## Photobiomodulation induces drusen regression with improvements in visual acuity and contrast sensitivity in subjects with dry AMD.



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Drs. Merry and Dotson report a significant financial interest in Photospectra and Lumithera. The other authors report receiving consulting fees from Lumithera Inc.

## **AIM and METHODS**

- The aim of this study was to assess **both functional** and **anatomical** benefits of Photobiomodulation (PBM) utilizing ETDRS BCVA, FACT Contrast Sensitivity and OCT changes of drusen volume.
- PBM is the application of low energy, eye safe, light of specific wavelengths to modify and improve the function of targeted cells by action on cytochrome c oxidase, a key enzyme for cell bioenergetics.
- 42 eyes of 24 subjects with dry AMD, AREDS categories 2, 3 and 4 (GA), who had consented and completed a treatment course with PBM were evaluated for changes in Vision, Contrast sensitivity and Drusen volume with linear mixed analyses.
- The PBM treatment is a non invasive, easily administered and comfortable intervention consisting of LED sourced multi wavelength light of Red (670nm), Yellow (590nm) and Infra Red (790nm) applied to subjects eyes for 5 minutes per eye over nine sessions in a 3 week period.
- Results are graphically represented on the next 2 pages.







A statistically significant improvement of mean ETDRS VA of 5.9 letters (p<0.001) was seen immediately following the treatment. The improvement was maintained for 3 months.

Immediately following the treatment 48% of eyes improved between 6 to 10 ETDRS letters, i.e. a BCVA gain of greater than 1 line. 12% of study eyes improved between 11 to 15 ETDRS letters, i.e. a BCVA gain of greater than 2 lines.

A statistically significant improvement of  $+0.11 \log$ units at 3 cycles per degree (CPD) (p = 0.02) was seen in contrast sensitivity immediately following the treatment course. The improvement was maintained for 3 months.

### **DRUSEN VOLUME REDUCTION**

Group	∆ Baseline Mean mm <sup>3</sup>	p Value
Central Drusen Volume Baseline vs. Visit 1 (1 month)	.024	P = 0.0008
Central Drusen Volume Baseline vs. Visit 2 (3 month)	.029	P = 0.02



Significant mean drusen volume reduction of  $0.024 \text{ mm}^3$  (p < 0.001) and central drusen thickness reduction of mean 3.78 microns (p < 0.001) was seen immediately following the treatment. The improvement was maintained for 3 months.

Some representative OCT (Heidelberg Spectralis) scans are shown on the next page.

#### **EXAMPLES OF INDIVIDUAL OCT SCANS**



This shows a segmented subtraction map of RPE layer change in an eye from an AREDS Grade 3 subject at 3 months post treatment depicting a significant drusen regression.



This individual cut subtraction scan of another subject shows significant drusen regression at 3 months following the treatment course.



Shown here are the subtraction scans from both eyes of a 72yr old female immediately following the treatment with a better than 5 letter VA increase.

# CONCLUSIONS

- This is the first study to show improvements in functional (VA and CS) and anatomical outcomes (drusen reduction) with PBM. Positive benefits are seen immediately post treatment and maintained out to 3 months suggesting disease modifying benefits.
- Based on the presented data the LIGHTSITE clinical trial has been initiated. This is a Health Canada and IRB approved clinical trial of 30 subjects, randomized, sham controlled and double masked with the Lumithera LT300 LED class 2 device pictured opposite.
- The trial is currently enrolling in Toronto, Canada and has been partially funded by a N.I.H. National Eye Institute grant.
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