Non-invasive Treatment of Early Diabetic Macular Edema

by Multi-Wavelength Photobiomodulation with the Valeda Light Delivery System

[1]Inken S. Becker, MSc, [1]Hartmut Schwahn, PhD, [2,4]Marion R. Munk, MD, PhD, [3]Stephanie Tedford, PhD, [3]Cindy Croissant, MBA, [3,4]René Rückert, MD, MBA, [3]Clark E. Tedford, PhD and [1,5]Hakan Kaymak, MD

Affiliations: [1]I.I.O. Breyer Kaymak Klabe, Dusseldorf, Germany [2]Department of Ophthalmology, Inselspital University Hospital Bern, Bern, Switzerland, [3]LumiThera, Inc., Poulsbo, United States, [4]Eyegnos Consulting, Bern, Switzerland, [5]Experimental Ophthalmology, University Hospital and Medical Faculty of the University of Saarland, Homburg/Saar, Germany ; Contact: i.becker@augenchirurgie.clinic

PURPOSE

The complex pathophysiology of DME results in extracellular fluid accumulation and in decreased visual function. Light-based Photobiomodulation (PBM) provides a non-invasive treatment strategy that directly targets the underlying pathology through light-sensitive cellular cascades. The Valeda Light Delivery System™ is a multiwavelength PBM device and provides clinical benefit in the treatment of AMD (cf. LIGHTSITE I & II).

We investigate the beneficial effects of Valeda PBM on objective and subjective visual function in early DME.

METHODS

Treatment:

30 eyes from 19 DME patients (56 ± 14 yrs, range: 27-76, 68% male) with good visual acuity (VA) (0.08 ± 0.13 logMAR, range: -0.1 – 0.4) and macula edema were treated with one series of 9 PBM treatments (about 3 times a week for 3 to 4 weeks). The Valeda device delivers 590, 660 and 850 nm of light produced by a non-coherent light source. Each session takes less than 5 minutes with 2 rounds of 2 distinct consecutive periods.

Assessment:

The patients were assessed for clinical (i.e., best-corrected VA), anatomical (i.e., Central Retinal Thickness (CRT), Intraretinal Fluid (IRF), Epiretinal Membrane (ERM), Disorganization of the retinal inner layers (DRIL) and Hard Exudates (HE)) and safety outcomes (integrity of EZ, IZ, ELM, RPE). Wide field color fundus photography (Optos) prior and after PBM treatment was assessed using diabetes retinopathy severity scale (DRSS) by a retina expert. OCT (Zeiss) assessments and patients´ subjective evaluations (via questionnaire) were conducted before PBM treatments at baseline (BL), after final treatment and at follow up visits that extended up to 16 months.

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RESULTS

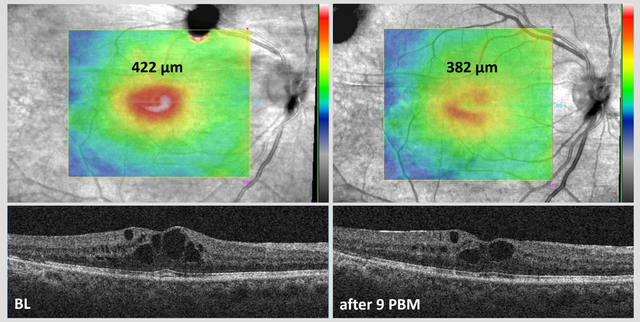
A total of 9 of the 30 eyes were previously treated with IVTs of a-VEGF (8) or Ozurdex (1) and 7 eyes with focal laser. 17 of the 30 eyes did not need any IVT during the observation period.

DRSS score	Baseline (%)
20.00	21.4
35.00	46.4
43.00	10.7
47.00	14.3
53.00	3.6
65.00	3.6
Total	100.0

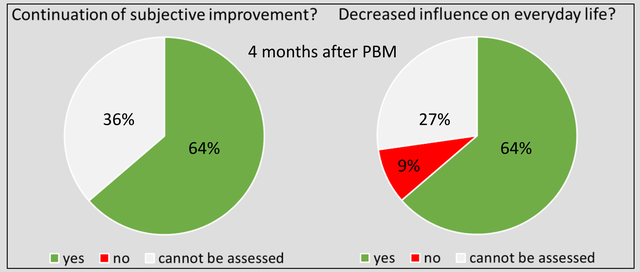
Table 1.
DRSS score at BL.

DRSS at BL scores ranged from very mild NPDR (20) to moderate PDR (65) (Tab. 1). DRIL was present at BL in 3.3%, an ERM in 23.3%. Disrupted RPE and photoreceptor layers due to prior focal laser treatment were present in 16.7% and 23% of cases, respectively. RPE and photoreceptor attenuation due to the underlying disease were found in 10% and 17% of eyes, respectively. After 9 PBM treatments the DRSS scores showed a 1 step improvement in 17% of the eyes, in 83% the DRSS score remained stable.

A selected patient showed a 1 step improvement in DRSS scoring from 47 (moderate DRP) to 43. Significant reduction of hemorrhage and IRMAs is seen in color fundus imaging from BL (top) after 9 PBM treatments (bottom). The VA slightly increased from 0.08 ± 0.12 to 0.06 ± 0.08 (logMAR).



CRT at BL was 294 ± 51 µm and significantly reduced to 286 ± 42 µm (**p=0.027**; paired T-test). After the Valeda treatment, the presence of IRF overall was reduced from 90% to 70% (**p=0.031**; McNemar). Presence of IRF in the central 1 mm reduced from 70% to 57% (**p=0.125;** McNemar). HE were present at BL and were significantly reduced by the PBM treatment from 66.7% to 46.7% (**p=0.031**; McNemar). There was no change in the other morphological efficacy and safety parameters including DRIL, ERM and integrity of the outer retina during the whole follow up period.



More than 60% of the patients treated with one series of PBM for 3 to 4 weeks noted a continuation of their subjective improvement and a decreased influence on their daily life 4 months after the PBM treatments.

SUMMARY - PBM ON DME

The early treatment of DME using PBM is a viable and safe approach to stabilize functional and anatomical parameters and prevent DME and DR progression.

DISCUSSION

This ongoing pilot study in patients with early-stage DME provided compelling evidence that the PBM treatment with the Valeda device is effective even after only a single treatment course of 9 treatments over a course of 3 to 4 weeks.

Several anatomical parameters showed a significant improvement without the need for invasive treatments. The PBM treatment was very well tolerated, no signs of (photo-) toxicity were observed based on functional and anatomical outcomes assessed. Moreover, the subjective evaluation concerning continuation of improvement and decreased influence on daily life showed positive results. This data supports the benefit of PBM treatment using the Valeda device in retinal pathologies and adds to the successful use demonstrated in prospective clinical trials for dry AMD and expands the potential use to DME and DR.

CONCLUSION

Anatomical benefits and subjective evaluations suggest disease-modifying effect with PBM treatment in patients with early DME. The patients typically had good vision and nearly normal CRT but clear evidence of macular edema. This data supports the safe and effective use of the Valeda and PBM in early diabetic retinopathy and macular edema patients.

REFERENCES

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