Improvement of Visual Function following Multi-wavelength Photobiomodulation with the Valeda Light Delivery System on Electroretinography (ERG) and Best Corrected Visual Acuity (BCVA) in Dry Age-related Macular Degeneration in the ELECTROLIGHT Study (Interim Analysis)

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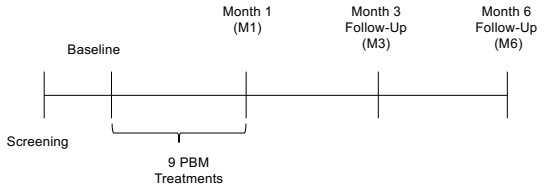
Introduction

Dry age-related macular degeneration (AMD) demonstrates underlying mitochondrial dysfunction which contributes to disease pathology. Photobiomodulation (PBM) utilizes wavelengths in the 500-1000 nm range to induce cellular effects resulting in improved cellular bioenergetics and mitochondrial output. Studies suggest the benefit of PBM in subjects with Dry AMD (Markowitz et al., Retina, 2020; Merry et al., Acta Ophthalmol, 2017). Electroretinography (ERG) is a quantitative and functional indicator of visual function and is an important tool for the early diagnosis and management of retinal function in ocular disease. The multiwavelength Valeda Light Delivery System, and the Diopsys NOVA ERG device were used to investigate the effects on multiple parameters of visual function in the ELECTROLIGHT dry AMD study.

ELECTROLIGHT Study Design



A total of 23 eyes from 15 subjects with intermediate Dry AMD were enrolled into the prospective clinical study and treated with one series of PBM treatments using the Valeda (3x per week for 3 weeks). Valeda uses a multiwavelength treatment comprised of 590 nm, 660 nm and 850 nm wavelengths applied to the subjects eyes for a total of 4-5 minutes per treatment per eye. Subjects were assessed for clinical and safety outcomes (i.e., visual acuity (BCVA), contrast sensitivity (CS), color vision, amsler grid test, perimetry, and ERG). Independent OCT outcomes at 3- and 6-months post-treatment were analyzed by an imaging center. An interim analysis was performed following the completion of all month 1 study visits.

LumiThera Valeda® Light Delivery System

Valeda Light Delivery System designed for the Ophthalmology office setting.

Table 1. Valeda PBM Specifications

Light Source	LED
590 nm	4 mW/cm^2
660 nm	65 mW/cm^2
850 nm	0.6 mW/cm^2
Treatment exposure	Total of 250 seconds/ eye

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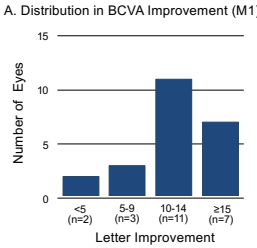
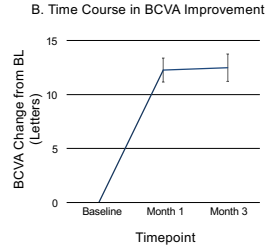
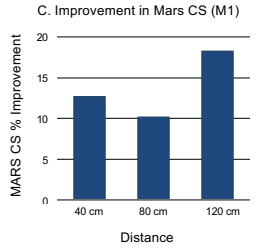
Results

Table 2. Patient Demographics

Patient, (n)	15
Total # eyes, (n)	23
Mean Age, (yrs)	75.1
Gender, (M, F)	8 (53.3%), 7 (46.7%)
Mean Time since diagnosis, (yrs)	5.0
Race	Caucasian (100%)



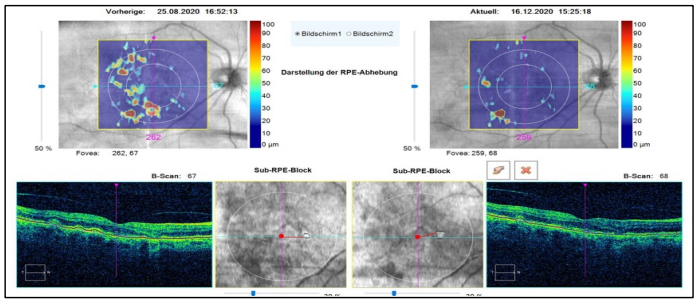




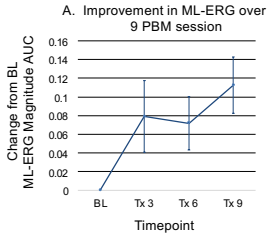
Patient demographics are outlined in Table 2 (left). A. At month 1, the majority of eyes (47.8%) showed an improvement in BCVA of 10-14 letters. B. The observed benefit in BCVA letter gain was observed at month 1 and maintained at month 3, approximately 2 months following PBM intervention. C. At month 1, eyes showed an improvement at the three testing distances for the Mars CS with the biggest benefit observed at 120 cm (18.27%).

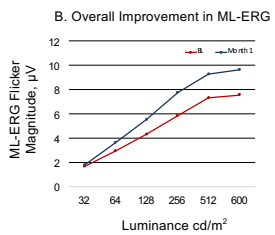
Table 3. Correlation Between ERG Parameters in PBM-Treated Eyes (n=23)

Parameters	Pearson (R2)	Sig (2-tailed) (p)	Positive Benefit
ML Magnitude AUC and FL Magnitude	0.870	<0.01	✓
Chromatic B-Wave Amplitude and FL Magnitude	0.710	<0.01	✓
Chromatic B-Wave Amplitude and ML Magnitude AUC	0.676	<0.01	✓
Chromatic B-Wave Latency and FL Phase	-0.667	<0.01	✓
Chromatic PhNR Latency and Chromatic B-Wave Latency	0.611	<0.01	✓
Chromatic PhNR Latency and FL Phase	-0.516	<0.01	✓
mfERG N1P1 Amplitude R2 and Chromatic B-Wave Amplitude	0.490	<0.01	✓
mfERG N2P1 Amplitude R2 and Chromatic B-Wave Amplitude	0.453	<0.01	✓



A representative dry AMD Patient with Drusen Reduction following PBM intervention. OCT-SD imaging was conducted 4 months from pre-baseline imaging.





ERG provides a functional output for measuring PBM effect on retinal function following treatment intervention. A. Subjects showed an improvement in multi-luminance (ML) ERG that was additive across the 9 PBM treatment sessions and resulted in improvement compared to baseline at month 1 (Tx9). B. PBM improved ML-ERG magnitude by 14.4% from the first session (baseline) to month 1 (Tx9). Table 3 provides additional statistical correlations between ERG parameters following PBM treatment at month 1.

Summary and Conclusions

The ELECTROLIGHT study investigated clinical, anatomical and ERG output following PBM intervention in Dry AMD subjects. Dry AMD patients treated with PBM demonstrated both functional and anatomical improvements following PBM treatment. PBM-treated patients showed improvements in BCVA, CS and ML-ERG immediately following PBM that were maintained at follow up visits. Improvements in ML-ERG showed an additive pattern throughout course of treatment. OCT readouts showed reductions in drusen volume demonstrating potential disease-modifying effects on key anatomical disease features. These results strongly support further clinical testing of PBM as a non-invasive treatment for dry AMD patients and the utility of ERG as a functional indicator for changes in retinal output.

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