Visual Function and Anatomic Outcomes Stratified by Baseline Visual Acuity in Patients Undergoing Suprachoroidal Injections for Macular Edema Associated with Noninfectious Uveitis

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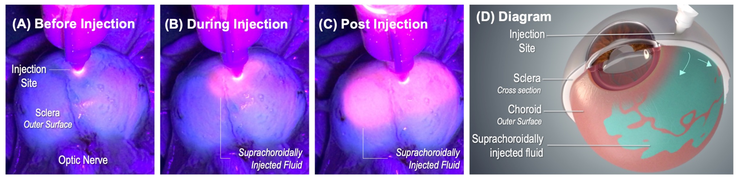
BACKGROUND

Uveitic Macular Edema

Macular edema associated with noninfectious uveitis, also known as uveitic macular edema (UME) , is the leading cause of vision loss and blindness in patients diagnosed with uveitis and can occur from the disease affecting any anatomic location—anterior, intermediate, posterior or panuveitis[1].

Suprachoroidal Injection via Microinjector

Suprachoroidal injection (SCI) via a microinjector is an in-office ocular injection procedure designed to deliver therapeutic suspensions to tissues in the back of the eye, compartmentalized away from non-diseased anterior segment tissues[2]. SCIs are currently under investigation for therapies in uveitis, neovascular age-related macular degeneration, diabetic retinopathy, and choroidal melanoma[3].



Suprachoroidal injection via the SCS Microinjector® into in an ex vivo porcine eye before (A), during (B), and immediately post (C) injection shows posterior and circumferential spread of the injectate(fluorescing particles) within the suprachoroidal space[3].

PEACHTREE & AZALEA Clinical Trials

The PEACHTREE[4] (NCT02595398) and AZALEA[5] (NCT03097315) clinical trials were phase 3 trials evaluating the efficacy and safety of CLS-TA (triamcinolone acetonide for suprachoroidal injection) for NIU. Patients receiving CLS-TA received a suprachoroidal injection via Microinjector at baseline and week 12, and were followed for 24 weeks.

METHODS

This post hoc analysis included data from the PEACHTREE and AZALEA in patients that received CLS-TA. BCVA and central subfield thickness (CST) outcomes were evaluated in eyes that received CLS-TA, stratified by baseline vision:

- ≥ 20/40,
- <20/40 to 20/80,
- <20/80 to 20/200, and
- ≤ 20/200

Demographics and baseline disease characteristics were summarized. Mean and mean change from baseline (±SEM) values were calculated for BCVA and CST values for the intent-to-treat (ITT) population. Values for missing data or post rescue were imputed using the last observation carried forward method.

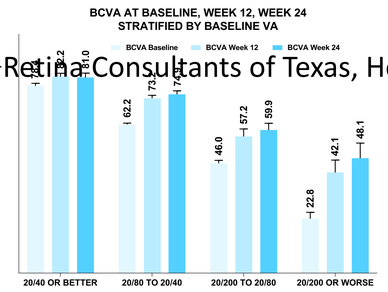
RESULTS

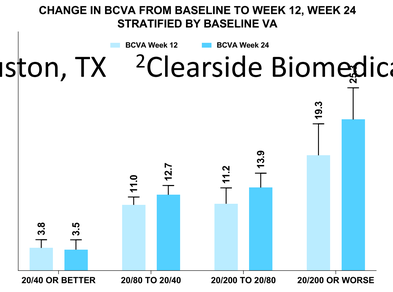
A total of 134 patients were included in this post hoc analysis.

	20/40 OR BETTER	20/80 TO 20/40	20/200 TO 20/80	20/200 OR WORSE
No. of participants	32	57	34	11
Mean Age (yrs.)	52.8	53.2	46.9	46.9
Females (%)	65.6%	61.4%	41.2%	81.8%
Duration of Uveitis (wks)	118.9	1813.3	181.0	215.2
Presence of, (%)				
Anterior uveitis	28.1%	35.1%	17.6%	36.4%
Intermediate uveitis	43.8%	42.1%	20.6%	36.4%
Posterior uveitis	28.1%	15.8%	32.4%	27.3%
Panuveitis	18.8%	24.6%	38.2%	45.5%

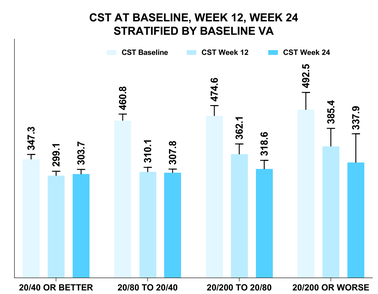
RESULTS

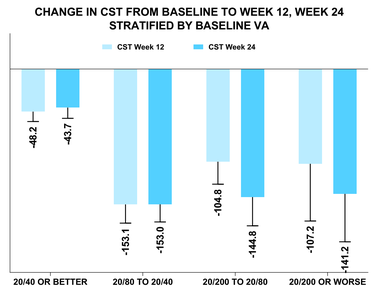
An inverse relationship between BCVA improvement and baseline vision was observed in CLS-TA patients. Lower baseline visual acuity corresponded to greater improvements in BCVA over 12 and 24 weeks:



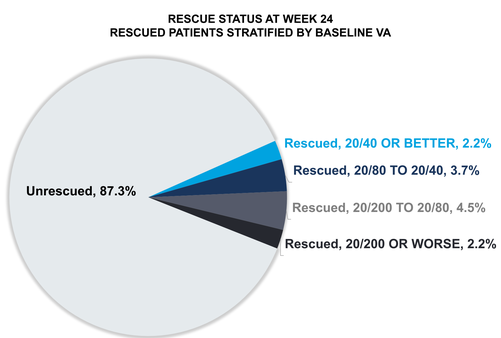


Macular thickness was improved to approximately 300 microns regardless of baseline vision in CLS-TA patients:





Overall, **17 out of 134 (12.7%) CLS-TA patients required rescue**. The type of rescue administered was at the discretion of the investigator.



DISCUSSION

- Patients with macular edema associated with noninfectious uveitis treated with CLS-TA experienced visual and anatomic benefits at 24 weeks regardless of baseline visual acuity status.
- For this post hoc analysis, patients with worse vision at baseline gained more letters over the 24 weeks of the studies than those with better vision at baseline; a ceiling effect was observed in better seeing baseline groups.
- Patients with worse vision at baseline experienced a greater reduction in CST; a floor effect was observed in retinal thickness values as the retina approached normal thickness.
- NOTE: Patients in the AZAELEA trial were not required to have ME. Patients in PEACTHREE had to have a retinal thickness of ≥ 300 µm as measured by SD-OCT at baseline.

CONCLUSION

Patients in the CLS-TA study arm of both PEACHTREE and AZALEA Phase 3 clinical trials experienced a clinically significant improvement in vision relative to the sham procedure, regardless of visual acuity at baseline, demonstrating the efficacy of suprachoroidal injection of CLS-TA for the treatment of ME in noninfectious uveitis.[4]

SOURCES

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Financial Disclosures

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C = Consultant, E = Employee, S = Shareholder