

An Evaluation of the Safety and Efficacy of Aminolevulinic Acid Hydrochloride Topical Gel, 10% with Red Light in the Treatment of Facial Cutaneous Squamous Cell Carcinoma in situ

Aysham Chaudry, DO¹; Robert J. Vanaria, BS^{1,2}; Wilhelmina Lam, DO¹; Alexandra DeVries, BS^{1,3}; Alec Lawson^{1,4}; Mark S. Nestor MD, PhD^{1,5,6}

¹Center for Clinical and Cosmetic Research, Aventura, FL; ²Hackensack Meridian School of Medicine, Nutley, NJ; ³Rocky Vista University College of Osteopathic Medicine, Parker, CO; ⁴Arizona College of Osteopathic Medicine, Glendale, AZ; ⁵Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine Miami, Miami, FL; ⁶Department of Surgery, Division of Plastic Surgery, University of Miami Miller School of Medicine Miami, Miami, FL

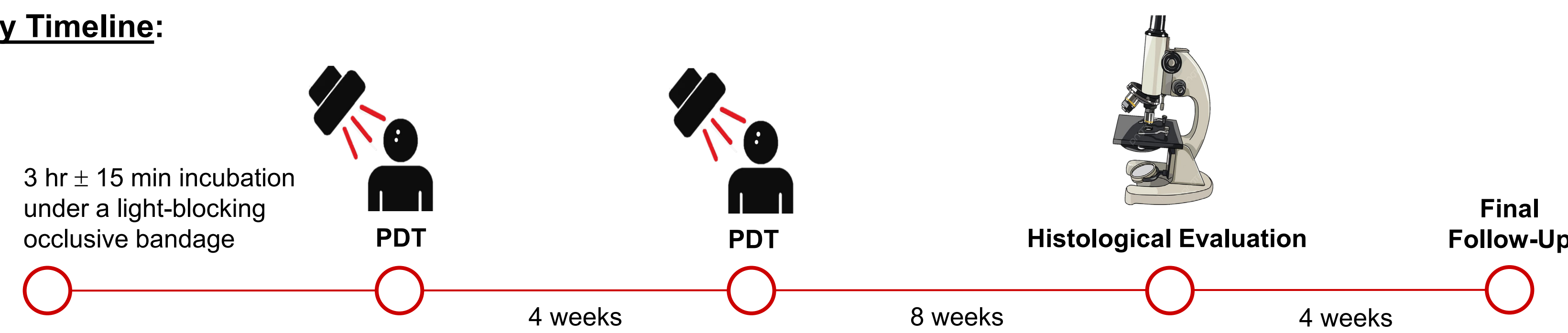
BACKGROUND

Cutaneous squamous cell carcinoma in situ (SCCis) is a common skin cancer associated with chronic sun exposure and frequently arises on the face. While surgical excision remains the standard of care, there is growing interest in less invasive options. This study evaluates the safety, tolerability, and efficacy of red-light photodynamic therapy (PDT) with 10% aminolevulinic acid (ALA) topical gel for the treatment of facial SCCis.

METHODS

- 20 patients enrolled
- Median age 72 (range 56-86)
- 65% male (n=13)
- 35% female (n=7)
- Most with Fitzpatrick skin type II or III
- 20 biopsy-confirmed facial SCCis; size 0.4–1.1 cm

Study Timeline: N:20



Treatment Protocol

20 patients with biopsy-confirmed facial SCCis
2 PDT treatments
28 ± 3 days apart

- Debridement of lesions with gauze and acetone
- Application of 10% ALA gel to SCCis and surrounding skin
- 3 hrs ± 15min incubation under a light-blocking occlusive bandage
- Redlight illumination (RhodoLED® XL, 13.5 mins, 635 nm, 37 J/cm²)

Histopathological evaluation 8 wks ± 7 days after last treatment

Safety assessment
Adverse event assessment

Endpoints

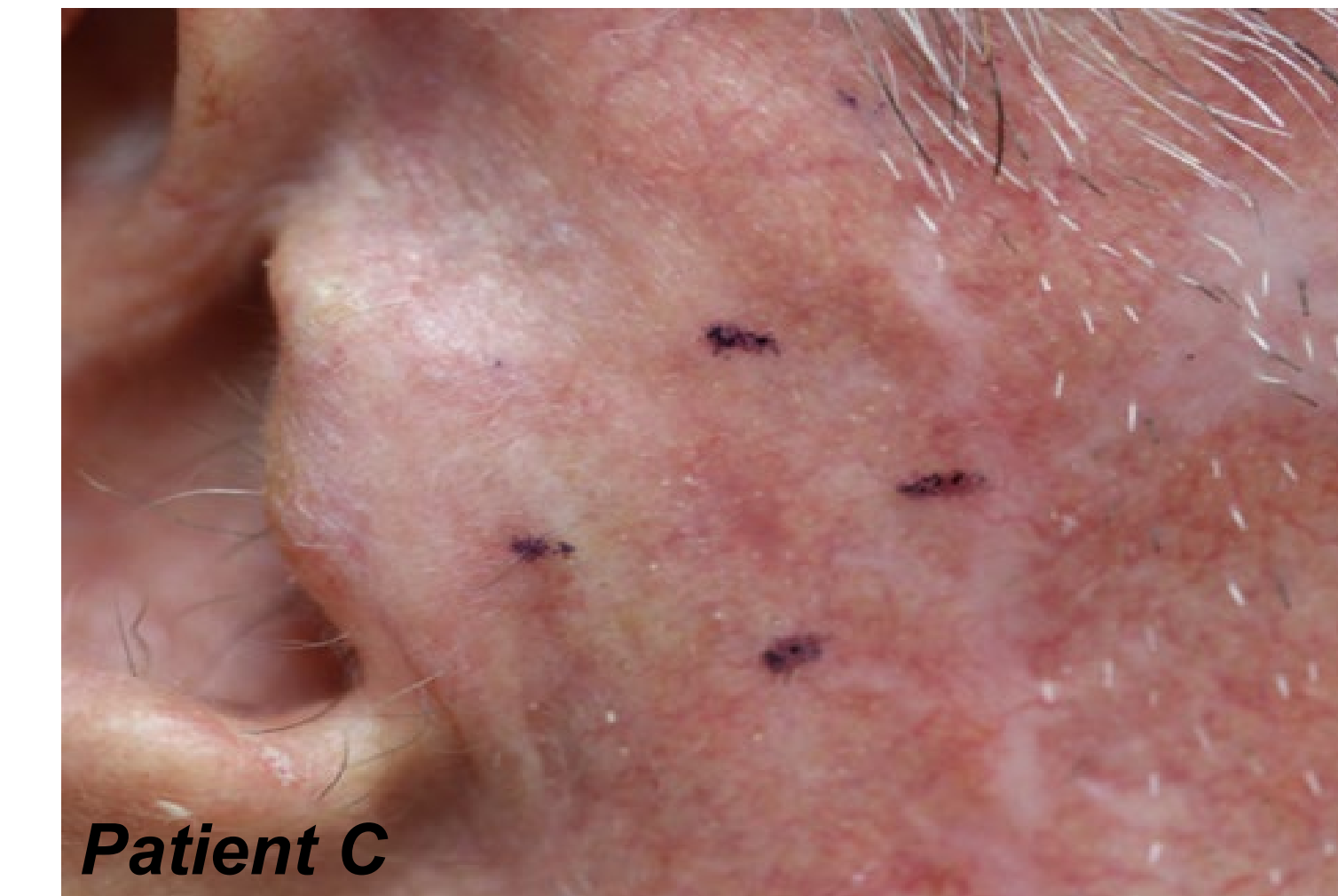
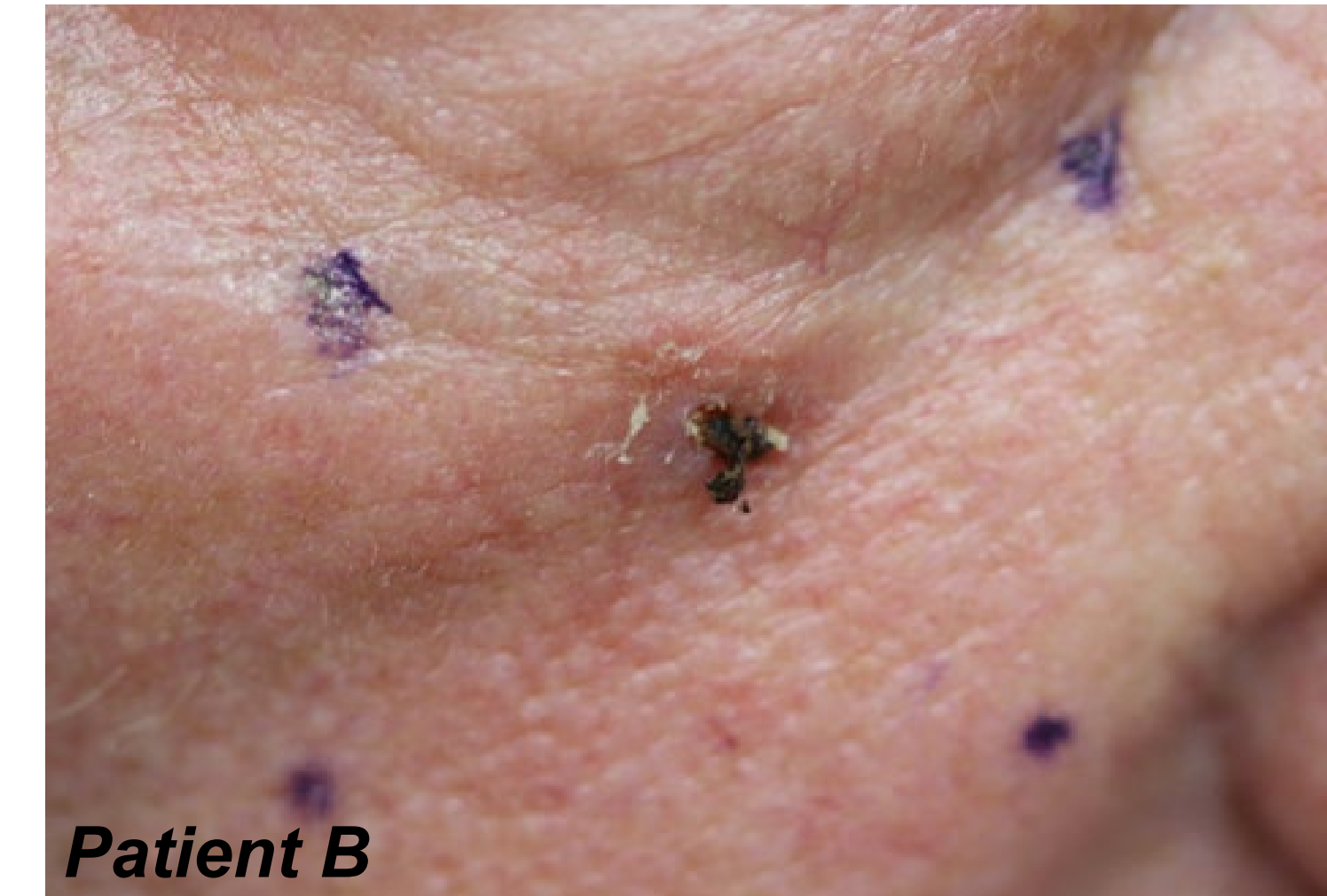
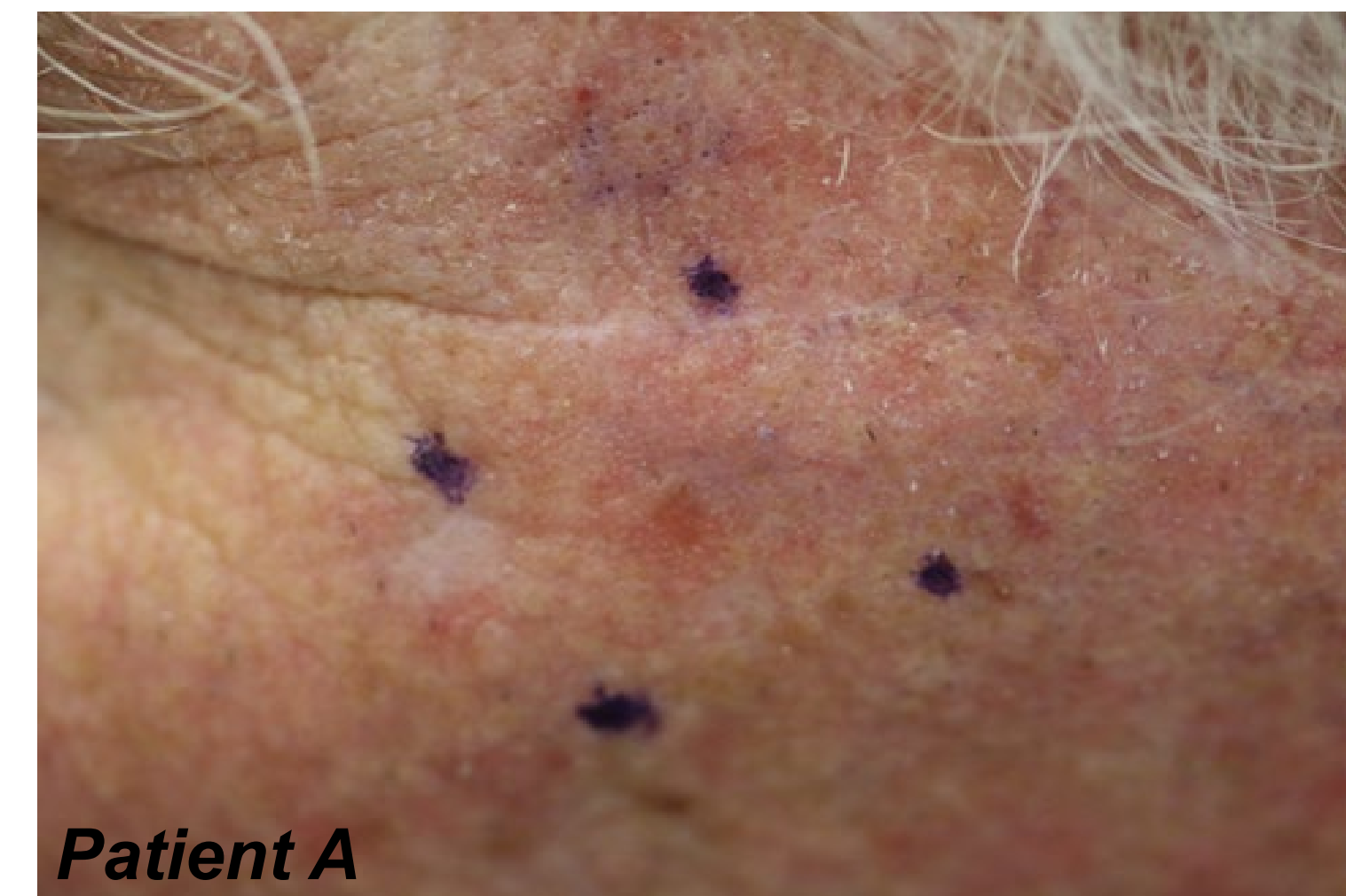
Primary Endpoint

- Complete histological clearance

Secondary Endpoints

- Complete clinical clearance (CCC)
- Change in lesion size
- Cosmetic outcomes
- Safety assessments
- Adverse events (AEs)
- Local skin reactions (LSRs)
- Site Pain (11-point numeric rating scale)

(A) Visit 1 (before treatment)



(B) Visit 8 (after treatment)

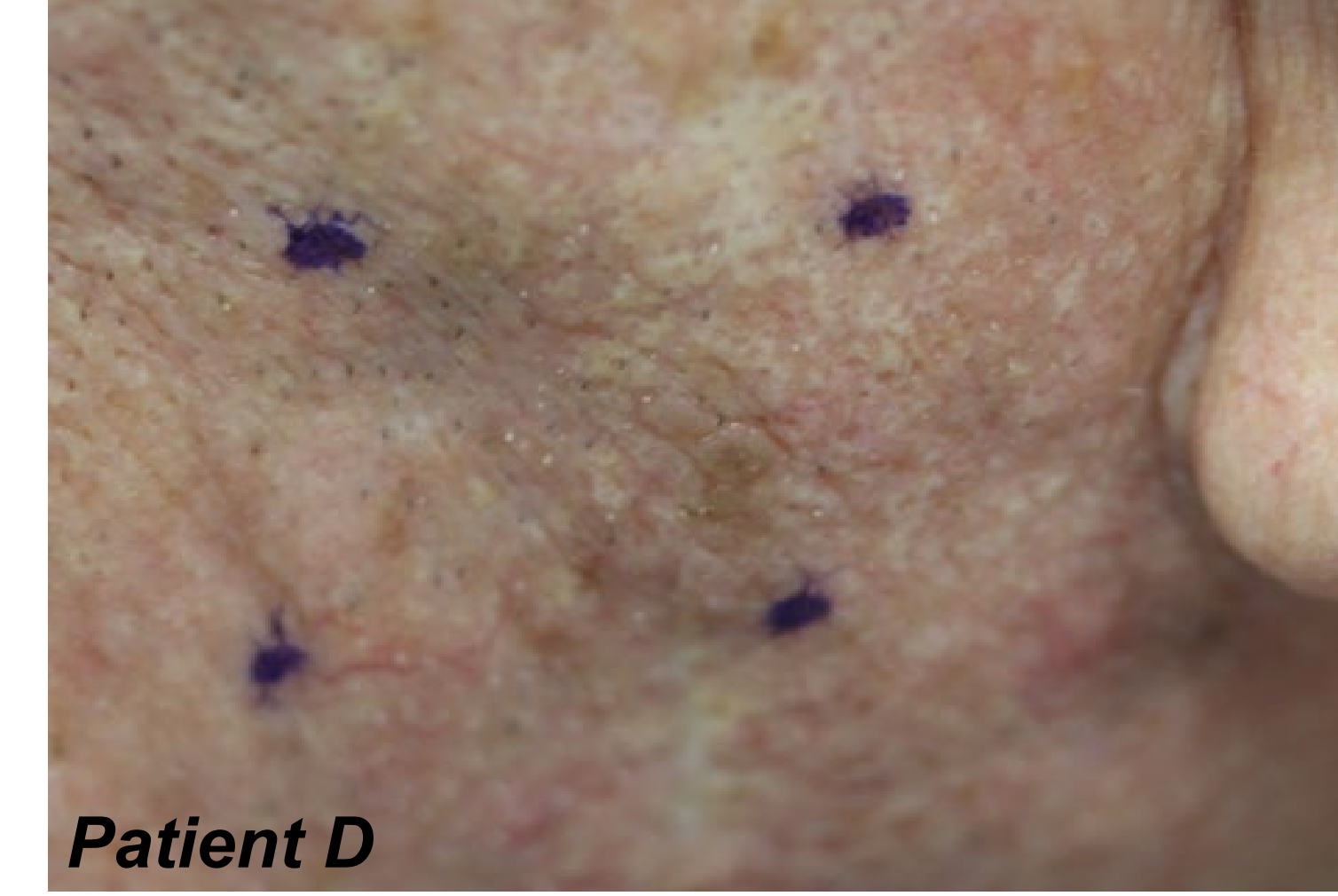
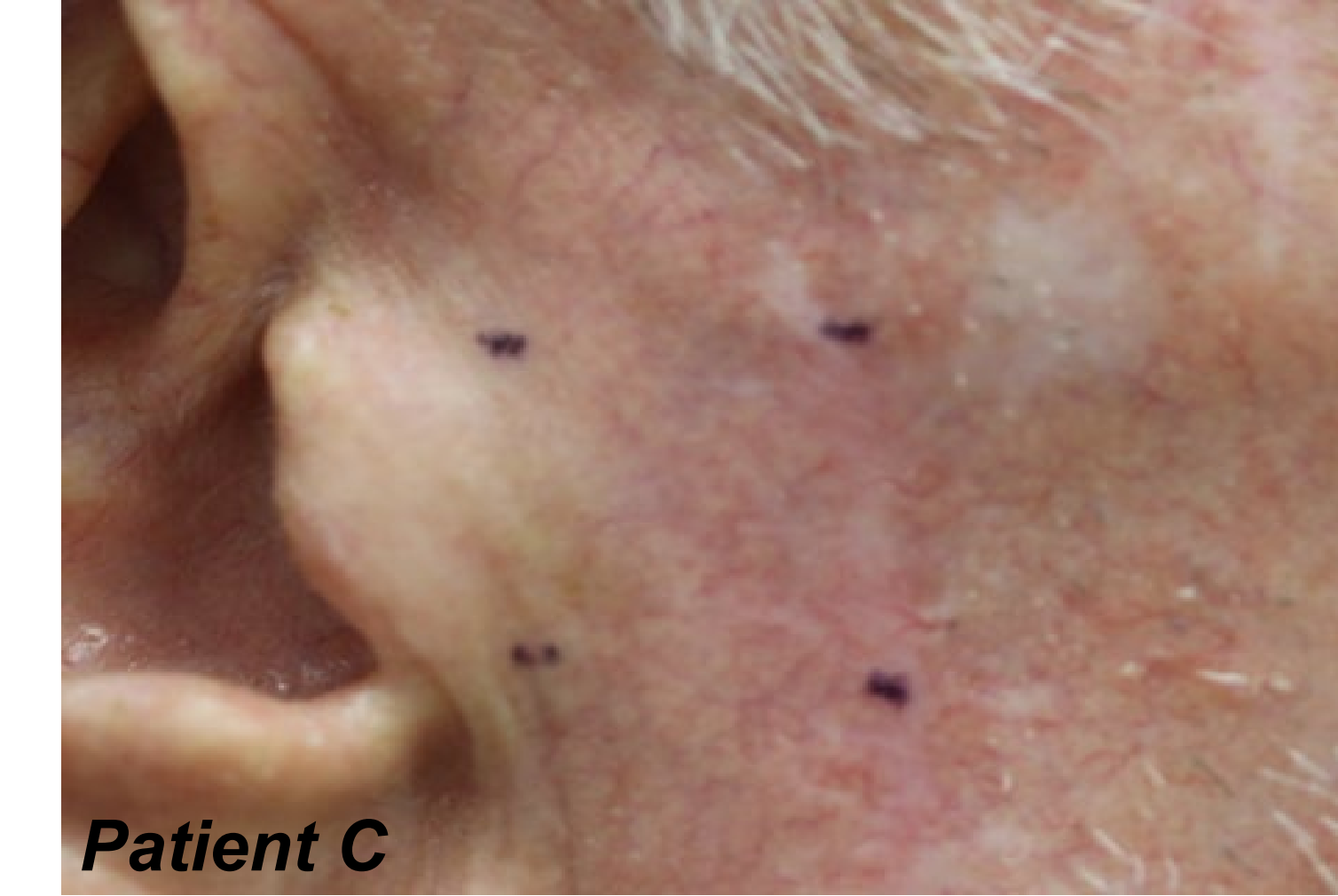
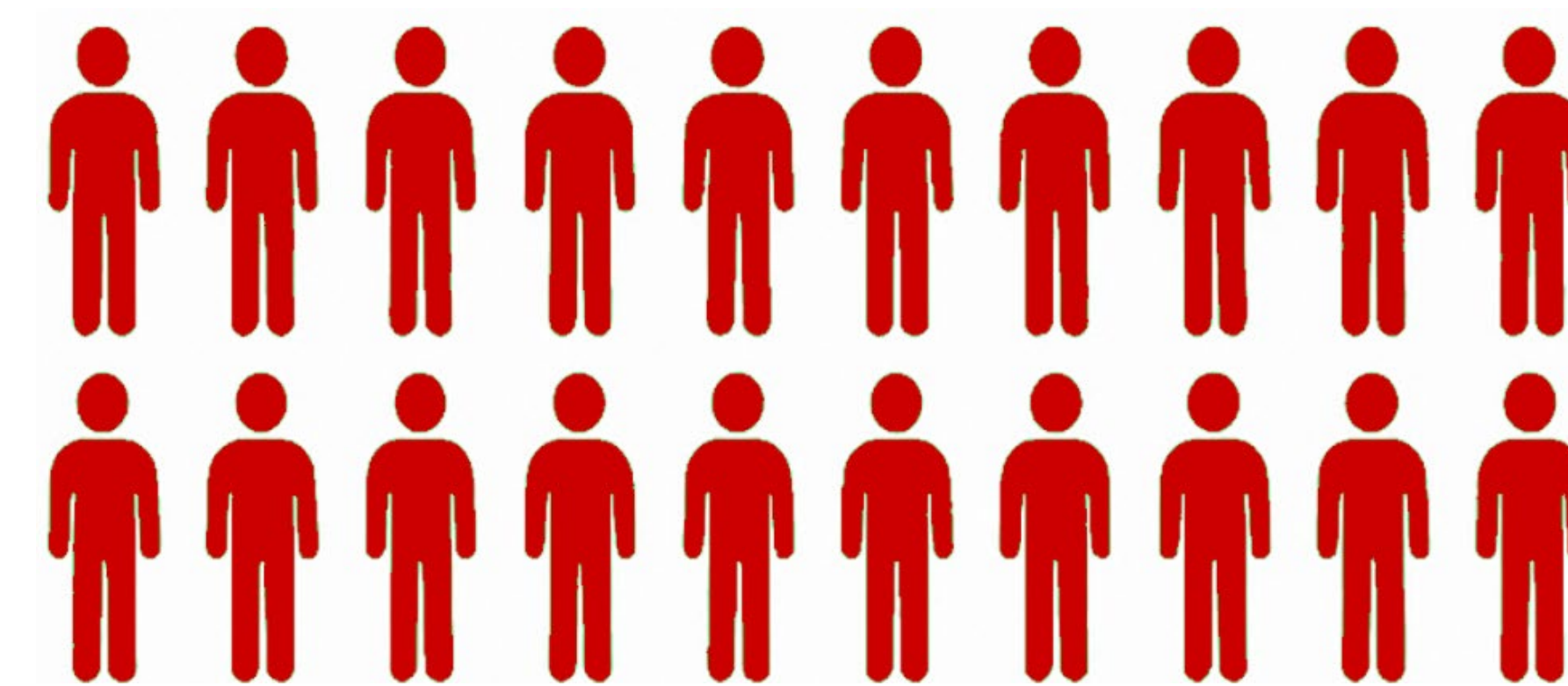


Figure 1. SCCis before and after treatment with 10% ALA Gel + Red Light

RESULTS

- All patients (n=20) achieved complete histological clearance of SCCis at end of treatment (EOT).
- CCC was observed in all patients prior to excision (median time 62 days; range 42-90 days; SD 14 days).
- Moderate erythema was the most common LSR; mild flaking/scaling also reported. Both resolved by EOT.
- Occasional mild erosion observed, resolved by the next visit; no pigmentary changes observed.
- Pain scores: median 0 (range 0-3) within 15 mins after 10% ALA gel application; 3.5 (range 0-10) within 15 mins after red light illumination.
- 19/20 patients reported no AEs; one case of mild contact dermatitis secondary surgical adhesive.

100% Complete
Histological Clearance



CONCLUSION

Topical 10% ALA-PDT is a well-established treatment for actinic keratosis (AK) and has previously shown promise as a non-invasive option for SCCis.

In this study, red light PDT with 10% ALA gel achieved 100% histological and clinical clearance of facial SCCis, with excellent tolerability and favorable cosmetic outcomes.

The greater depth of tissue penetration achieved with red light may enhance activation of PpIX within the lower epidermal layers, where atypical keratinocytes frequently reside.

Our findings demonstrate that 10% ALA gel in combination with red light achieved 100% histologic and clinical efficacy, with superior cosmetic outcomes compared to surgery.

REFERENCES & DISCLOSURES

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