Red-Light PDT with 10% ALA Gel following Microneedling in the Treatment of Facial AK- Cosmetic and Clinical Outcomes

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OBJECTIVE

This prospective 3-month study evaluates the cosmetic outcomes and AK clearance of PDT using microneedling-assisted delivery of a 10% ALA gel (Ameluz®, Biofrontera, Woburn, MA) with 30-minute incubation and followed by illumination with a red light (BF-RhodoLED®, 635 nm, 37 J/cm^2).

CONCLUSIONS

PDT using microneedling-assisted delivery of 10% ALA gel with 30-minute incubation followed by red-light illumination is a safe and tolerable procedure which resulted in good cosmetic outcomes in several skin quality parameters such as texture, skin tone evenness, and a total AK lesion clearance rate of 89.2% at week 8.

REFERENCES

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INTRODUCTION

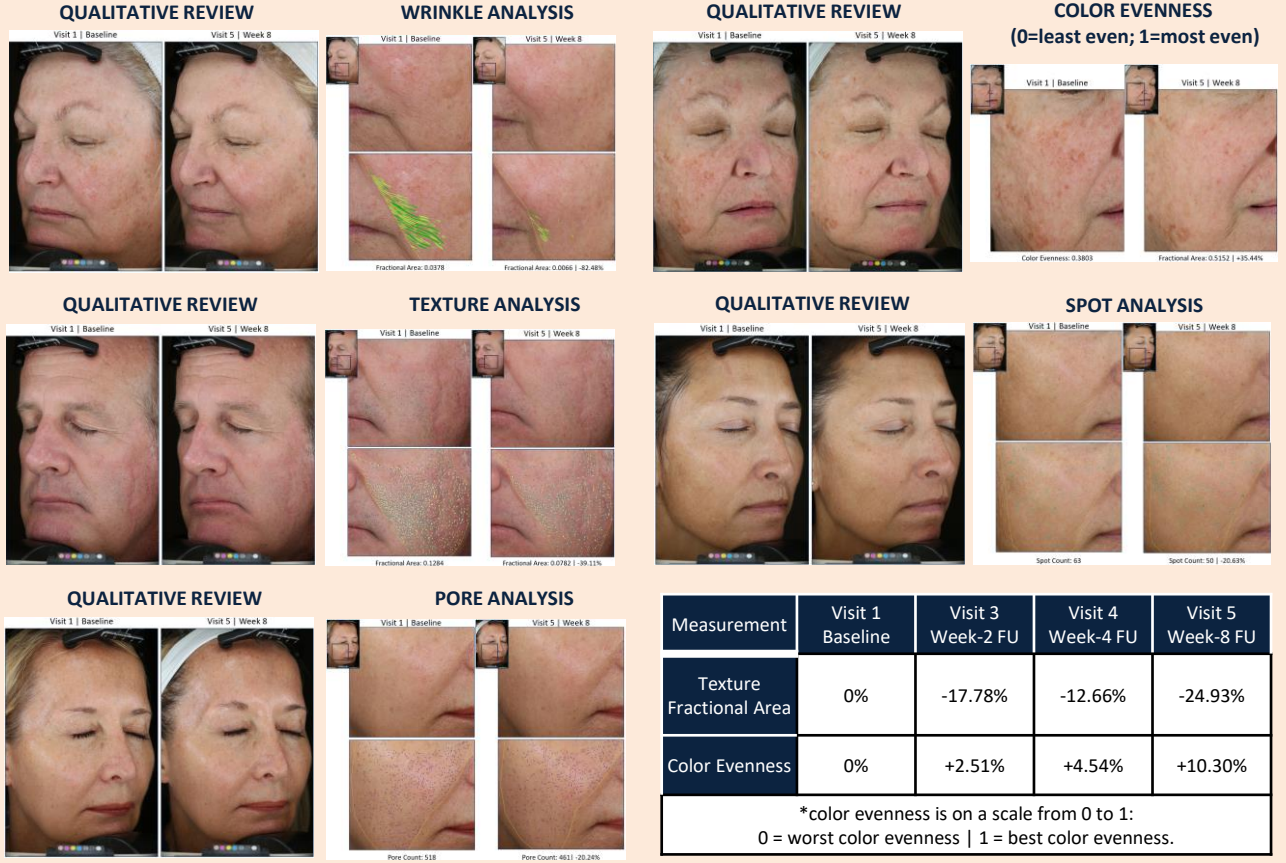
Photodynamic Therapy (PDT) with 10% Aminolevulinic acid (ALA) gel and red-light illumination is an approved and efficacious method for the treatment of actinic keratoses (AKs) on the face and scalp.[1] Drug penetration, prolonged incubation time, and pain during light exposure are however drawbacks to this field-directed therapy. Though popular as a cosmetic procedure and collagen induction therapy for facial scars and skin rejuvenation,[2] microneedling is also widely used as a transdermal delivery system for therapeutic drugs, and several clinical studies have shown enhanced AK clinical clearance and cosmetic outcomes when microneedling was performed prior to ALA incubation.[3,4]

METHODS

Five qualified subjects (aged 18-75 years, skin types I-IV) with 4 to 8 mild-to-moderate facial AKs were enrolled. All subjects received microneedling of their face followed by the application of 10% ALA gel for 30 minutes, before the treated area was illuminated with red light for 10 minutes. Follow-up (FU) visits were made at weeks 1, 2, 4, and 8. Primary endpoints were changes in photodamage/aging as quantified by the Canfield Visia-CR imaging System, and subject- and investigator-graded Global Aesthetic Improvement Scale (GAIS) scores. Secondary endpoints were AK clearance as quantified by AK count at week-8 vs. baseline, and safety as measured by patient-reported pain on 11-point VAS during illumination and adverse events (AEs) documented at treatment time and each FU visit.

RESULTS

All five subjects completed the study. At the 8-week FU, there was an average 24.93% improvement in Texture and an average 10.30% improvement in Skin Tone (Color) Evenness. Subject- and investigator-GAIS scores (mean ± SD) improved across all visits and were accompanied by 89.2 ± 14.9% (mean ± SD) in AK clearance at week 8. Mean pain score during red light illumination was 3.2 ± 1.6.



Measurement	Visit 1 Baseline	Visit 3 Week-2 FU	Visit 4 Week-4 FU	Visit 5 Week-8 FU
Texture Fractional Area	0%	-17.78%	-12.66%	-24.93%
Color Evenness	0%	+2.51%	+4.54%	+10.30%

*color evenness is on a scale from 0 to 1:
0 = worst color evenness | 1 = best color evenness.

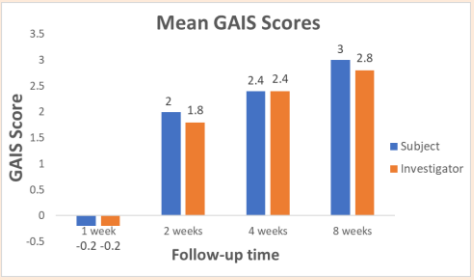


Figure 1. Mean GAIS scores at follow-up visits. 3 = very much improved, 2 = much improved, 1 = improved, 0 = no change, -1 = worse, -2 = much worse, and -3 = very much worse.

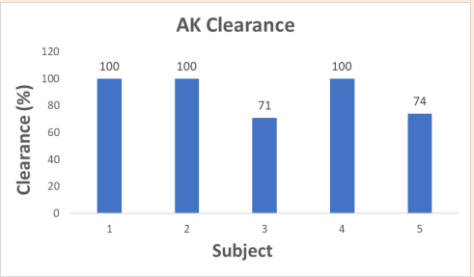


Figure 2. AK Lesion Clearance (%) 8 weeks post- treatment.

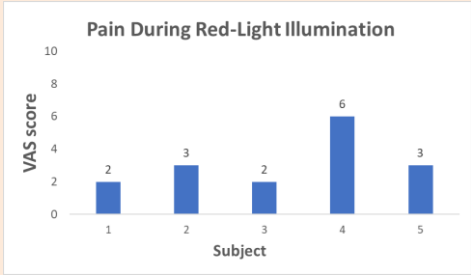


Figure 3. Subject -reported pain during illumination. Subjects graded pain according to the visual analog scale (VAS) scale in which 0 = no pain, 5 = moderate pain, and 10 = worst pain.

This study was investigator-initiated and funded by Biofrontera Inc. The authors have no financial relationships to disclose.