

The Valeda Light Delivery System Improves Visual Acuity in Intermediate and Late-Stage Dry Age-Related Macular Degeneration Patients at Month 13

LIGHTSITE III MONTH 13 DATA RESULTS



VALEDA[®]

Light Delivery System

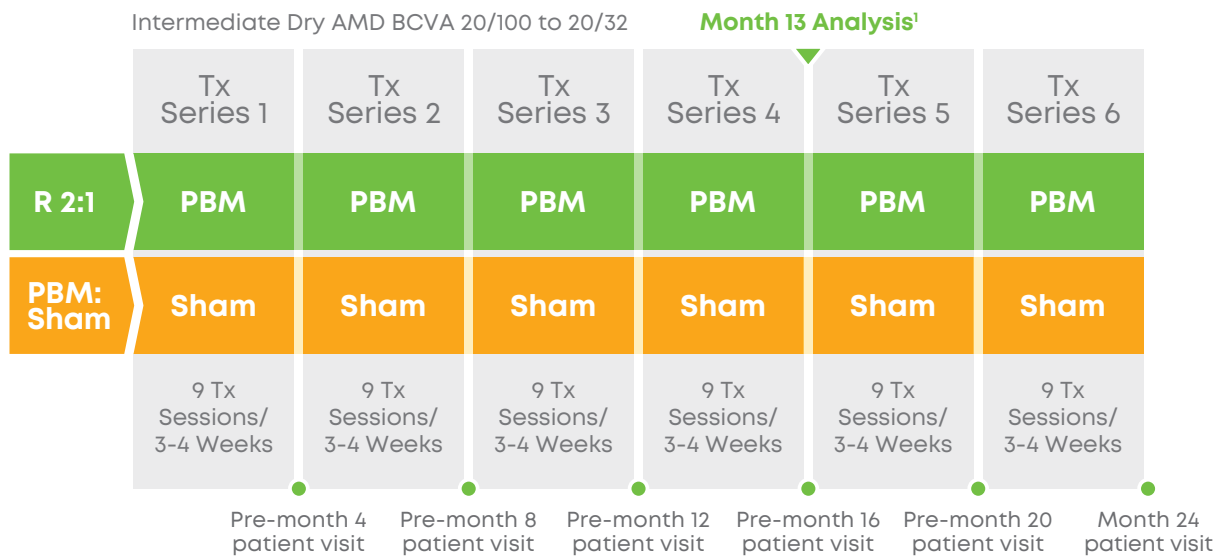


LIGHTSITE III Month 13 Analysis

Double-masked, randomized, sham-controlled, parallel group, multi-center study to assess the safety and efficacy of photobiomodulation (PBM) in subjects with dry age-related macular degeneration (AMD)

PBM Tx: 590, 660, and 850 nm wavelengths

Sham Tx: 50x/100x reduction of 590/660 nm; No 850 nm wavelengths



1. The primary endpoint is the 13 month comparison between PBM and Sham groups

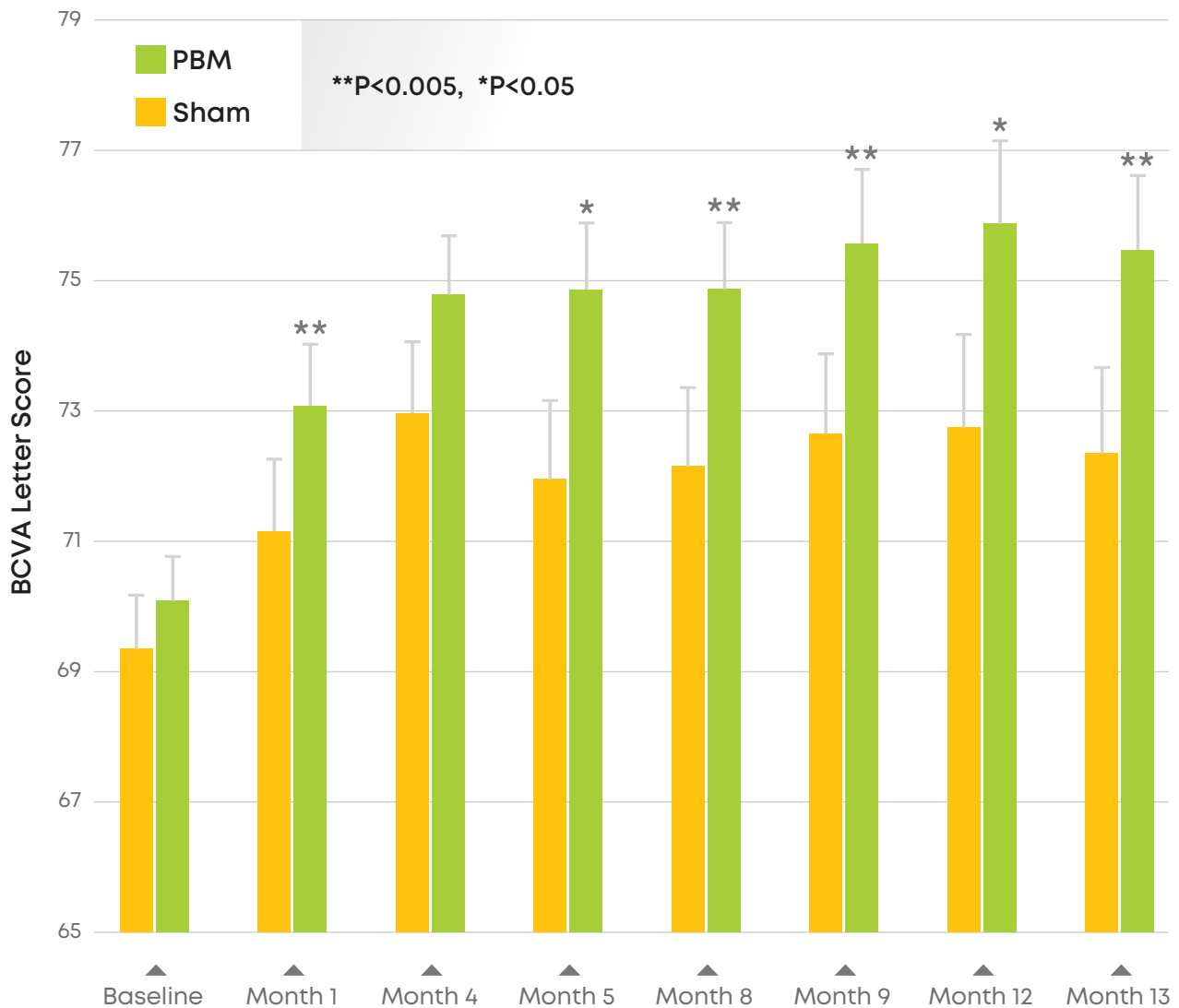


PATIENTS - BASELINE CHARACTERISTICS

- Patients - 100
- Eyes - 148 (2:1 PBM to Sham)
- Race - 99% Caucasian, 1% Black/African American
- Gender - 32 M (32%), 68 F (68%)
- Mean Age - 75
- Mean Time from Diagnosis - 4.9 years
- AREDS supplements - 86 (86%) yes 14 (14%) no
- BCVA Baseline (BL) \geq 70 letters (20/40) - 103 eyes (70%)
- BCVA Letter Score - Masked 70.6 ± 5.3

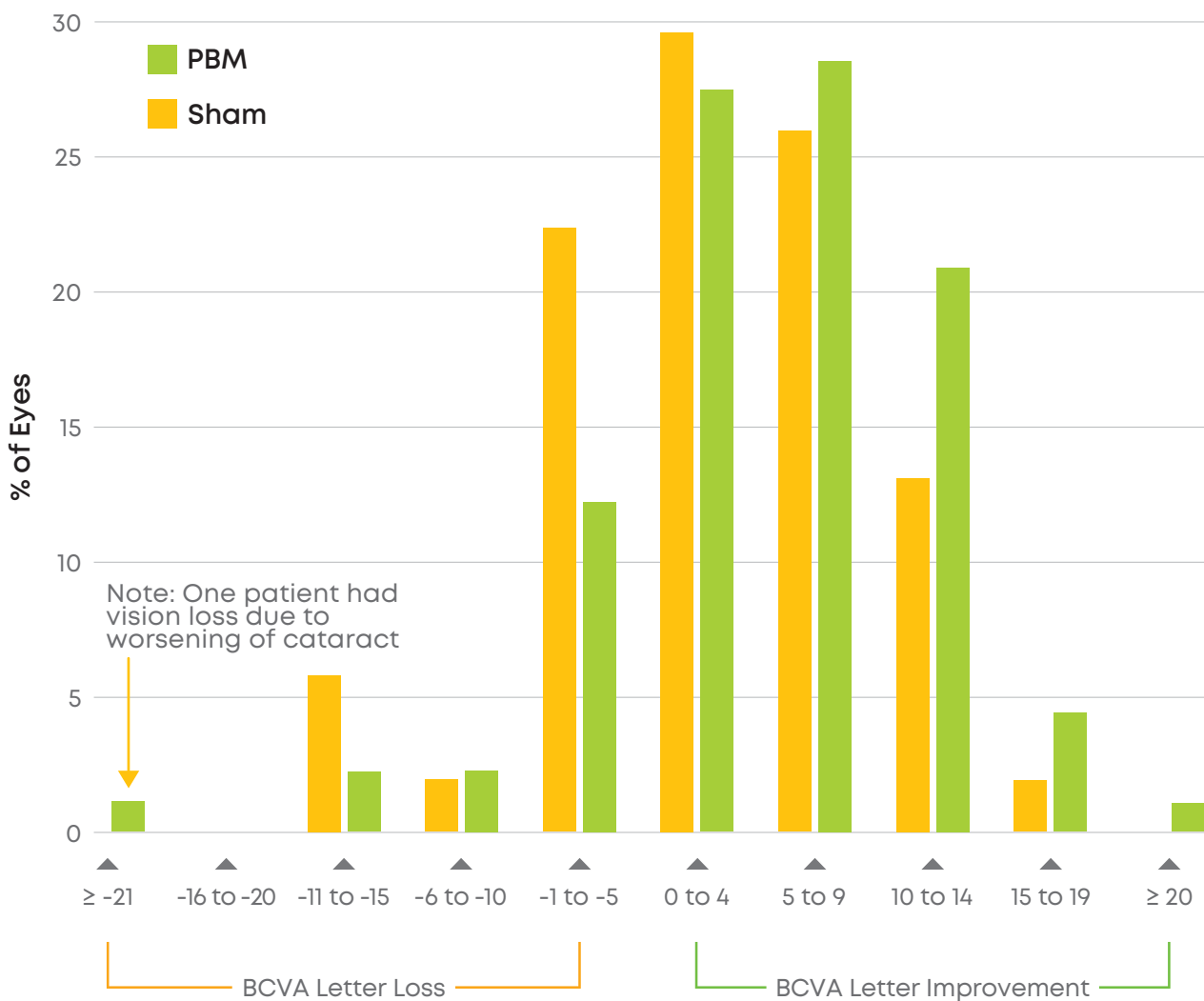
BCVA Letter gain

- Valeda demonstrated a statistically significant difference between the PBM and Sham treatment groups ($P=0.02$)
- PBM provided a sustained and improved BCVA with a mean 5.5 letter change from BL gain ($P < 0.0001$)

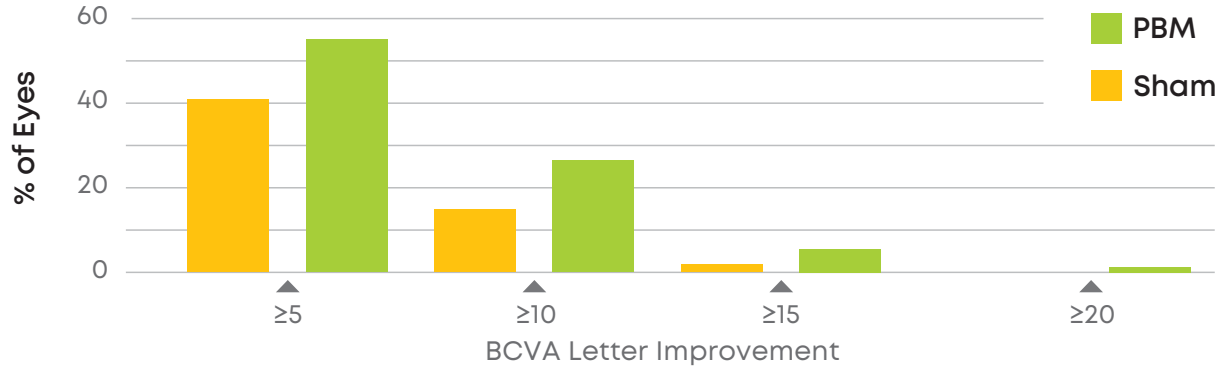


BCVA Letter Distribution

- PBM patients versus Sham patients showed a statistically significant improvement in BCVA letter score at 13 months (P=0.02)
- Approximately two times more patients lost BCVA letter scores in the Sham eyes versus the PBM treated eyes

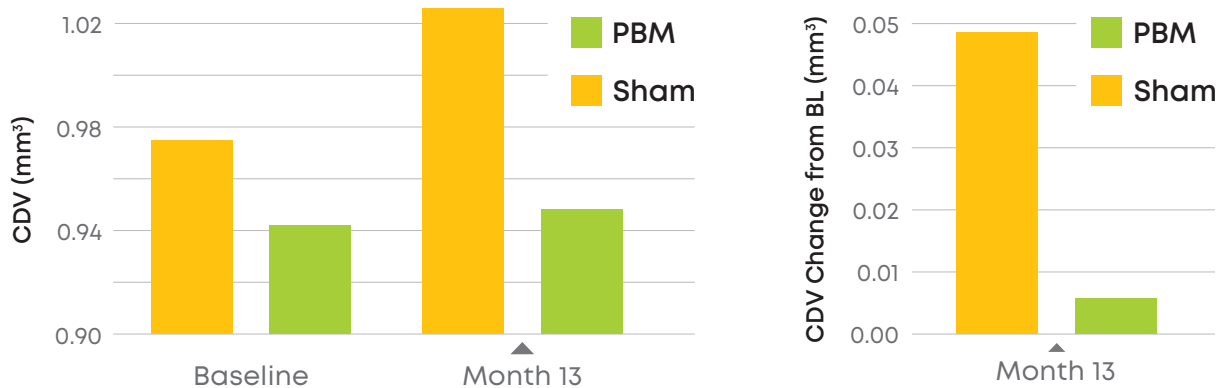


BCVA High Responder Group



- 55% of PBM eyes responded with a ≥ 5 letter gain, Mean = 9.7 ± 0.52 letters
- 26.4% of PBM eyes responded with a ≥ 10 letter gain, Mean = 12.8 ± 0.54 letters
- 5.5% of PBM eyes responded with a ≥ 15 letter gain, compared to 1.9% of Sham

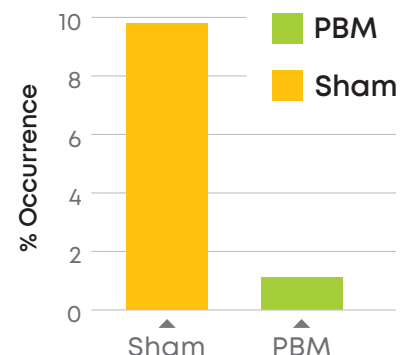
Central Drusen Volume (CDV) – Mean Values and Change From BL



- No numerical change in CDV was observed in PBM treated group (0.006 mm³)
- An increase in CDV was seen in the Sham treated group (0.049 mm³) from BL

Occurrence of New Onset GA

- Occurrence of new Geographic Atrophy (GA) in intermediate dry AMD subjects was significantly higher in Sham compared to PBM group (P = 0.025, Fisher exact test, odds ratio 9.3)
- 5/51 (9.8%) of Sham patients presented with new onset GA compared to 1 of 88 (1.1%) of PBM patients



LIGHTSITE III met the predetermined primary efficacy BCVA endpoint with a statistically significant difference between the Valeda (PBM) group versus the Sham treatment group (P = 0.02) at month 13

An improved BCVA with a mean 5.5 letter gain in PBM eyes from baseline values was observed (P < 0.0001)



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Approximately two times more patients lost BCVA letter scores in the Sham eyes versus the PBM treated eyes.

An increase in CDV was observed in the Sham group (0.049 mm³) from baseline. No increase in CDV was observed in the PBM group. These results are consistent with LIGHTSITE I and II studies, suggesting a disease modifying benefit.

Consistent with LIGHTSITE I and II clinical studies, LIGHTSITE III showed an excellent safety profile with no signs of phototoxicity.



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