

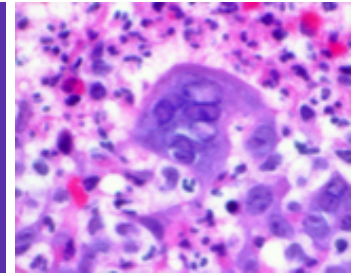


# eLITERATURE REVIEW

## eMedicalDermatology Review

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- HOME
- CME/CNE INFORMATION
- PROGRAM DIRECTOR
- NEWSLETTER ARCHIVE
- EDIT PROFILE
- RECOMMEND TO A COLLEAGUE

## April 2007: VOLUME 1, NUMBER 1

### Welcome...

Johns Hopkins University School of Medicine, The Institute for Johns Hopkins Nursing and the University of Tennessee College of Pharmacy are pleased to welcome you to this premier issue of **eMedicalDermatology Review**. Over the course of this series, we will be reporting on issues critical to providing effective and safe care for patients with medical dermatological conditions.

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### In This Issue...

#### *Photodynamic Therapy for Acne*

Acne is one of the most prevalent skin diseases and a leading reason patients seek dermatologic care. With few new treatments available for acne, we often must rely on our standard topical and oral agents. Nodulocystic acne continues to plague both patients and dermatologists alike, with little therapeutic options other than oral isotretinoin, which has become cumbersome to use in the past year because of the new regulatory issues.

However, over the past several years, research has provided us with a new technology to offer our acne patients. Photodynamic therapy, which has been used for a variety of other skin disorders, has now been studied in acne. In this issue, we review some of the research into photodynamic therapy for acne, focusing on the mechanism of action and the use of different light sources.

## THIS ISSUE

- [COMMENTARY](#) from our Guest Editor [Opinion](#)
- [PHOTODYNAMIC THERAPY \(PDT\) FOR ACNE: EFFICACY](#)
- [PDT WITH RED LIGHT FOR ACNE: CLINICAL EFFICACY AN MECHANISMS](#)
- [PDT FOR ACNE: INTENSE PULSED LIGHT \(IPL\)](#)
- [PDT FOR ACNE: PULSED DYE LASER](#)

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- [CE Info](#)
- [Accreditation](#)
- [Credit Designations](#)
- [Target Audience](#)
- [Learning Objectives](#)
- [Internet CME/CNE Policy](#)
- [Faculty Disclosure](#)
- [Disclaimer Statement](#)

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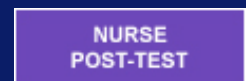
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**Guest Faculty Disclosure**

**Susan Matra Rabizadeh, MD, MBA,** has disclosed no relationship with commercial supporters.

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The author has indicated the off-label use of Levulan in the treatment of acne.

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**At the conclusion of this activity, participants should be able to:**

- Describe the mechanism by which photodynamic therapy (PDT) is theorized to work in the treatment of acne
- Identify at least three different light sources that have been tested in the treatment of acne using photodynamic therapy
- Describe the side effects associated with photodynamic therapy for acne

## COMMENTARY

Acne affects approximately 50 million Americans, and is responsible for an estimated \$3.1 billion spent annually on direct and indirect medical costs<sup>[1]</sup>. The variety of topical and oral agents available generally only control the disease; recurrences are frequent once the medication is discontinued. While oral isotretinoin has been the most successful treatment for moderate to severe acne, there is increasing concern about its potential for side effects. Further, with the advent of the iPLEDGE system, many dermatologists and patients are looking for alternative treatments for acne.

The pathogenesis of acne is often associated with several factors, including increased sebum production, altered differentiation of the pilosebaceous duct, colonization of the follicle by *P. acnes*, and inflammation<sup>[2]</sup>. Light based and laser therapies have long been used to treat acne, primarily by targeting *P. acnes*, the sebaceous gland, or both.

Topical photodynamic therapy (PDT) uses the application of aminolevulinic acid (ALA), which is preferentially taken up by the pilosebaceous units and metabolized through the heme synthesis pathway to produce protoporphyrin IX. When protoporphyrin is photoactivated, the singlet oxygen species and free radicals produced are cytotoxic. This results in death of *P. acnes* and damage to the pilosebaceous unit itself, as demonstrated in the study by Hongcharu et al (reviewed herein). This information has led to numerous other studies that have tried to delineate which light source is optimal for treating acne with

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photodynamic therapy.

Initially, visible light was studied, as ALA is activated in the visible spectrum. Small pilot studies with PDT using blue light did find modest improvement in inflammatory acne<sup>[3,4]</sup>; however blue light may be limited by the depth of penetration. Red light-PDT appears to be effective for inflammatory acne, as demonstrated in the Hongcharu, Pollock, and Horfelt reports. However, in all of these studies, there were severe adverse effects, in particular pain, erythema, and hyperpigmentation. This may have been due to the long incubation times used for the ALA, the light source, or a combination of both.

Interestingly, the results from studies using intense pulsed light (IPL) with photodynamic therapy (which has one of the widest wavelength spectrums) have been more varied, as demonstrated by both the Yeung and Santos studies. This may be attributable to the variability in both settings and IPL units used among the different studies. So far, the most impressive results stem from the study by Alexiades-Armenakas, which analyzed the use of a long pulsed dye laser with photodynamic therapy for acne. Other reports have also found benefit with pulsed dye laser alone<sup>[5]</sup>. Photodynamic therapy using the pulsed dye laser appears to be more effective than other light or laser sources; it is speculated that part of this efficacy may be the result of treating the erythema associated with inflammatory acne.

Photodynamic therapy is an exciting new technology that is being used for a variety of dermatologic disorders, and the initial studies for acne (reviewed herein) are quite promising. The stage has been set for larger, randomized controlled trials that will allow us to ultimately identify the best light source, settings, incubation time, and protocol for treating our acne patients.

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1. Bickers DR, Lim HW, Margolis D, Weinstock MA, Goodman C, Faulkner E, Gould C, Gemmen E. [The burden of skin diseases: 2004 a joint project of the American Academy of Dermatology Association and the Society for Investigative Dermatology](#). Journal of American Academy of Dermatology. 2006 Sep; 55(3) 490-500.
2. Nestor MS. [The use of photodynamic therapy for treatment of acne vulgaris](#). Dermatology clinics. 2007 Jan; 25(1): 47-57.
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4. Taub AF. [Photodynamic therapy for the treatment of acne: a pilot study](#). Journal of drugs in dermatology. 2004 Nov-Dec; 3(6 suppl): S10-4
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## PHOTODYNAMIC THERAPY (PDT) FOR ACNE: EFFICACY

Wichai Hongcharu, Charles R. Taylor, Yuchaio Chang, David Aghassi, Kittisak Suthamjariya, R. Rox Anderson. **Topical ALA-photodynamic therapy for the treatment of acne vulgaris**. Journal of Investigative Dermatology, 115: 183-192, 2000.

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One of the first open label prospective studies using photodynamic therapy for acne was performed in 2000 by Hongcharu et al. 22 subjects with acne on the

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back were treated in four sites with aminolevulinic acid (ALA) plus red light, aminolevulinic acid alone, red light alone, or untreated control. 20% topical ALA was applied for 3 hours under occlusion and 150J/cm<sup>2</sup> of broad band light (550-700nm) was given. Subjects were randomized to single-treatment and multiple-treatment groups. In the multiple-treatment group, subjects were treated once a week for 4 consecutive weeks. Clinical evaluation using an inflammatory acne score was globally assessed by three blinded dermatologists. Fluorescence of hair follicles populated with *P. acnes* was measured, and sebum-absorbent tape was used to evaluate human sebum excretion. These parameters were measured at baseline, and at 2, 3, 10, and 20 weeks after treatment. Punch biopsies were taken immediately after PDT, a few weeks after, and at 20 weeks after, from both untreated control and ALA-PDT treated areas. Sebaceous gland area and the cytoplasm/nuclear area ratio in sebocytes were calculated and compared between the control and PDT areas at each follow-up. Protoporphyrin IX production and localization was also analyzed from biopsies taken 3 hours after ALA incubation.

The researchers found statistically significant improvements in acne with ALA-red light for up to 20 weeks in the multiple-treatment group, and for up to 10 weeks in the single-treatment group — compared to ALA alone, light alone, or untreated sites. The global clinical improvement score of the PDT sites also showed significant improvement compared to controls. Only the PDT treated sites showed significant loss of fluorescence related to *P. acnes* in both the single and multiple treatment groups, a finding that was reported out to 20 weeks. Also, only those groups treated with PDT showed a significant decrease in sebum output at all follow-up visits. Histologically, there was a decrease in sebaceous gland size with frank sebaceous gland destruction by a mixed neutrophil predominant infiltrate, as well as a decrease in the cytoplasm/nuclear area ratio. These results were more pronounced at 20 weeks in the multi-treatment group than in the single treatment group. An acute eruption of inflammatory acneiform lesions was observed in the ALA-PDT sites in all patients starting 3-4 days post treatment. In the multiple-treatment group, less acne was produced after each treatment, such that almost no new lesions were observed after treatment four. Subjects reported pain, burning and itch during treatment, and erythema, edema, hyperpigmentation, and exfoliation were seen, although in most patients these resolved within several weeks.

In normal epidermis, hair follicles and sebaceous glands accumulate protoporphyrin IX after systemic ALA administration<sup>[1]</sup>. Hongcharu's study shows that ALA-induced protoporphyrin IX fluorescence is greater in acne lesions than in surrounding tissue. This sentinel study suggests therefore that ALA-PDT may have several modes of action, including: direct damage to sebaceous glands that may inhibit sebum production; killing of *P. acnes*; and possibly reducing follicular obstruction by changing keratinocyte shedding and hyperkeratosis. Note, however, that the study is limited by its small size and aggressive approach to applying and incubating ALA. Further, the long incubation may have led to fairly significant pain and side effects. Those concerns notwithstanding, this pilot study was one of the first to show clinical improvement in acne using photodynamic therapy; in addition, the histological and fluorescence evaluations suggest mechanistically how photodynamic therapy may work in acne.

## References

1. Divaris DX et al [Phototoxic damage to sebaceous glands and hair follicles of mice after systemic administration of 5-aminolevulinic acid correlates with localized protoporphyrin IX fluorescence](#). Am Journal of Pathology. 136. 891-897. 1990)

Pollock B, Turner D, Stringer MR, Bojar RA, Goulden V, Stables GI, Cunliffe WJ. **Topical aminolevulinic acid-photodynamic therapy for the treatment of acne vulgaris: a study of clinical efficacy and mechanism of action.** British Journal of Dermatology. Sep 2004, 151(3): 616.

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Horfelt C, Funk J, Frohm-Nilsson M, Wiegleb Edstrom D, Wennberg AM. **Topical methyl aminolevulinate photodynamic therapy for treatment of facial acne vulgaris: results of a randomized, controlled trial.** British Journal of Dermatology. Sep 2006; 155(3) 608-613.

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Pollock's 2004 follow-up to Hongharu's 2000 study looked at 10 patients with acne and evaluated four equally affected sites on their backs with ALA-PDT, light alone, ALA alone, or an untreated control site. Lesion counts were performed, sebum excretion measured, and P. acnes swabs performed at baseline and following each treatment. 20% ALA cream was applied under occlusion to the treatment sites for 3 hours. Diode laser was used (635nm, 25 mW/cm<sup>2</sup>, 15 J/cm<sup>2</sup>) as a red light source. Porphyrin fluorescence spectra were recorded at the skin surface before and after each treatment. Patients were treated weekly for 3 weeks.

Two years later, Horfelt et al studied 30 patients with moderate to severe acne in a blinded, prospective, randomized, placebo-controlled multicenter trial. A split-face design randomized subjects to either methyl aminolevulinic acid (MAL) cream or placebo, occluded and incubated for 3 hours. A non-coherent red light (average wavelength of 635 nm, light dose 37 J/cm<sup>2</sup>) was used to illuminate both sides. All subjects received a second treatment 2 weeks later. They were evaluated at baseline and again at 4 and at 10 weeks after the last PDT treatment.

Results from Pollock's study showed a statistically significant reduction in inflammatory acne lesion counts from baseline after the second treatment only at the ALA-PDT site. Although the number of P. acnes was reduced in the ALA-PDT site, and there was a trend toward decreased sebum production in the ALA-PDT and light alone sites, neither finding reached statistical significance. Main adverse events were discomfort during the procedure, and mild urticarial or perifollicular eruption that resolved within 1-2 hours after the procedure. Post inflammatory hyperpigmentation was seen in all subjects.

The Horfelt study found that the MAL-PDT therapy was significantly more effective than placebo in treating inflammatory lesions, with a median reduction of 63% vs 28% and 54% vs 20% at weeks 6 and 12 respectively. No statistical difference was noted in non-inflammatory lesions. Seventy percent of subjects reported adverse events, most frequently pain, erythema, and edema that lasted 7-10 days. Three subjects dropped out because of erythema and pain.

Although the number of patients enrolled was small, both studies found improvement with the 2 different (20% ALA cream and MAL) topical formulations used for photodynamic therapy. It is interesting to note that Pollock's group was able to achieve clinical results without significantly affecting sebum production or density of P. acnes as previously suggested by Hongharu - part of that difference could lie in the light source (one wavelength vs broad band light), a different

formulation of ALA (20% ALA cream vs 20% solution), and/or the length and number of treatments. Regardless of the true mechanism, it appears that ALA-PDT does have a clinical impact in improving acne. Although both red and blue light in the visible spectrum have been studied with PDT, these reports indicate that red light may be more effective than blue light, partially owing to its greater depth of penetration.

## PDT FOR ACNE: INTENSE PULSED LIGHT (IPL)

Yeung CK, Shek SY, Bjerring P, Yu CS, Kono T, Chan H. **A comparative study of intense pulsed light alone and its combination with photodynamic therapy for the treatment of facial acne in asian skin.** *Lasers in surgery and medicine* 39(1): 6, 2007.

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Santos MA, Belo VG, Santos G. **Effectiveness of photodynamic therapy with topical 5-aminolevulinic acid and intense pulsed light verses intense pulsed light alone in the treatment of acne vulgaris: comparative study.** *Dermatologic Surgery* 2005 August; 31(8 part 1): 910-5.

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Yeung et al studied 30 Chinese subjects with phototypes IV or V skin and moderate acne in a randomized, prospective, single blind, split-face trial. Subjects were randomized to half-facial treatments with methyl aminolevulinate (MAL) plus intense pulsed light (IPL), IPL alone, or control. One group received half-face with IPL and other side control; the other group received half-face PDT-IPL vs IPL alone. Photographs were taken before each treatment and at one month and at three months after the last treatment. Subjects received a total of four treatments at 3 week intervals. P. acnes fluorescence was also measured. The IPL wavelengths used were 532 nm and 577 nm, fluences of 7-9 J/cm<sup>2</sup> and spot size of 10x48 mm. All patients used adapalene 0.1% gel throughout the study.

The Santos study also looked at 15 subjects with acne using IPL with PDT. After a 3 week washout period, 20% ALA was applied to half the face; after 3 hours the entire face was then exposed to intense pulsed light with settings of 560 nm, fluence of 26 J/cm<sup>2</sup>. The procedure was done twice at 2 week intervals. Clinical evaluation was done on the second, fourth, and eighth weeks.

The results of the Yeung study were surprising, showing a 53% reduction in inflammatory lesion counts in the PDT-IPL group, 22% in the IPL alone group, and 72% in the control group after 4 weeks of treatment. Further, after 12 weeks post treatment, reduction in lesion counts were 65%, 23%, and 88% in the PDT-IPL, IPL alone, and control group respectively. Interestingly, reduction in non-inflammatory lesion counts was statistically significant for the ALA-PDT group compared with IPL alone or control groups after both 4 and 12 weeks, which is not a finding consistently seen in other studies. Although there was a trend toward greater reduction in fluorescence of P. acnes in the PDT group, the results were not statistically significant. Adverse effects were stinging, burning, erythema and edema, acute acneiform eruption, and some subjects in the PDT group had hyperpigmentation and crusting.

The Santos study found that most of the patients had visible improvement of facial acne on the ALA treated side of the face that persisted until 8 weeks post treatment, while at 8 weeks from the first treatment the IPL side was not

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significantly different. Most patients developed an acute eruption of acneiform lesions on the ALA-treated side 2 weeks after the first treatment, which improved by the fourth week.

Why did these two studies using IPL-PDT for acne show such different results, with Yeung's group reporting no improvement over baseline in the treatment group (in fact the control group improved more overall), versus the majority of Santos' patients responding clinically to IPL-PDT? Possible reasons for this difference in outcome include the small sample size of both studies, the use of different IPL machines with different settings, possibly darker skin subjects in Yeung's study (which limits the IPL settings), and the use of methyl aminolevulinic acid versus 20% 5-aminolevulinic acid. Further, an additional randomized split-face study (by Wiegell<sup>[1]</sup>) comparing the treatment effect and tolerability of 5-aminolevulinic acid and methyl aminolevulinic acid for acne using red light found no difference in response rate, tolerability, or adverse events.

As one of the biggest issues with using an IPL as a light source is the variability among the different machines and adjustable variables within the same machine; studies therefore are often difficult to compare. Ultimately, however, there appears to be ample evidence that IPL-PDT can be an effective adjuvant treatment for acne in some patients.

## References

1. Wiegell SR, Wulf HC. [Photodynamic therapy of acne vulgaris using 5-aminolevulinic acid versus methyl aminolevulinate](#). JAAD 2006;54(4):647-651.

## PDT FOR ACNE: PULSED DYE LASER

Alexiades-Armenakas, M. **Long-pulsed dye laser-mediated photodynamic therapy combined with topical therapy for mild to severe comedonal, inflammatory or cystic acne.** *Journal of drugs in dermatology*. Jan 2006; 5(1): 45-55.

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In this 2006 report, pulsed dye laser was used to evaluate efficacy in acne with concomitant use of PDT. This prospective, controlled, proof-of-principle study evaluated 19 patients with mild to severe acne. Skin types I-VI were included. 20% ALA was incubated for 45 minutes on the face, then treated with pulsed dye laser 595 nm, 7.0-7.5 J/cm<sup>2</sup>, 10 ms, 10 mm spot size. Patients received 1-6 monthly treatments. 14 patients were treated and 4 patients were used as controls. Patients were clinically evaluated at baseline and at each monthly follow-up.

In the pulsed dye mediated PDT group, Alexiades-Armenakas found complete clearance in 100% of patients, which was maintained for up to 13 months. Mean number of treatments to achieve clearance was 2.9 with mean follow-up of 6.4 months. Mean percent lesional clearance was 77% per treatment. All patients were maintained on their topical regimen, and additionally four patients received chemical peels every 2-4 months during follow-up. In the control patients who received just pulsed dye laser, the mean clearance rate per treatment was 32% without complete clearance after 3-4 treatments. In controls receiving conventional treatments (oral antibiotics and/or oral contraceptives, chemical peels, and topical medications without PDT), mean lesional clearance was 20% per treatment and clearance was not achieved after 6-10 months. Side effects reported in the pulsed-dye-PDT group include mild pain, erythema, and desquamation over a 1 week interval.

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The findings of this small study hold significant promise for pulsed-dye laser PDT as a safe and effective therapy for acne of all severities. In particular, the procedure appears to be a good alternative to isotretinoin in severe acne cases. However, the study's limitations include small sample size, inadequate number of controls, and a significant number of variables and potential confounders, such as variability in topical acne regimens and number of treatments. In addition, only a visual clinical scale was used to evaluate clearance and efficacy. More definitive data would have been provided had the authors also reported on histology of the sebaceous glands, sebum production, and fluorescence of P. acnes.

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- Identify at least three different light sources that have been tested in the treatment of acne using photodynamic therapy
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The presenting faculty reported the following:

- Bernard A. Cohen, MD has indicated a past and current financial relationship with Novartis, Pharmaceuticals, Astellas Pharma Inc., Medicis and Connetics. He served on the Speaker's Bureau for Novartis, Pharmaceuticals, Astellas Pharma Inc., and Medicis. He has also received grants for studies from Novartis, Pharmaceuticals and Astellas Pharma Inc. and received support for a fellowship program from Connetics.
- Susan Matra Rabizadeh MD, MBA has disclosed no relationship with commercial supporters.
- Mark Lebwohl, MD has disclosed that he has received grants for clinical research and educational activities from, has served as an advisor or consultant to, and has served as an investigator for Novartis and Astellas. Dr. Lebwohl has also disclosed that he serves as a speaker for Astellas.

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