



ORAL PRESENTATION

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# Utilizing 5-aminolevulinic acid and pulsed dye laser for photodynamic therapy of oral leukoplakia – pilot study

Gal Shafirstein<sup>1\*</sup>, Wolfgang Bäuml<sup>2</sup>, Eric Sigel<sup>3</sup>, Chun-Yang Fan<sup>4,5</sup>, Kimberly Berry<sup>1</sup>, Emre Vural<sup>1,5</sup>, Brendan C Stack<sup>1</sup>, James Y Suen<sup>1</sup>

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## Objective

Determine the safety and efficacy of photodynamic therapy (PDT) in the treatment of oral leukoplakia with 5-aminolevulinic acid (5-ALA) and pulsed dye laser (PDL).

## Methods

A total of 24 subjects, between 18 - 80 years old, with a confirmed diagnosis of leukoplakia with or without dysplasia, measuring at least 10 mm in diameter were enrolled in cohorts of 3 within 24 months. Twenty percent solution of 5-ALA, Levulan Kerastick<sup>TM</sup> were applied to the lesions, for 1 to 3 hours, by utilizing custom fixtures made from hygienic polymer. The drug application was confirmed with Fluorescence diagnosis system (Dyaderm<sup>TM</sup>). High power pulsed dye laser emitting 585-nm wavelength was used to activate the 5-ALA. The laser dose was escalated from 6 to 8 J/cm<sup>2</sup>. The safety was evaluated via clinical observation 48 hours post treatment, and the clinical and pathological efficacy were evaluated 30 and 90 days after treatment, respectively. Histopathology and immunohistochemistry were conducted on fixed tissue samples collected at screening and 90 days post treatments, from the lesion and an adjacent healthy site.

## Results

No significant adverse events and minor pain (3 out of 10) was observed, during and following PDT in the safety phase of the study. The maximum tolerated dose was 8 J/cm<sup>2</sup>. Partial response was observed in 54% of the treated subjects and significant response was

observed in 46% of the subject treated in the efficacy phase of the study.

## Conclusions

Photodynamic therapy (PDT) with 5-Aminolevulinic Acid (5-ALA) and PDL could be use to regress oral leukoplakia. The treatment is safe and well tolerated. Thick and progress lesions require multiple treatments. An application time of 2 hours and laser radiant exposure of 8 J/cm<sup>2</sup> were found to be the best settings, in this study. The high power laser allows completing the laser therapy within 1-3 minutes. More work is underway to determine the optimal laser radiant exposure and drug application to improve the rate of complete regression.

## Author details

<sup>1</sup>Department of Otolaryngology, University of Arkansas for Medical Sciences, Little Rock, United States . <sup>2</sup>Department of Dermatology, Regensburg University, Regensburg, Germany . <sup>3</sup>Department of Biostatistics, University of Arkansas for Medical Sciences, Little Rock, USA . <sup>4</sup>Department of Pathology, University of Arkansas for Medical Sciences, Little Rock, USA . <sup>5</sup>Medical Research Service, Central Arkansas Veterans Healthcare System, Little Rock, USA.

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<sup>1</sup>Department of Otolaryngology, University of Arkansas for Medical Sciences, Little Rock, United States

Full list of author information is available at the end of the article