Photodynamic Therapy for Facial Actinic Keratosis with Aminolevulinic Acid 10% Gel, Microneedling, and Red-Light Illumination

Ziv Schwartz, MD, MHA
Department of Dermatology and Cutaneous Biology
Sidney Kimmel Medical College at Thomas Jefferson University
Philadelphia, PA

Gary Goldenberg, MD
Assistant Clinical Professor, Dermatology
Icahn School of Medicine at Mount Sinai Hospital
New York, NY
Email: garygoldenbergmd@gmail.com

SYNOPSIS

Photodynamic therapy (PDT) treats both visible actinic keratosis (AK) lesions and field cancerization. Drug delivery via topical ALA has limited penetration through the skin. The present study evaluated aesthetic improvement, AK clearance, pain during treatment, and adverse events in five subjects treated by PDT with microneedling-assisted delivery of 10% ALA gel and red-light illumination. Aesthetic appearance was much improved to very much improved at 4 and 8 weeks, respectively; the mean AK clearance was 89.2% at 8 weeks; red light illumination was well tolerated, and adverse events were not observed.

BACKGROUND

Chronic sun exposure may result in actinic keratosis (AK) with malignant potential. Photodynamic therapy (PDT) treats both visible AK lesions and field cancerization. In PDT, a photosensitizing agent (5-aminolevulinic acid, ALA) is topically applied to the treatment area and selectively taken up by the target cells. Drug delivery via topical ALA has limited penetration through the skin, so microneedling has been used to facilitate deeper penetration.

OBJECTIVE

The present study evaluates the efficacy and safety of PDT using microneedling-assisted delivery of 10% ALA nanoemulsion gel (Biofrontera, Woburn, MA) with 30-minute incubation followed by red-light illumination (Biofrontera, 635 nm, 37 J/cm2).

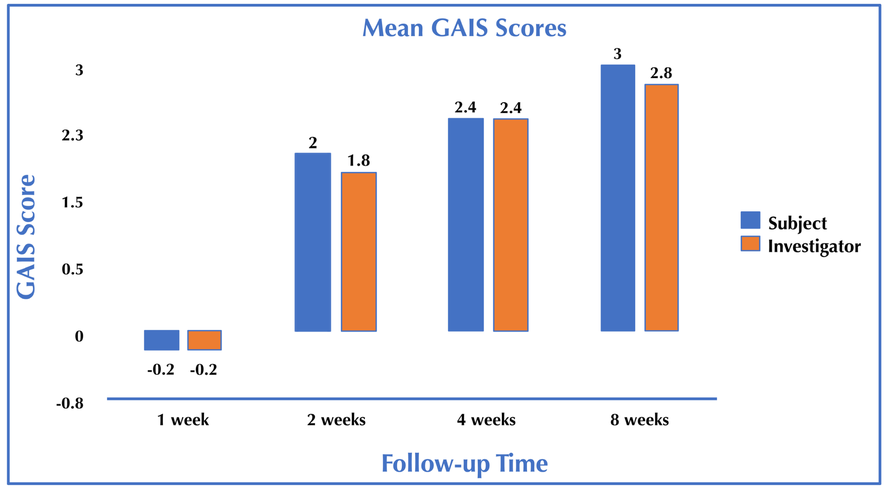

Figure 1. The mean Subject and Investigator Global Aesthetic Improvement Scale (GAIS) scores at follow-up visits. 3 = very much improved, 2 = much improved, 1 = improved, 0 = no change, -1 = worse, -2 = much worse, and -3 = very much worse.

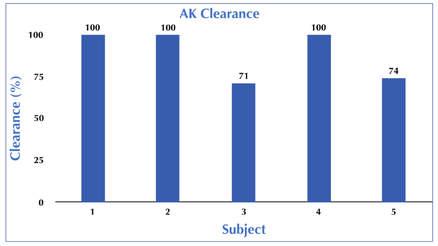

Figure 2. Clearance (%) of actinic keratosis (AK) lesions 8 weeks after microneedling-assisted photodynamic therapy (PDT).

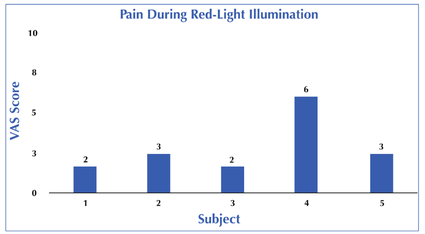

Figure 3. Subject-reported pain during illumination. Subjects graded pain according to a VAS score in which 0 = no pain, 5 = moderate pain, and 10 = worst pain.

METHODS

A prospective 3-month study was conducted to evaluate aesthetic improvement and AK clearance relative to baseline in each of five subjects treated by PDT with microneedling-assisted delivery of 10% ALA gel and red-light illumination. Follow-up (FU) visits were made at weeks 1, 2, 4, and 8. Five qualified subjects (aged 18-75 years, skin types I-IV) with 4 to 8 mild to moderate facial AKs enrolled in the study and provided signed informed consent. The study outcome was used to set the foundation for future clinical trials. The primary endpoints were changes in subject- and investigator-graded Global Aesthetic Improvement Scale (GAIS) scores in which 3 = very much improved, 2 = much improved, 1 = improved, 0 = no change, -1 = worse, -2 = much worse, and -3 = very much worse. Secondary endpoints were (1) AK clearance as quantified by count of AKs at 8-week FU vs. baseline and (2) safety as measured by patient-reported pain on an 11-point visual analog scale (VAS) (in which 0 = no pain, 5 = moderate pain, and 10 = worst pain) during red-light illumination and adverse events documented at the time of treatment and at each FU visit.

RESULTS

All five subjects completed the study. The mean GAIS scores are shown in Figure 1. AK clearance (mean ± SD) at 8 weeks was 89.2 ± 14.9%. Pain was well tolerated and mean pain score during illumination was 3.2 ± 1.6 on the 11-point VAS. Adverse events were not observed during the study.

CONCLUSION

PDT using microneedling-assisted delivery of 10% ALA nanoemulsion gel with 30-minute incubation followed by red-light illumination results in much improved to very much improved GAIS at 4 and 8 weeks, respectively; 89.2% AK clearance at 8 weeks; and tolerable pain during red light illumination.

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