Correlation of Best Corrected Visual Acuity and Central Subfield Thickness in Macular Edema Due to Retinal Vein Occlusion, Diabetic Retinopathy and Uveitis

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Financial Disclosures

- MI: Consultant: Clearside, Boehringer Ingelheim, Thrombogenics, Genentech, Astellas, Allergan, Novartis, Alimera, Regeneron, RegenexBio

- TC: Clearside Biomedical, Inc. (Employment, Personal Financial Interest)

Summary Slide

- Variable-frequency anti-vascular-growth (anti-VEGF) factor and corticosteroid treatment is often guided by OCT outcomes.

- Thus, it is important to understand the relationship between OCT outcomes and visual acuity.

- We conducted this analysis to examine the relationship between visual acuity and OCT across 6 clinical studies (certified visual acuity examiners and personnel) that included 3 different disease states.

- This analysis showed that there were moderate correlations between BCVA and CST in all diseases at baseline and for change at Week 24.

- These correlations provide context around the use of OCT outcomes in clinical decision making and in clinical trial results.

2015 PAT Survey

Over 90% of retina specialists, both in the U.S. and internationally, utilize OCT-guided variable frequency anti-vascular endothelial growth factor (VEGF) treatment protocols for nAMD.[1]

1. Stone T, *American Society of Retina Specialists Preferences and Trends Survey*. 2015.

Background

- In clinical practice, physicians often base treatment decisions on both BCVA and OCT assessment.

- Given the clinical importance of visual acuity and macular edema, this analysis demonstrates structure-function correlations

1. Stone T, *American Society of Retina Specialists Preferences and Trends Survey*. 2015.
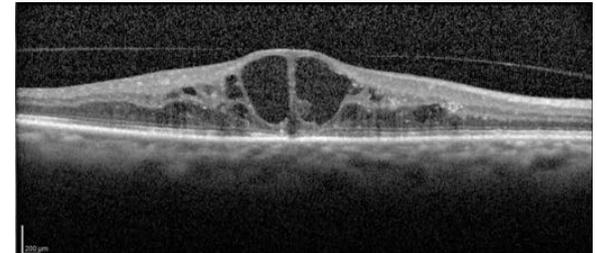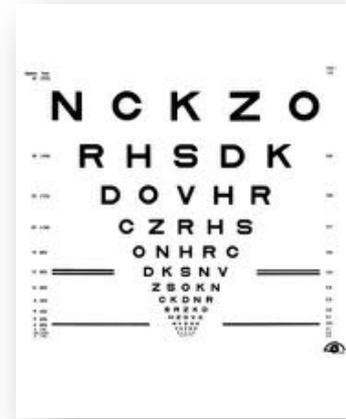
Methods

- Relationships between BCVA and CST at baseline and changes from baseline at week 24 were analyzed
- Data from from 6 clinical trials across 3 disease states
  - Standardized protocol refractions and OCT reading center evaluation

Disease State	Trial (Phase)
Noninfectious Uveitis (NIU)	PEACHTREE (Ph 3) AZALEA (Ph 3)
Retinal Vein Occlusion (RVO)	SAPPHIRE (Ph 3) TANZANITE (Ph 3)
Diabetic Macular Edema (DME)	HULK (Ph 1 / 2) TYBEE (Ph 2)

Disease states and clinical trials included in BCVA, CST analyses

- Correlations were calculated, univariate regressions were conducted to assess the analyses were performed for pooled data and separate disorders

Across diseases and trials:
Moderate negative correlation between BCVA and CST

| **Baseline**[1]	**At Week 24**[2]
Average improvement of **3.3 ETRDS letters for every 100µm reduction in CST**	Average improvement of **3.5 ETRDS letters for every 100µm reduction in CST**
95% CI: 3.0 - 3.7 ETDRS letters, CST accounted for 30.1% of the total variation in BCVA, r = -0.55, (P < 0.001)	*95% CI: 2.8 – 4.3 ETDRS letters, CST accounted for 16.2% of the total variation in BCVA, r = -0.40, (P < 0.001)*

1 . 1063 eyes from 1063 subjects

2. 721 subject eyes who completed 24 weeks of follow-up

Pooled By Disease: RVO
Moderate relationship between BCVA and CST

BCVA v. CST at Baseline
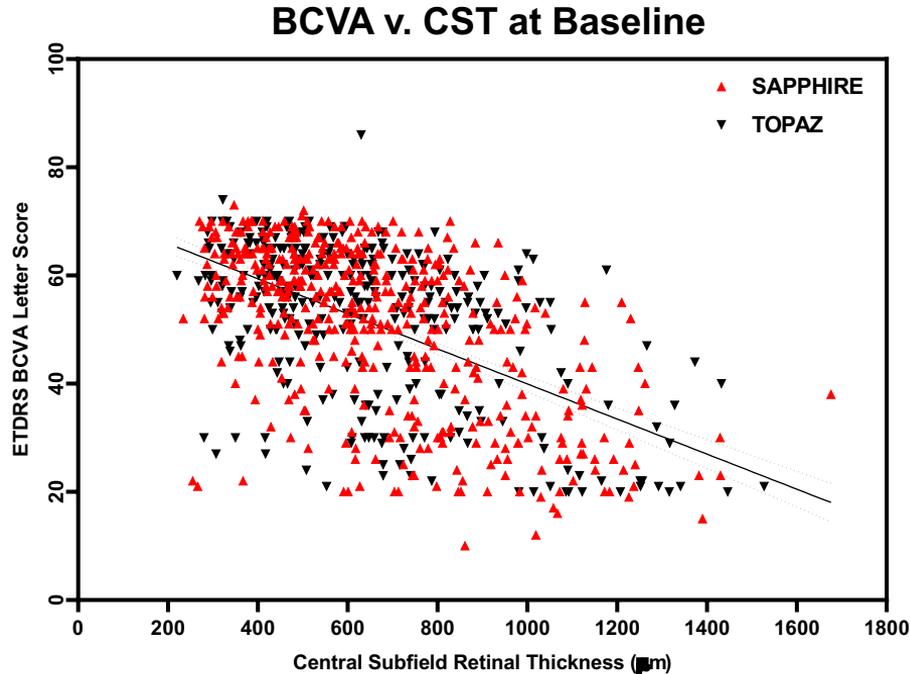
PCC: **-0.56** (-0.61, -0.51; p<0.001)

Pooled By Disease: RVO
Moderate relationship between BCVA and CST

**BCVA v. CST,
Change from Baseline at Week 24**
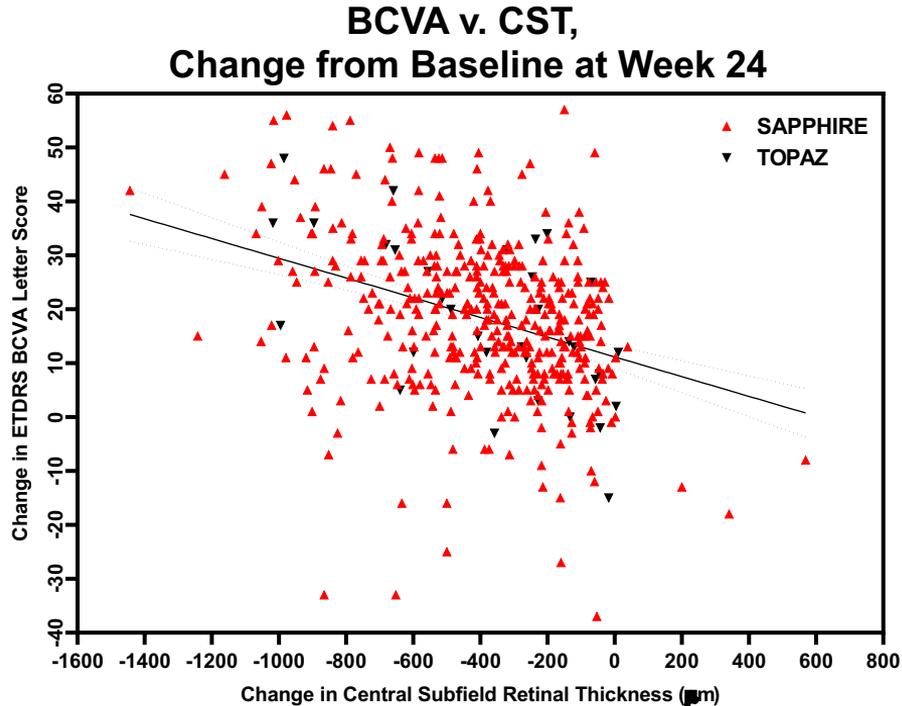
PCC: **-0.35** (-0.43, -0.27; p<0.001)

Pooled By Disease: DME
Moderate relationship between BCVA and CST

BCVA v. CST at Baseline
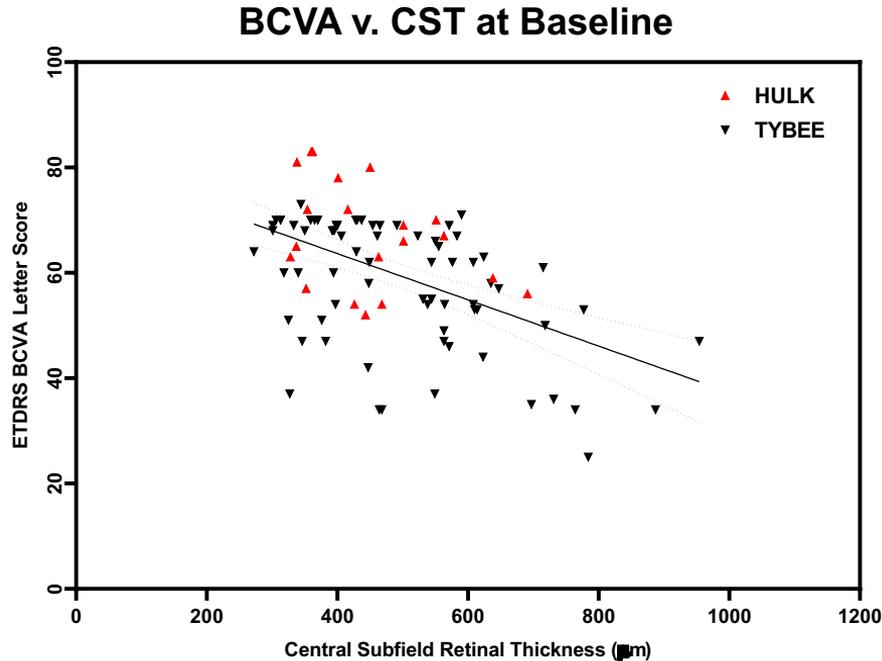
PCC: **-0.50** (-0.64, -0.33; p<0.001)

Pooled By Disease: DME
Moderate relationship between BCVA and CST

**BCVA v. CST,
Change from Baseline at Week 24**
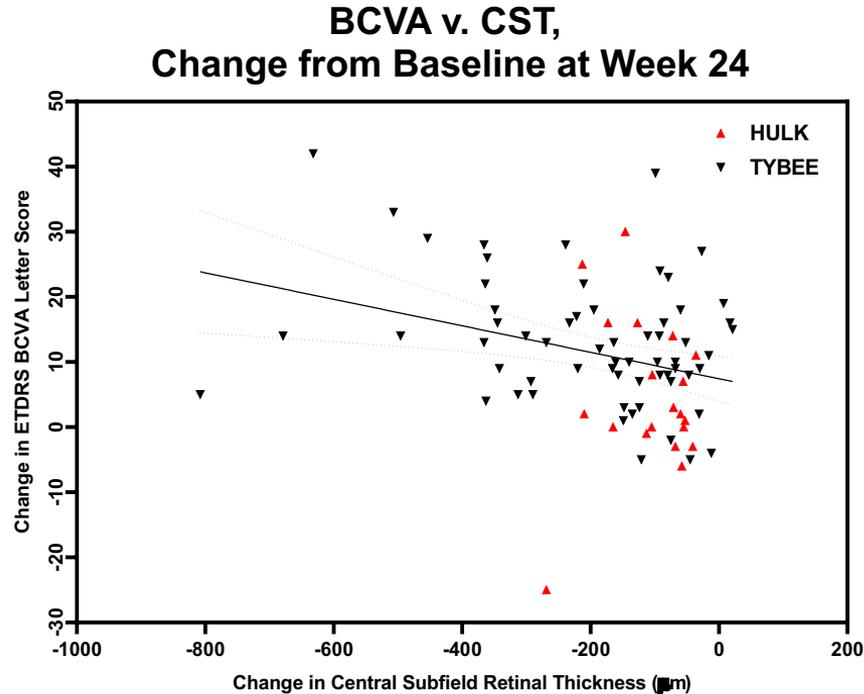
PCC: **-0.30** (-0.48, -0.09; p=0.006)

Pooled By Disease: NIU
Moderate relationship between BCVA and CST

BCVA v. CST at Baseline
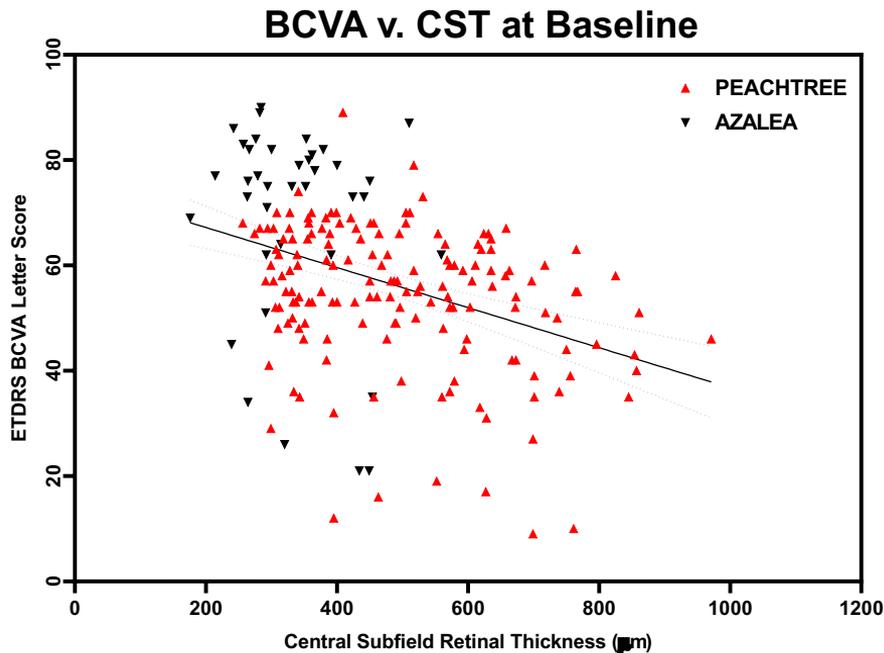
PCC: **-0.38** (-0.49, -0.26; p<0.001)

Pooled By Disease: NIU
Moderate relationship between BCVA and CST

BCVA v. CST,
Change from Baseline at Week 24
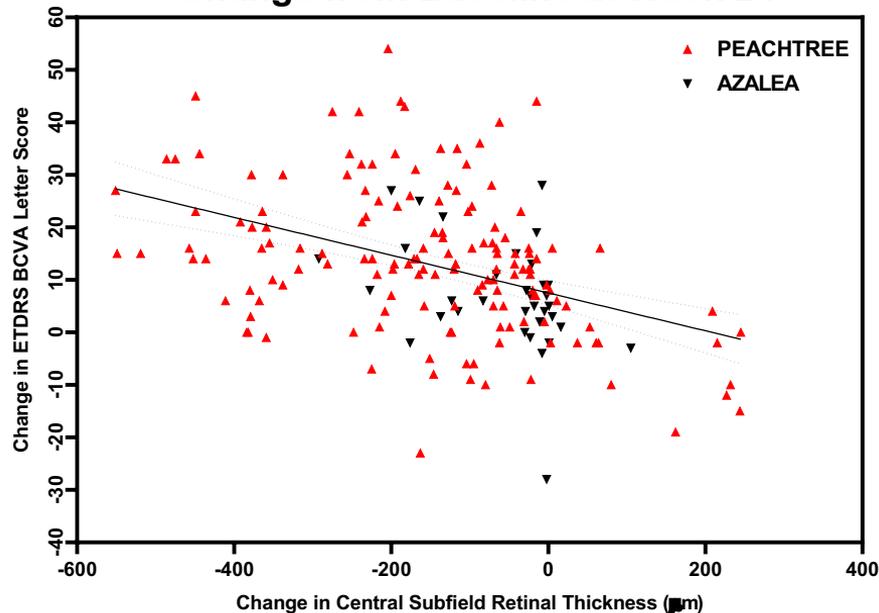
PCC: **-0.42** (-0.53, -0.29; p<0.001)

Conclusion

- The relationship between OCT outcomes and visual acuity is important.

- We conducted this analysis to examine the relationship between visual acuity and OCT across 6 clinical studies (certified visual acuity examiners and personnel) that included 3 different disease states

- This analysis showed that there were moderate correlations between BCVA and CST in all diseases at baseline and for change at Week 24.

- These correlations provide context around the use of OCT outcomes in clinical decision making and in clinical trial results.