COSMETIC LASER DERMATOLOGY
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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

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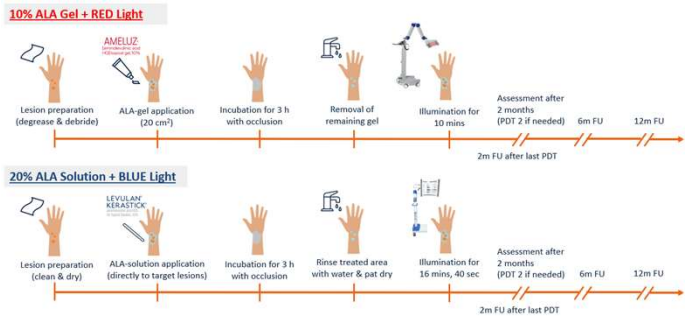
Background and Objectives:

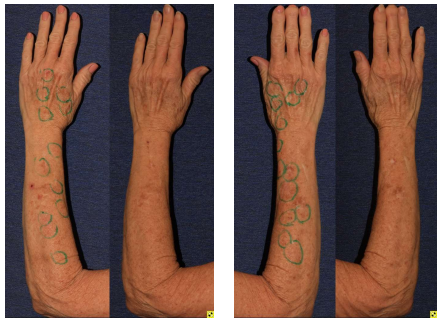
- Actinic Keratoses (AKs) are common precancerous skin lesions caused by chronic sun exposure, with potential to progress into squamous cell carcinoma
- Photodynamic therapy (PDT) is a well-established, non-invasive, FDA-approved treatment option using either 10% ALA gel + red light (face/scalp) or 20% ALA solution + blue light (face/scalp/upper extremities)
- The purpose of this study was to compare the safety, tolerability, and efficacy of both therapeutic combinations for PDT treatment of AKs on the upper extremities

Study Design and Methods:

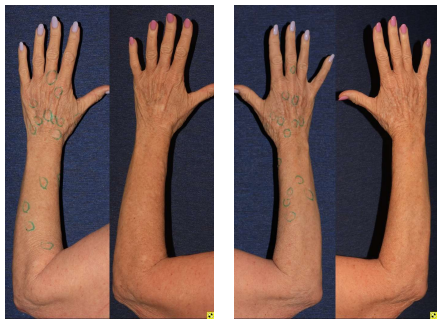
- Prospective, single-center, split-arm randomized clinical trial
- 30 adults with 4-17 clinically confirmed mild-to-moderate AKs on both distal upper extremities (graded by Olsen criteria)
  - One arm: PDT with ALA 10% gel + red light
  - Contralateral arm: PDT with 20% ALA solution + blue light
  - Side assignment randomized
- Primary endpoint: total lesion clearance rate (TLCR) at 120 days after first PDT
- Secondary endpoints: TLCR of moderate grade 3 lesions, TLCR at 6- and 12-months after last PDT, investigator-assessed cosmetic outcomes, and patient-reported satisfaction



Left: 20% ALA *Right: 10% ALA*



Baseline 6 months Baseline 6 months



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, Borking 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:S0190-9622(21)00575-2. doi:10.1016/j.jaad.2021.03.031.
5. Brian Jiang, S. I., Kempers, S., Rich, P., Moreno, S., Houlihan, A., Piacquadio, D., & Parlser, 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.

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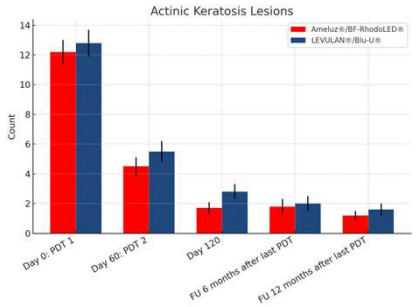
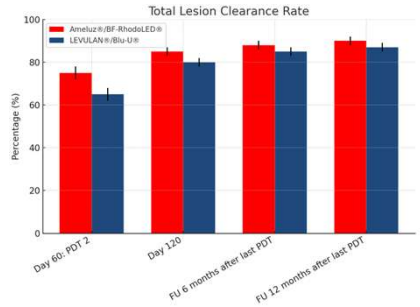
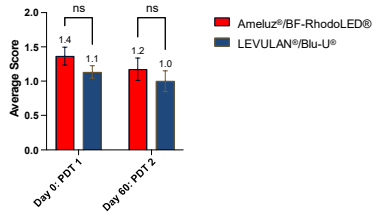
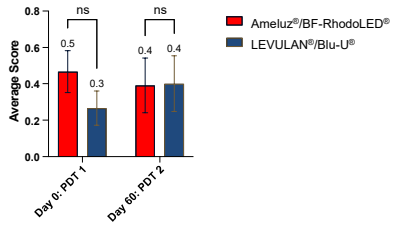




Investigator Review of Adverse Events: Erythema



Investigator Review of Adverse Events: Edema



Results:

- 27 of 30 enrolled patients completed the study
- Both regimens showed significant TLCR improvement ($p<0.0001$); 6-months post-2 PDTs: 87.6% (10% ALA gel) vs. 84.5% (20% ALA solution); 12-month FU: 90.5% (10% ALA gel) vs 86.9% (20% ALA solution)
- 10% ALA gel demonstrated higher clearance of grade 3 AK lesions (94.12%) vs. 20% ALA solution (88.24%)
- No statistical difference in subject reported pain or satisfaction rating
- Moderate erythema: 41.5% (10% ALA gel) vs. 23.6% (20% ALA solution); all resolved

Conclusion:

- First head-to-head comparison of 10% ALA gel + red light vs. 20% ALA solution + blue light for the treatment of AKs on the upper extremities
- Overall, both regimens were effective treatment options, with 10% ALA gel offering additional advantages in ease of application as a field therapy and potentially higher clearance rates in patients with more severe AKs