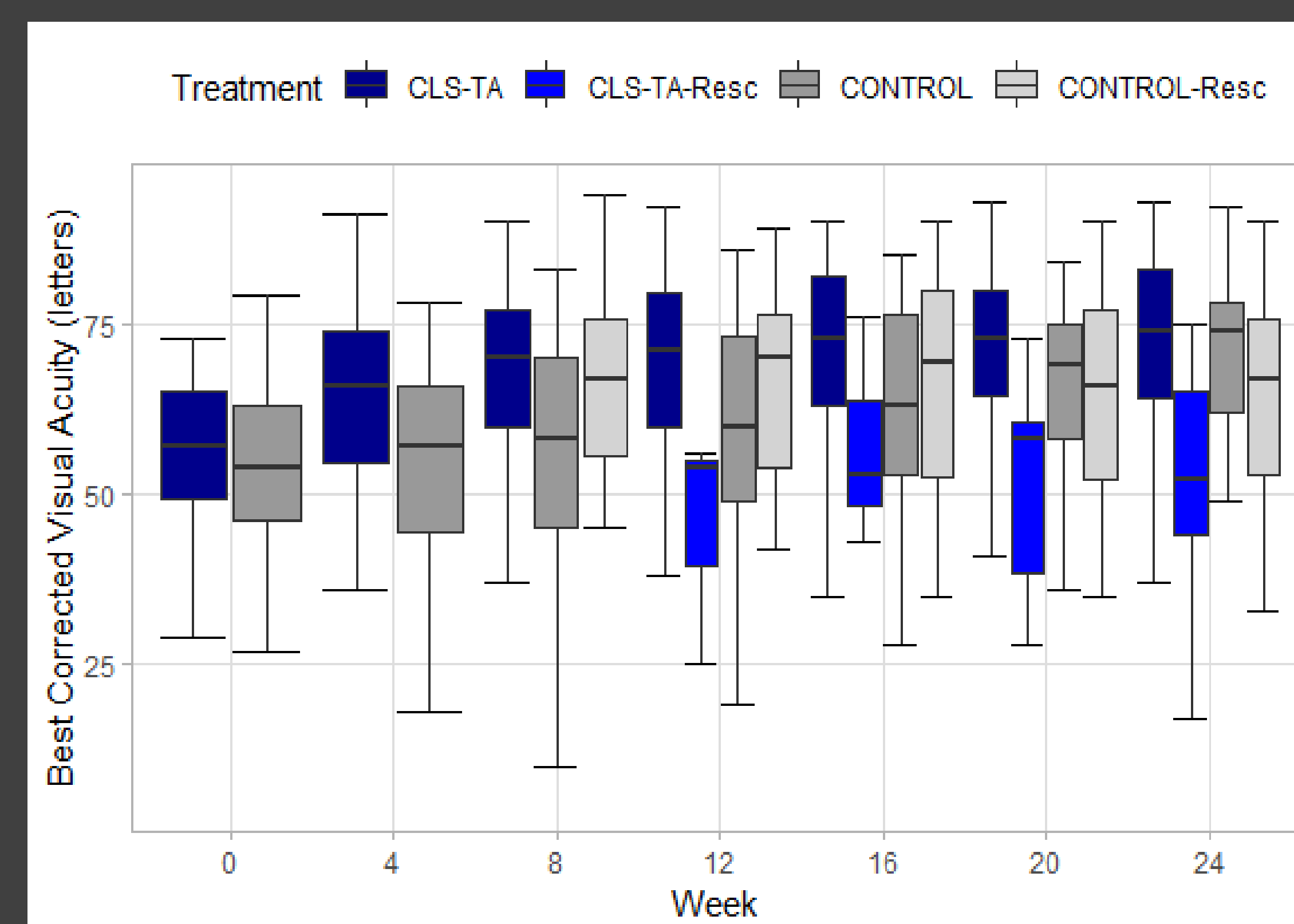### Intent-to-Treat Observed Population

Figure 2: Box plots demonstrating BCVA over time including median BCVA (horizontal line), interquartile range (boxes), 1.5-fold interquartile range (whiskers), and outlier points.
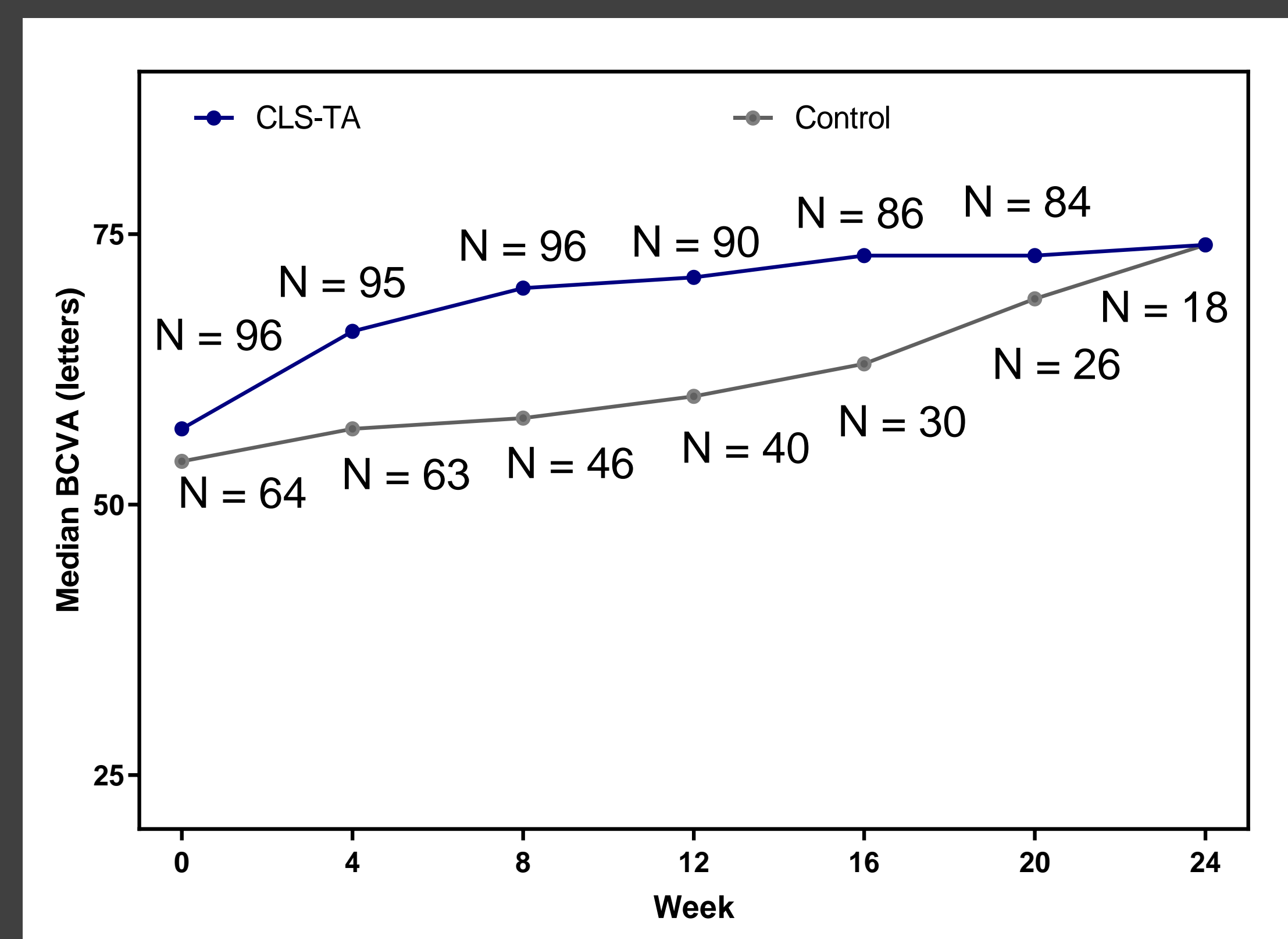

Figure 3: Line graph demonstrating median BCVA over time. Control subjects who are rescued drop out of control across time.

Central Subfield Thickness (CST)
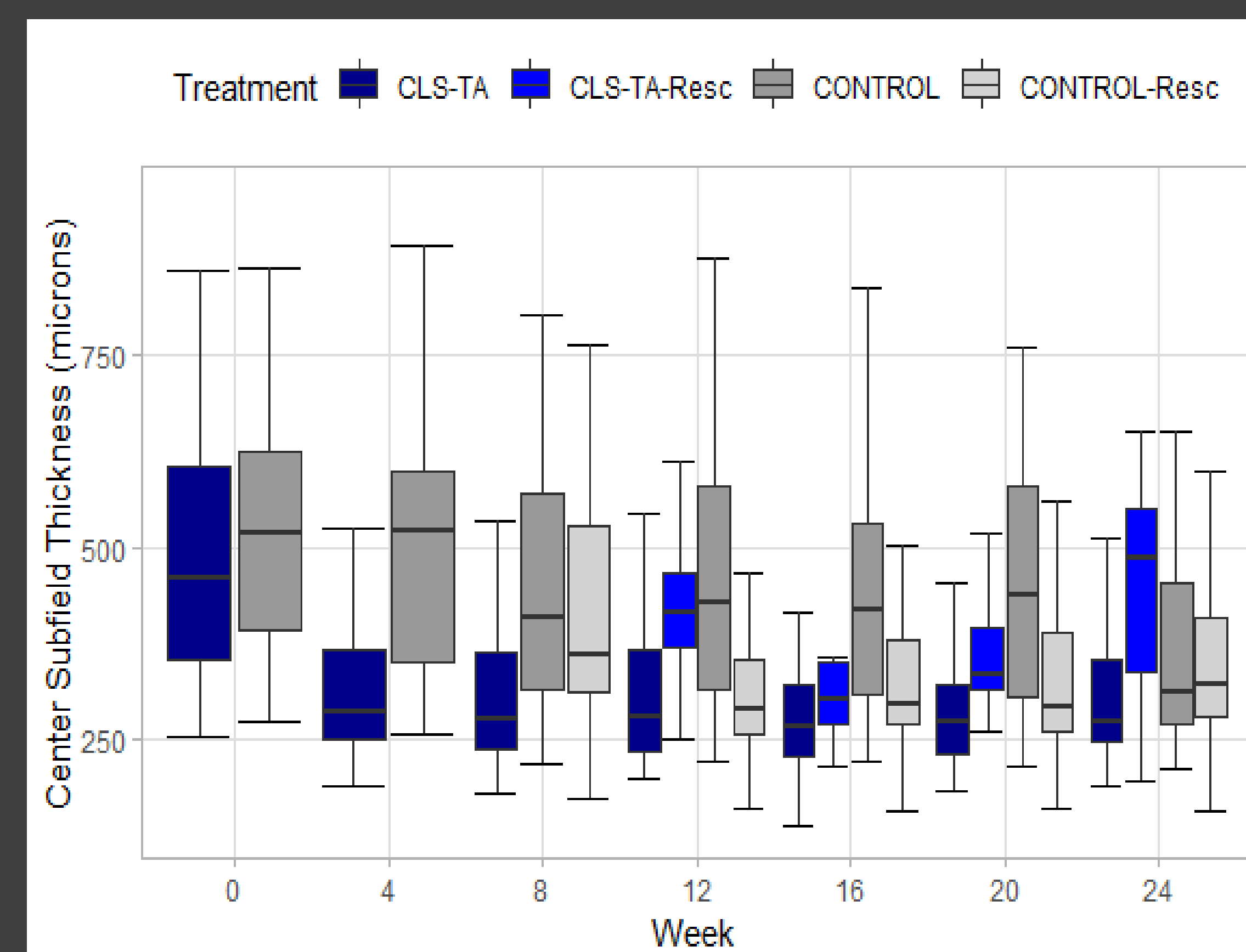### Intent-to-Treat Observed Population

Figure 4: Box plots demonstrating CST over time including median CST (horizontal line), interquartile range (boxes), 1.5-fold interquartile range (whiskers), and outlier points.
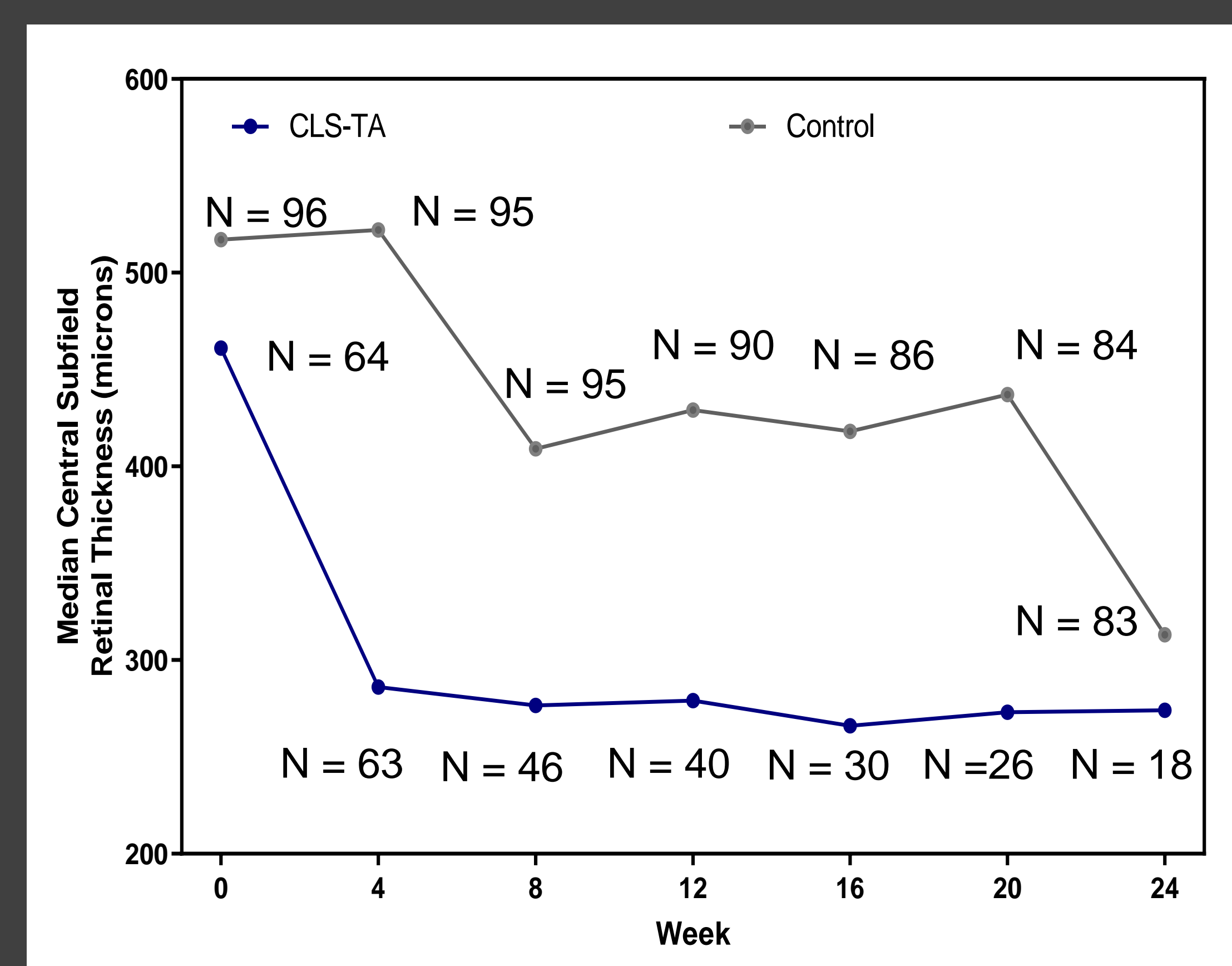

Figure 5: Line graph demonstrating median CST over time. Control subjects who are rescued drop out of control across time.

Results

❖ Data from 198 subjects in PEACHTREE and AZALEA were included.

❖ Results of the analysis showed that:
  ❖ BCVA exhibits CLS-TA treatment-dependent saturable increases over time
  ❖ CST exhibits CLS-TA treatment-dependent saturable reductions over time

❖ For the BCVA response model, the baseline BCVA score was significantly influenced by:
  ❖ Baseline CST
  ❖ Age
  ❖ Study enrollment criteria (AZALEA had less strict enrollment criteria)

❖ Maximum improvement in BCVA was influenced by the baseline BCVA (greater improvement in subjects with lower baseline BCVA)

❖ The typical subject had a baseline BCVA of 56 ETDRS letters read and a baseline CST of 463 microns.

❖ The typical improvement was 12 ETDRS letters read and 157 microns decrease in CST following suprachoroidal CLS-TA.

❖ Subjects in the control arm demonstrated an improvement in BCVA of approximately 2 letters and an improvement in CST of approximately 17 microns.

Conclusions

❖ A model-based treatment-response longitudinal model was developed that characterized changes in both BCVA and CST following administration of CLS-TA.

❖ Result of this analysis shows that the typical patient will have a 12-letter improvement in BCVA and 157 microns decrease in CST after treatment with CLS-TA.