Safety and Efficacy of Photodynamic Therapy with Aminolevulinic Acid 10% Topical Gel Activated by Red Light versus Aminolevulinic Acid 20% Topical Solution Activated by Blue Light for the Treatment of Actinic Keratosis on the Upper Extremities: A Blinded Randomized Study

Payvand Kamrani, DO[1]; Maya Firsowicz, MD[1]; Misha Zarbafian, MD[2]; Kavita Darji, MD[1]; Raheel Zubair, MD[1]; Lisa Ishii, MD[3]; Mitchel Goldman, MD[1]; Monica Boen, MD[1]

[1]Cosmetic Laser Dermatology; San Diego, CA, USA, [2]Rejuvenation Dermatology; Vancouver, BC, CA, [3]Aesthetic Solutions; Chapel Hill, NC, USA

Background and Objectives:

- Actinic Keratosis (AK) is a pre-cancerous skin neoplasm that can arise due to ultraviolet light damage
- Photodynamic therapy (PDT) using aminolaevulinic acid (ALA) 10% gel activated by red light is approved by the FDA for the treatment of AKs on the face and scalp, and ALA 20% solution activated by blue light is approved for PDT treatment of AKs on the face, scalp, and upper extremities
- No side-by-side studies comparing efficacy and safety of both treatments have been done

Study Design and Methods:

- Prospective, single-center, split-arm randomized clinical trial with 30 adult subjects with 4-17 clinically confirmed mild-moderate (Olsen grading) on each distal arm
- Subjects were treated with ALA 10% gel/red light and ALA 20% solution/blue light PDT on respective randomly selected upper extremities
- Primary endpoint: Lesion complete clearance rate (LCCR)
- Secondary endpoints: Complete lesion clearance per patient side (PatCR), LCCR of moderate lesions, LCCR 12 weeks after PDT-1, PatCR 12 weeks after PDT-1, overall cosmetic outcome assessed by the investigator, and patient satisfaction

Results:

- 30 patients enrolled and received PDT1, 25 patients received PDT2
- Mean baseline AK was 11 for ALA 10% and 12 for ALA 20%
- LCCR was significantly greater for ALA 10% vs ALA 20% at Day 120
- LCCR after PDT1 was 65% and 58% for ALA 10% and ALA 20%, respectively
- LCCR after PDT2 was 88% and 72% for ALA 10% and ALA 20%, respectively
- No statistical difference in subject reported pain or satisfaction rating

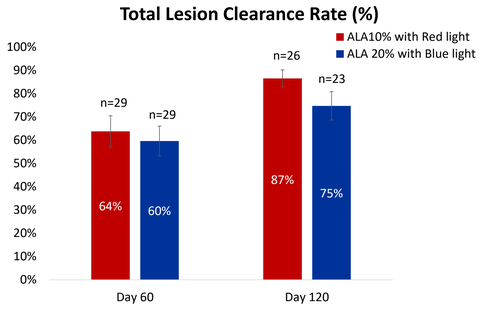


Figure 1. Total lesion clearance rate (TLCR) at 60 days, 120 days

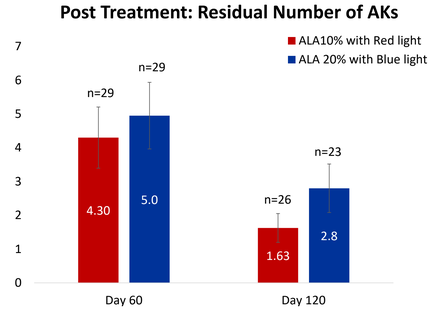
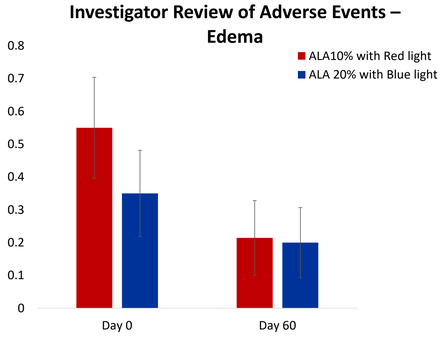


Figure 2. Residual AK count following 2 PDT treatments



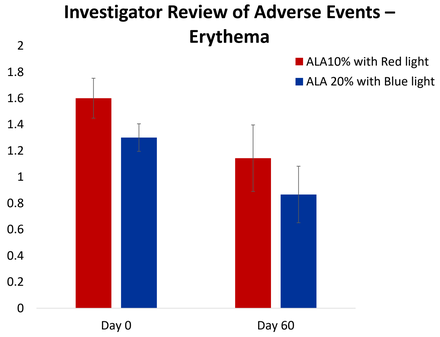
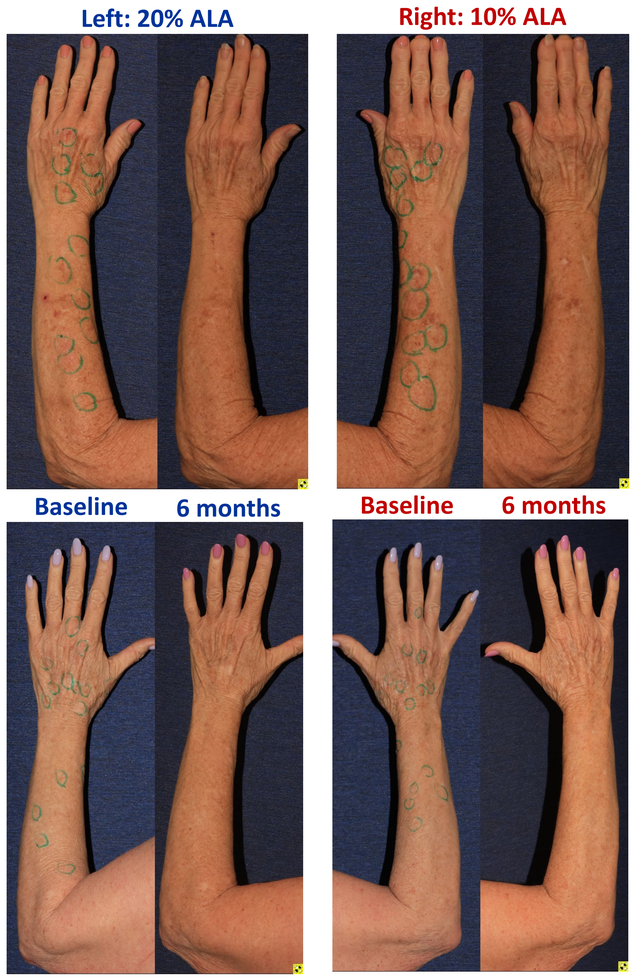


Figure 3a and b. Incidence of adverse events of edema and erythema a day 0 and day 60

Conclusion:

- Both ALA 10% and ALA 20% appear to be safe and effective for PDT treatment of AKs on the upper extremities
- There is a trend for increased efficacy with ALA 10%, and it may be easier to apply
- Additional data for 6 and 12 months are in the process of being collected



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References:

1. Szeimies RM, Radny P, Sebastian M, Borrosch F, Dirschka T, Krahn-Senftleben G, et al. Photodynamic therapy with BF-200 ALA for the treatment of actinic keratosis: results of a prospective, randomized, double-blind, placebo-controlled phase III study. *Br J Dermatol*. 2010;163(2):386-94.
2. Dirschka T, Ekanayake-Bohlig S, Dominicus R, Aschoff R, Herrera-Ceballos E, Botella-Estrada R, et al. Photodynamic therapy with BF-200 ALA for the treatment of actinic keratosis: results of a multicentre, randomized, observer-blind phase III study in comparison with a registered methyl-5-aminolaevulinate cream and placebo. *Br J Dermatol*. 2012; 166(1):137-46.
3. Reinhold U, Dirschka T, Ostendorf R, Aschoff R, Berking C, Philipp-Dormston WG, et al. A randomized, double-blind, phase III, multicentre study to evaluate the safety and efficacy of BF-200 ALA Ameluz® vs. placebo in the field-directed treatment of mild-to-moderate actinic keratosis with photodynamic therapy (PDT) when using the BF-RhodoLED® lamp. *Br J Dermatol*. 2016;175(4):696-705.
4. Ulrich M, Reinhold U, Dominicus R, Aschoff R, Szeimies RM, Dirschka T. Red light photodynamic therapy with BF-200 ALA showed superior efficacy in the treatment of actinic keratosis on the extremities, trunk, and neck in a vehicle-controlled phase III study. *J Am Acad Dermatol*. 2021 Mar 17:50190-9622(21)00575-2. doi:10.1016/j.jaad.2021.03.031.
5. Brian Jiang, S. I., Kempers, S., Rich, P., Marcus, S., Houlihan, A., Piacquadio, D., & Pariser, D. A Randomized, Vehicle-Controlled Phase 3 Study of Aminolevulinic Acid Photodynamic Therapy for the Treatment of Actinic Keratoses on the Upper Extremities. *Dermatol Surg*, 2019;45(7), 890-897.