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ORIGINAL RESEARCH

Multiwavelength Photobiomodulation Improves Multiple Aspects of Visual Function in Early-Stage Dry Age-Related Macular Degeneration

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ABSTRACT

***Introduction*:** This study aimed to evaluate the safety and efficacy of multiwavelength photobiomodulation (PBM) treatment (Tx) in earlier stages of nonexudative (dry) age-related macular degeneration (AMD).

***Methods*:** Participants were enrolled with a diagnosis of dry AMD. Participants were treated with a single or repeated series of multiwavelength PBM treatment (LumiThera Valeda® Light Delivery System; 590, 660, and 850 nm) delivered three times per week over 3–5 weeks every 4 months with follow-up extending out to 16 months. Outcomes analyzed included visual acuity (VA), contrast sensitivity (CS), and electroretinography (ERG).

***Results*:** A total of 41 eyes (27 participants) were evaluated after single (1 series of Tx, $n=41$ eyes) and repeat (2–4 series of Tx, $n=26$ eyes) PBM treatment with up to 16 months of follow-up. Participants were mostly female ($n=22$, 81.5%) with a mean time since AMD diagnosis of 5.6 years. Participants enrolled had earlier stage dry AMD with better vision (~20/32 Snellen) and a mean baseline VA of 76.5 letters. Single and repeated PBM Tx improved VA, CS, multi-luminance ERG, and fixed luminance ERG parameters. No significant visual decline was noted in any outcome measure or signs of phototoxicity.

***Conclusions*:** PBM treatment of patients with earlier stage dry AMD showed improvements on multiple visual outcome measures and no adverse effects. Earlier stage AMD populations may not show robust magnitude effects as their starting vision does not show serious deficits, however; as a result of the degenerative and progressive nature of the disease, repeat treatment and continued monitoring of these outcomes are of interest. These beneficial effects were improved with repeated PBM treatment series.

Keywords: Photobiomodulation; Valeda Light Delivery System; Dry age-related macular degeneration ; Multiwavelength; Age-related macular degeneration; Mitochondria; Ocular disease; Retina; Nonexudative macular degeneration; Light therapy

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Key Summary Points

Why carry out this study?

Multiwavelength photobiomodulation (PBM) treatment with the Valeda® Light Delivery System is a recently FDA-authorized treatment for earlier stages of dry age-related macular degeneration (AMD); additional data is useful to show safety and efficacy in real-world settings.

What did the study ask?/What was the hypothesis of the study?

Patients with earlier stage dry AMD demonstrate limited impairment in visual and anatomical metrics; early treatment with PBM aims to benefit bioenergetic cellular output and reduce disease outcomes in progressive and degenerative disease trajectories.

What was learned from the study?

Multiwavelength PBM treatment with Valeda in patients with earlier stage dry AMD with good vision improved multiple parameters of visual function in visual acuity, contrast sensitivity, and electroretinography with no safety concerns or phototoxicity observed in patients that received single or repeated PBM treatment series extending out to 16 months of follow-up.

PBM treatment with Valeda provided visual benefits to patients with earlier stage AMD and good vision with no safety concerns.

Future studies should assess longer-term benefits of patients treated with Valeda to determine impact on disease progression and outlook.

INTRODUCTION

A noninvasive treatment that utilizes light-based therapy, termed photobiomodulation (PBM), is the first approved treatment for early/intermediate stages of dry age-related macular degeneration (AMD). AMD is a progressive and degenerative disease that affects millions of individuals globally [1, 2]. The dry form affects 85–90% of patients with AMD and significantly impacts visual function [3, 4]. Until recently, no treatment has been available for this patient population that can influence vision outcomes. Treatments for later stages of the disease, such as the development of geographic atrophy (GA) and the more severe wet form of the disease, include complement inhibitors and anti-vascular endothelial growth factor (VEGF) injections [3].

The capacity to treat the degenerative disease earlier and potentially intervene prior to irreversible tissue loss is of interest. As there are not yet cures for these types of diseases, intervention at earlier stages to delay severe decline aims to significantly improve the trajectory of a disease, patient outcomes, and quality of life (QoL). This is especially important when considering the typical AMD onset in an individual's 60s and the average life expectancy of 77 years of age. If treatment can reduce the natural decline and preserve visual status, this would be beneficial for most patients given the ageing timeline of those affected. The global prevalence of AMD is expected to reach 288 million by 2040 [1]. Reducing disease burden for this growing population is necessary.

PBM is a treatment modality that uses light wavelengths to directly influence cellular tissues in a wide-ranging capacity [5, 6]. The primary mechanism is through photoacceptors to regulate mitochondrial activity to increase bioenergetic output [7, 8]. Improvement in mitochondrial function is associated with cell survival and other processes impacting by ageing [9]. These effects are important in degenerative disease states and therefore PBM has been evaluated as a treatment approach for AMD [10]. Visual and anatomical benefits have been reported in many clinical reports for dry AMD including larger randomized controlled trials which use the Valeda Light Delivery System (Valeda®), a medical device that delivers multiwavelength PBM for ocular indications. Repeated PBM treatment with Valeda shows positive effects on visual acuity (VA) in patients with dry AMD with limited visual deficits (i.e., patients with Snellen equivalent: 20/32 to 20/100) [11]. The LIGHTSITE III

trial showed greater than one-line improvement in BCVA (best-corrected visual acuity) following PBM, with more than 60% of participants gaining a mean of 9.0 letters, and reduction in progression of disease to GA over 2 years in this early/intermediate patient population [11].

Additional data supporting the acute and long-term effects of PBM in early-stage patients is necessary to replicate the trial findings and provide further details on the effects in real-world populations. The current study evaluated acute and longer-term (up to 16 months) effects of multiwavelength PBM treatment with Valeda on participants with earlier stage dry AMD with good vision.

METHODS

The current study was a retrospective evaluation of the safety and efficacy of multiwavelength PBM using the Valeda® Light Delivery System [Valeda] (LumiThera Inc., Poulsbo, WA, USA) in participants with dry AMD. Participants were enrolled at a single center (Netgoz Eye Hospital, Izmir, Turkey) who had a diagnosis of early or intermediate dry AMD and received at least one series of multiwavelength PBM treatment using Valeda. Participants who had GA (advanced dry AMD) or any other ophthalmic pathology were excluded. Written informed consent was obtained from all participants in this study. Institutional Review Board/Ethics Committee approval was obtained from Netgoz Eye Hospital (Bayrakli, Izmir, Turkey). This study was conducted in compliance with the protocol, Good Clinical Practice guidelines, the guidelines of the Declaration of Helsinki and all other applicable regulatory requirements.

Study Design

Participants were tested at the 1-month and 3-month follow-up visits post treatment series (participants were treated with one or repeated (2–4) PBM series delivered every 4 months). Outcomes assessed included visual acuity (VA), contrast sensitivity (CS), multi-luminance electroretinography (ML-ERG), fixed-luminance electroretinography (FL-ERG), and optical coherence tomography (OCT) imaging analysis (choroidal thickness). Outcome measures were obtained by trained staff. VA was measured by an automatic chart projector (ACP-8 Auto Chart Projector, Topcon, Japan) mounted on a phoropter under the same light conditions. CS was evaluated using the CliniCSF® program (Indaloftal SL, Spain) on an iPad® (Apple Inc., USA). The ERG results were obtained by a Diopsys device (Diopsys, Inc. c/o LumiThera Diagnostics, Pennsylvania, USA). OCT scans were taken using a swept-source OCT device (DRI-Triton®, Topcon, Inc., Japan). Two cohorts were analyzed to evaluate the effects of one series of PBM treatment (cohort 1) and the effects of repeated PBM treatment series (cohort 2):

Cohort 1 analysis: participants which received one series of PBM treatment.

Cohort 2 analysis: participants which received repeated PBM treatment (at least two series of PBM Tx delivered every 4 months) (Fig. 1).

Photobiomodulation Treatment

Valeda delivers three wavelengths in the yellow (590 nm; 4 mW/cm^2; 2 × 35 s), red (660 nm; 65 mW/cm^2; 2 × 90 s), and near infrared (850 nm; 0.6 mW/cm^2; 2 × 35 s) range. One PBM treatment session lasts less than 5 min per eye. The 590- and 850-nm wavelengths are pulsed and delivered through the open eyelid. The 660-nm wavelength is continuous and delivered through the closed eyelid. One treatment series totals nine sessions delivered over 3–5 weeks. If participants were evaluated after repeated treatment series, they received PBM treatment every 4 months. No pupil dilation was required for treatment.

Statistical Analysis

A total of 41 eyes (27 participants) were included in the cohort 1 analysis and 26 eyes (18

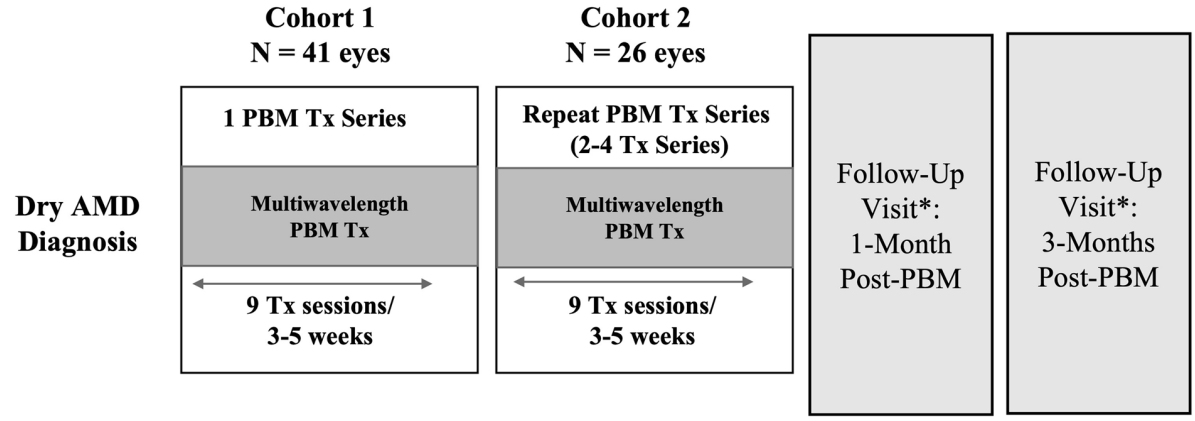

Fig. 1 Study design. *Following repeat PBM treatment (at least two series of treatment) data was analyzed after the last Tx series was conducted. Photobiomodulation (PBM), age-related macular degeneration (AMD)

participants) in the cohort 2 analysis. Analyses represent individual eyes, rather than participants, unless otherwise indicated. Data are presented at the 1-month and 3-month timepoints following the last PBM treatment series completed for the participant. Efficacy analyses were implemented using a repeated measures analysis of variance (ANOVA) with post hoc Dunnett's test with the p value set at $p<0.05$. Graphpad prism software (version 10.4.1) was used for statistical support.

RESULTS

Participants

Overall demographics for all participants evaluated are presented in Table 1. Participants were of mean 72.4 (SD 6.6) years of age with the majority (81.5%) female (22 female; 5 male). Participants enrolled had early/intermediate stage dry AMD with better vision (~20/32 Snellen), a mean baseline VA of 76.5 letters (range 45–85 letters), and a mean time since dry AMD diagnosis of 5.6 years. A total of 42.3% of participants were smokers, 73.1% had hypertension, 69.2% had a family history of AMD, and 15.4% had diabetes (Table 1). Cohort 2 included participants that had at least two series of Valeda treatment. The majority of participants had received two series of Valeda Tx ($n=12$), with four participants having received three series of Valeda, and two participants received four series of Valeda.

Efficacy Analyses

Cohort 1 Analysis: Single Valeda Treatment Evaluation

Visual Acuity In cohort 1, participants had a high baseline VA of 76.5 Letters (~20/32 Snellen). Following one series of Valeda treatment, significant improvements in VA were observed at month 1 ($p=0.0009$) and month 3 ($p=0.0034$) timepoints. At month 1, 0.0% of eyes showed vision loss, 26.8% of eyes showed vision gain (5 letters), and 73.2% of eyes showed maintained vision (no change). The mean change from baseline was 1.3 (month 1) and 1.1 (month 3) letters (Table 2, Fig. 2).

Contrast Sensitivity (CS) Significant CS improvements were observed following one series of Valeda treatment at month 1 and month 3 timepoints at 3, 6, 9, and 12 cycles per degree ($p<0.05$). The largest improvements were observed at 3 and 6 cycles per degree at both month 1 and month 3 (Table 3, Fig. 3).

Table 1 Participant demographics

Cohort 1	
Participants/eyes analyzed	27 participants; 41 eyes
Age	72.4 years (SD 6.6)
Gender	22 female; 5 male
Time since dry AMD diagnosis	5.6 years
BCVA baseline	76.5 letters (45–85 letters)
AMD risk factors	
Smoking	15 no; 11 yes
Hypertension	7 no; 19 yes
Diabetes	22 no; 4 yes
Family history of AMD	8 no; 18 yes
Cohort 2	
Participants/eyes analyzed	18 participants; 26 eyes
Age	72.7 years (SD 7.6)
Gender	13 female; 5 male
Time since dry AMD diagnosis	5.6 years
No. of repeat PBM Tx series	
2 PBM series	12 participants
3 PBM series	4 participants
4 PBM series	2 participants
BCVA baseline	76.7 letters (60–85 letters)
AMD risk factors	
Smoking	10 no; 8 yes
Hypertension	8 no; 10 yes
Diabetes	11 no; 7 yes
Family history of AMD	9 no; 9 yes

Photobiomodulation (PBM), age-related macular degeneration (AMD)

Table 2 Visual acuity

	Cohort 1	Cohort 2
Visual acuity		
VA, mean letters (SE)		
Baseline	76.5	76.7 (1.1)
Month 1	77.8	78.9 (1.0)
Month 3	77.6	78.5 (1.0)
Letter distribution, no. of eyes (%)		
Month 1		
Letter gain (5 letters)	11 (26.8%)	9 (34.6%)
Letter loss	0 (0.0%)	0 (0.0%)
No change	30 (73.2%)	17 (65.4%)
Month 3		
Letter gain (5 letters)	9 (22.0%)	8 (30.8%)
Letter loss	0 (0.0%)	1 (3.8%)
No change	32 (78.0%)	17 (65.4%)

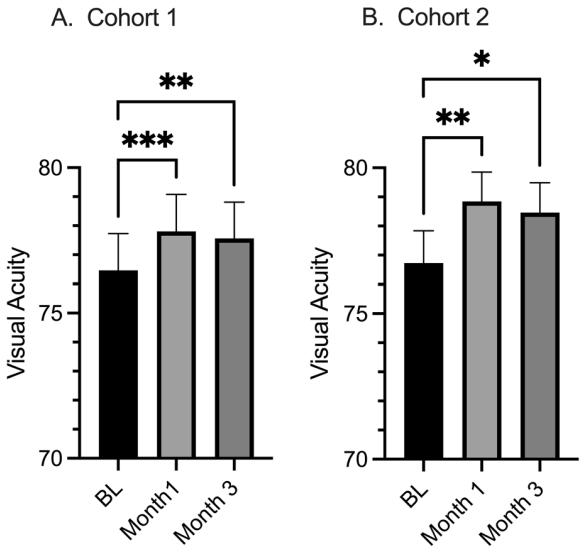

Fig. 2 Visual acuity analyses

Electroretinography (ERG) A significant improvement was observed in FL-ERG magnitude ($p=0.0105$) at month 3. No change was observed in FL-ERG phase, ML-ERG area ratio magnitude, or ML-ERG area ratio phase ($p>0.05$) at either timepoint (Table 4, Fig. 4).

Table 3 Contrast sensitivity

Contrast sensitivity	Cohort 1	Cohort 2
3 cycles per degree		
Baseline	1.4 (0.07)	1.4 (0.1)
Month 1	1.6 (0.06)	1.5 (0.1)
Month 3	1.6 (0.07)	1.6 (0.1)
6 cycles per degree		
Baseline	1.3 (0.07)	1.1 (0.0)
Month 1	1.5 (0.07)	1.3 (0.1)
Month 3	1.4 (0.09)	1.3 (0.1)
9 cycles per degree		
Baseline	0.8 (0.05)	0.6 (0.0)
Month 1	0.9 (0.07)	0.8 (0.1)
Month 3	0.9 (1.0)	0.8 (0.1)
12 cycles per degree		
Baseline	0.3 (0.05)	0.2 (0.0)
Month 1	0.4 (0.07)	0.3 (0.1)
Month 3	0.4 (0.09)	0.3 (0.0)

Cohort 2 Analysis: Repeat PBM Treatment Evaluation

Visual Acuity

In cohort 2, participants had a similar high baseline visual acuity of 76.7 letters (60–85 letters). Following repeat series of PBM treatment, significant improvements in VA were observed at month 1 ($p=0.0049$) and month 3 ($p=0.0313$) timepoints. At month 1, 0.0% of eyes showed vision loss, 34.6% of eyes showed vision gain (5–10 letters), 65.4% of eyes showed maintained vision (no change). The mean change from baseline was 2.1 (month 1) and 1.7 (month 3) letters (Table 2, Fig. 2).

Contrast Sensitivity

CS showed significant improvements following repeated PBM treatment at month 1 and month 3 timepoints at 3, 6, 9, and 12 cycles per degree ($p<0.05$). The largest improvements were observed at 3 and 6 cycles per degree at both month 1 and month 3 (Table 3, Fig. 3).

Electroretinography (ERG)

A significant improvement was observed in ML-ERG area ratio magnitude at month 1 ($p=0.0126$) and month 3 ($p=0.0109$). No effect was observed in ML-ERG area ratio phase ($p>0.05$). A significant improvement was observed in FL-ERG magnitude at month 1 ($p=0.0019$) and month 3 ($p=0.0440$). A significant improvement was observed in FL-ERG phase at month 3 ($p=0.0046$) (Table 4, Fig. 4).

Anatomical Analyses

OCT imaging was conducted for all eyes at baseline and after each treatment series. OCT analysis showed no signs of phototoxicity and no change in choroidal thickness in either cohort (data not shown).

DISCUSSION

This study explored the effects of multiwavelength PBM with Valeda in early-stage dry AMD participants with good vision. Participants received a single or repeated series of PBM treatment every 4 months with up to 16 months of follow-up. Treatment with Valeda showed improvements on multiple outcome measures including VA, CS, ERG, and no adverse effects. Beneficial effects were improved with repeated PBM treatment series. Participants with good vision observed visual benefits, even with outcome measures that showed a limited deficit at baseline. Furthermore, no decline in visual output extending out to 16 months was noted.

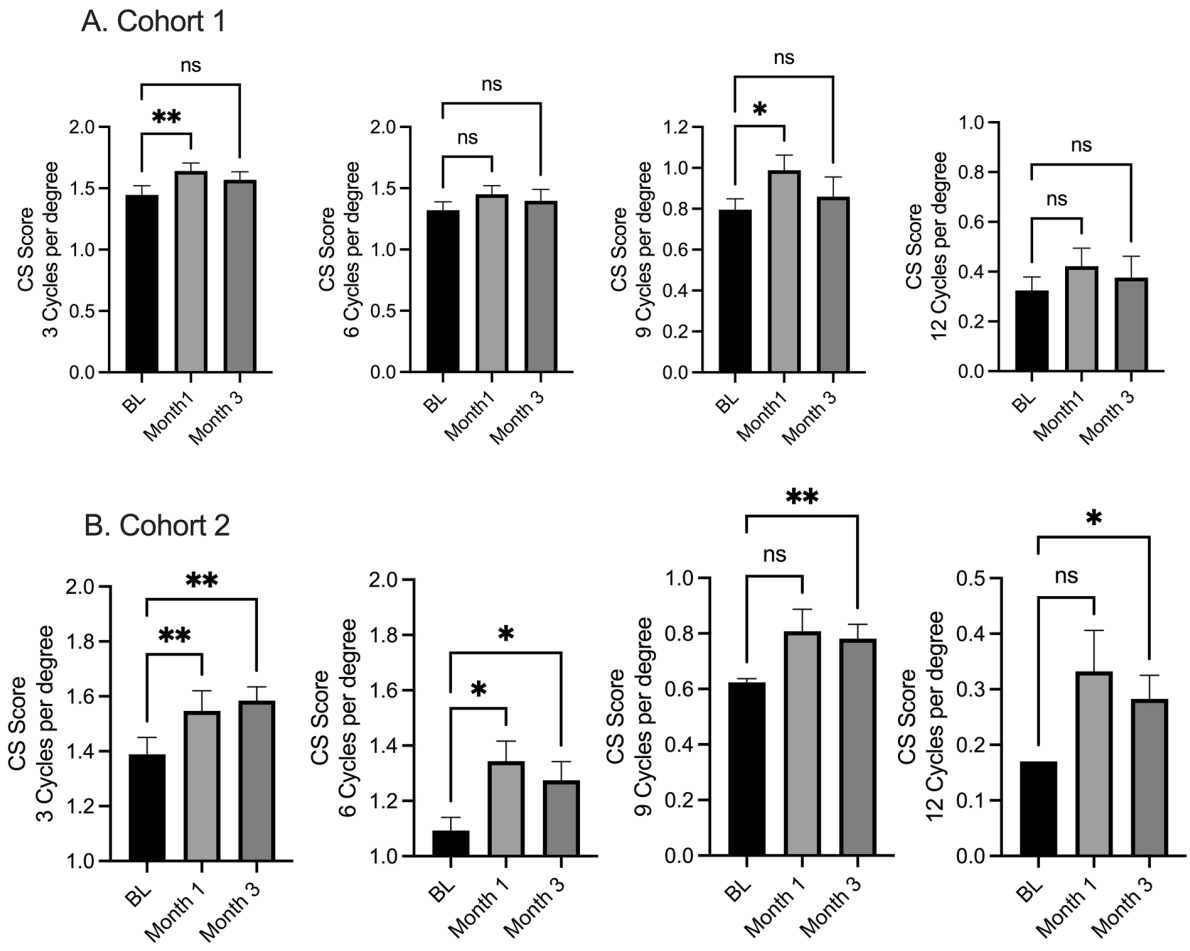

Fig. 3 Contrast sensitivity analyses. Contrast Sensitivity (CS)

No signs of toxicity or adverse effects related to the treatment were reported.

With degenerative disease states, it is imperative to intervene at earlier stages before pathological progression renders the diseased tissue incapable of salvation. PBM represents a modality that improves tissue health and integrity and is thereby poised for high impact by allowing intervention at an early stage to improve vulnerable tissue and thus delay progressive decline due to disease. When patients are diagnosed with AMD, a comprehensive eye exam confirms disease through pathology and clinical symptomology. Early detection and diagnosis allow for a window in which interventional treatments can impart benefits at initial signs of deterioration. PBM provides a mechanistic approach to promote bioenergetic output and cellular cytoprotection at the first sign of cellular disruption, when tissue is still viable. Treatment with Valeda in later stages of disease after significant and irreversible loss of tissue (e.g., GA) may not be as effective with less viable tissue available for mechanistic influence [12].

A challenge to starting treatment early is the limited capacity to demonstrate clinical benefits as the initial pathological deficits may not be robust. This study population included participants with a good starting VA baseline of approximately 20/32 Snellen. This population may not show robust magnitude effects as their starting vision does not show serious deficits; however, as a result of the degenerative and progressive nature of the disease, early treatment

Table 4 Multi-luminance and fixed-luminance electroretinography

	Baseline	Month 1	Month 3
Cohort 1			
ML-ERG			
Area ratio magnitude	0.9 (0.03)	0.9 (0.04)	0.9 (0.05)
Area ratio phase	0.9 (0.05)	1.0 (0.05)	1.1 (0.06)
FL-ERG			
Magnitude	7.5 (0.4)	8.1 (0.5)	8.7 (0.7)
Phase	281.0 (4.9)	279.6 (4.4)	290.5 (4.5)
Magnitude variance ratio	1.0 (0.01)	1.0 (0.01)	1.0 (0.03)
Phase variance ratio	105.9 (2.6)	1.1 (0.0)	1.1 (0.01)
Cohort 2			
ML-ERG			
Area ratio magnitude	0.7 (0.0)	0.8 (0.0)	0.8 (0.0)
Area ratio phase	0.9 (0.1)	0.9 (0.1)	0.8 (0.0)
FL-ERG			
Magnitude	6.3 (0.4)	7.5 (0.5)	7.0 (0.4)
Phase	279.1 (5.4)	282.2 (4.9)	288.9 (5.1)
Magnitude variance ratio	1.2 (0.2)	1.0 (0.02)	1.0 (0.02)
Phase variance ratio	1.1 (0.02)	1.1 (0.01)	1.1 (0.0)

Multi-luminance electroretinography (ML-ERG) and fixed-luminance electroretinography (FL-ERG)

and continued monitoring of these outcomes are of interest. The current study showed statistically significant improvements in all outcomes assessed, including VA, CS, and ERG using a repeated measure design. Moreover, additional benefits were observed in eyes that received more than one series of PBM treatment with Valeda. These findings demonstrate that patients with earlier stage dry AMD with good vision are capable of showing significant improvements in multiple measures of visual assessment following PBM treatment with Valeda.

This study builds on the LIGHTSITE trials [11–13] by evaluating participants with slightly better vision and similarly show improvements in VA and/or maintained vision. Participants had good starting baseline (~ 20/32 Snellen), but still showed a vision gain of 5 letters in 26.8% of eyes after one series of treatment, and a vision gain in 33.9% of eyes after multiple PBM treatment series was observed. No participants treated showed any loss of VA during the study follow-up time extending up to 16 months for some participants. The mean VA gains were approximately 1–2 letters and not considered a robust improvement; however, any gain in patients with good vision who have a progressive disease is beneficial, especially when a loss of 2.5 letters per year is projected for early/intermediate dry AMD diagnosis [14]. While VA is considered the hallmark clinical measure for visual function, CS and ERG provide supportive markers for overall visual output. These measures also showed

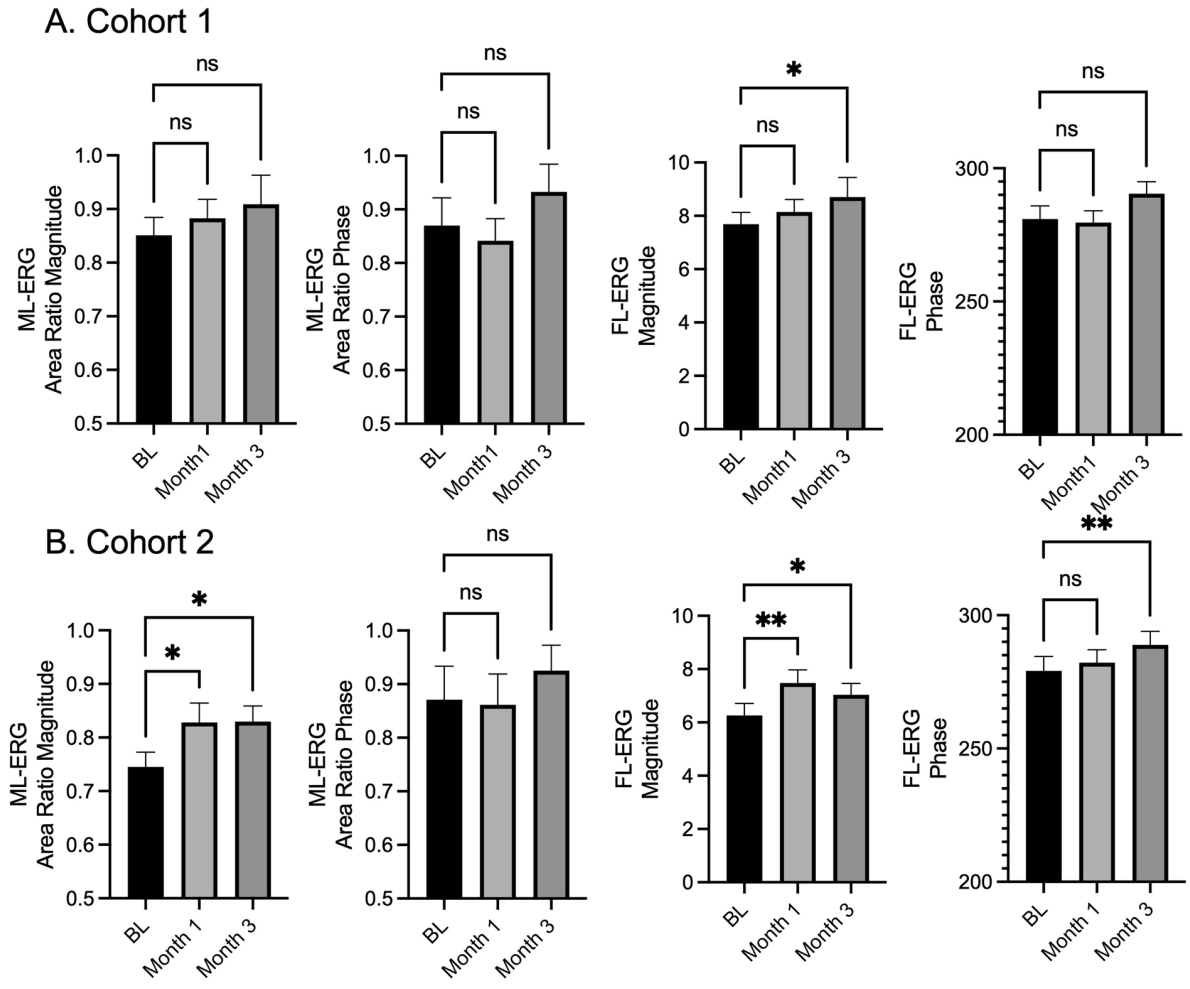

Fig. 4 Fixed-luminance and multi-focal electroretinography analyses. Multi-luminance electroretinography (ML-ERG) and fixed-luminance electroretinography (FL-ERG)

statistically significant improvement following Valeda. Collectively, these data indicate that even patients with early signs of disease can benefit from PBM treatment.

No safety issues were reported by any participants. This is consistent with prior PBM studies in the eye and the use of PBM in other medical indications [15]. Of note, the majority of participants with AMD are elderly. In this study the average age was over 70 years of age. Many patients in this age range are on a variety of medications. The use of PBM does not typically present a risk factor for any drug interactions or concerns with other medications. The only medications to consider would be those that may induce sensitivity to light. This is a major benefit to the use of this type of treatment and integration into a comprehensive patient health plan where multidrug use is common.

No issue with patient compliance using the recommended repeat PBM treatment protocol was observed. With proper patient education, patients understand the progressive nature of their AMD diagnosis and that PBM does not represent a cure but a treatment that can help stimulate and maintain the health of retinal tissue through repeat treatments. The elderly population is affected by other chronic conditions

that require repeated treatment protocols and similarly show high compliance. One such example is patients on dialysis who commonly undergo thrice-weekly dialysis sessions. Regardless, patients receiving dialysis treatment show a good rate of compliance with nonadherence to treatment generally reported at rates between 8.5% and 22.1% globally [16]. Compliance is also improved with patient education and understanding, and this can be expected in the AMD population as patients quite literally see the progressive impact of their disease in real time. This patient population is motivated to keep their vision so the repeat treatment protocol was not expected to affect compliance, as was observed in this study.

The study has several limitations. These include the retrospective and pilot nature of the design, the limited numbers of participants in the repeated treatment group, and lack of a control arm. While OCT imaging was reviewed for safety, fundus autofluorescence was not assessed and did not provide any monitoring of change over time. Evaluating early stages of disease represents a significant challenge wherein interventional treatment effects may be difficult to determine as vision deficits are not robust. Longer evaluations are necessary to watch the effects of PBM over time as disease pathological progression is expected to occur.

CONCLUSION

PBM treatment with Valeda improved multiple aspects of visual function in patients with earlier stage dry AMD with good vision. These findings add to the growing evidence demonstrating the benefit of treating early with Valeda and the strong benefit to risk profile with no adverse effects reported.

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Data Availability. The datasets generated during and/or analyzed during the current study are available on reasonable request from the corresponding author.

Declarations

Conflicts of Interest. Cem Küçükerdönmez declares that he has no competing interests. Stephanie Tedford is an employee of LumiThera.

Ethical Approval. Written informed consent was obtained from all participants in this study prior to receiving treatment with Valeda. Consent allowed for data review and publication efforts. Institutional review board/ethics committee approval was obtained from Netgoz Eye Hospital (Bayrakli, Izmir, Turkey). This study was conducted in compliance with the protocol, Good Clinical Practice guidelines, the guidelines of the Declaration of Helsinki and all other applicable regulatory requirements.

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