Enhancement of sun-damaged skin qualities with tirbanibulin (SunDamage Study)

Daisy Kopera[1]

[1]Medical University Graz, Graz, Austria

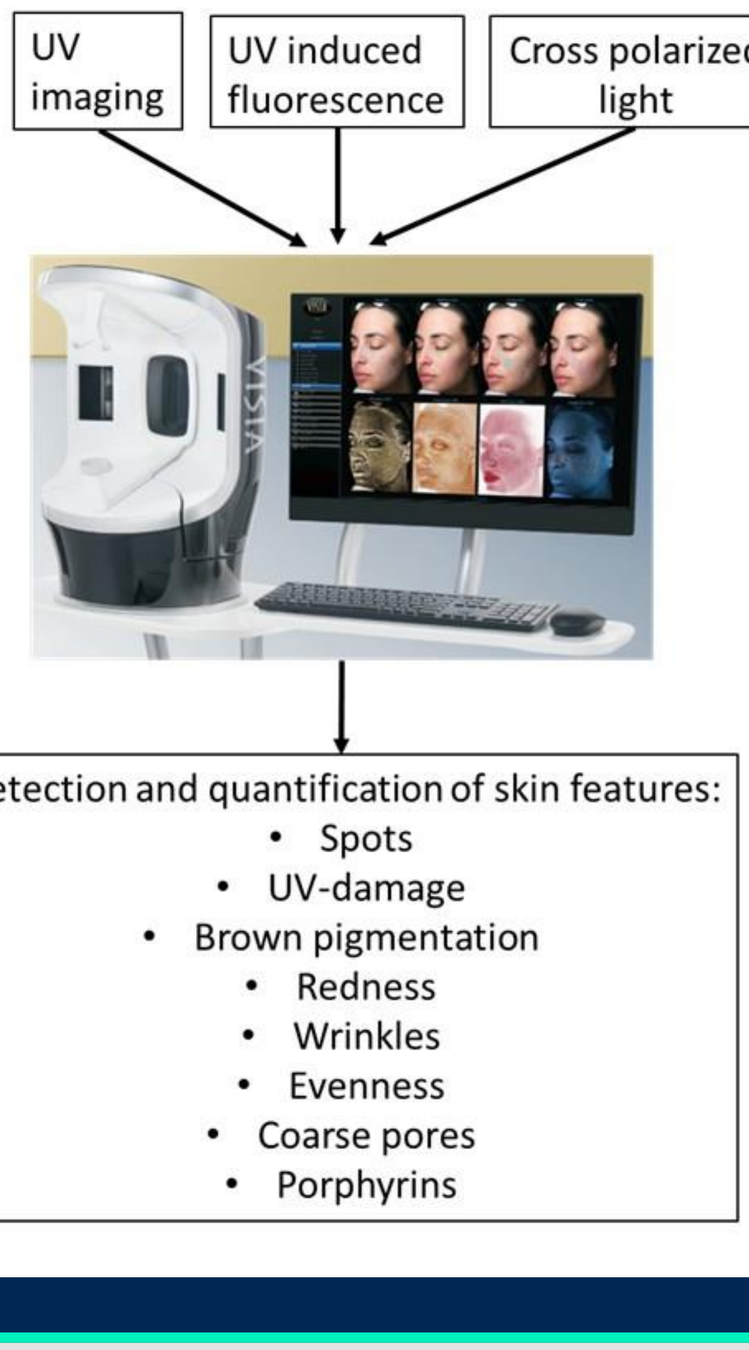
Introduction and Objectives

- Actinic keratosis (AK) is caused by photo damage, distinctly by ultraviolet (UV) radiation.
- Subclinical stages of AK are present in epidermal layers before becoming clinically visible.
- Tirbanibulin 1% ointment is approved for the field treatment of non-hyperkeratotic, non-hypertrophic AK of face or scalp in adults.
- The objectives were to assess efficacy and safety of the treatment with tirbanibulin, and the quality of sun-damaged skin before, immediately after and 2 months after the treatment by standardized VISIA® photography.

Material and Methods

- "SunDamage" is an interventional, monocentric, national, single-arm, uncontrolled, open, prospective phase IV study.
- Adult patients diagnosed with sun-damaged skin on the face applied tirbanibulin every night for 5 consecutive days.
- Disease specific skin parameters (AK lesions, subclinical lesions, sun damage, local skin reactions [LSRs] and other changes of the skin, including those not clinically relevant) were assessed both according to clinical routine and by VISIA® UV imaging (**Figure 1**)[1] at baseline, Day 8 (±2) and Day 57 (±7).
- Safety was analyzed by means of adverse events (AEs). LSRs were recorded and graded separately.

Figure 1. Description of VISIA® system



Results

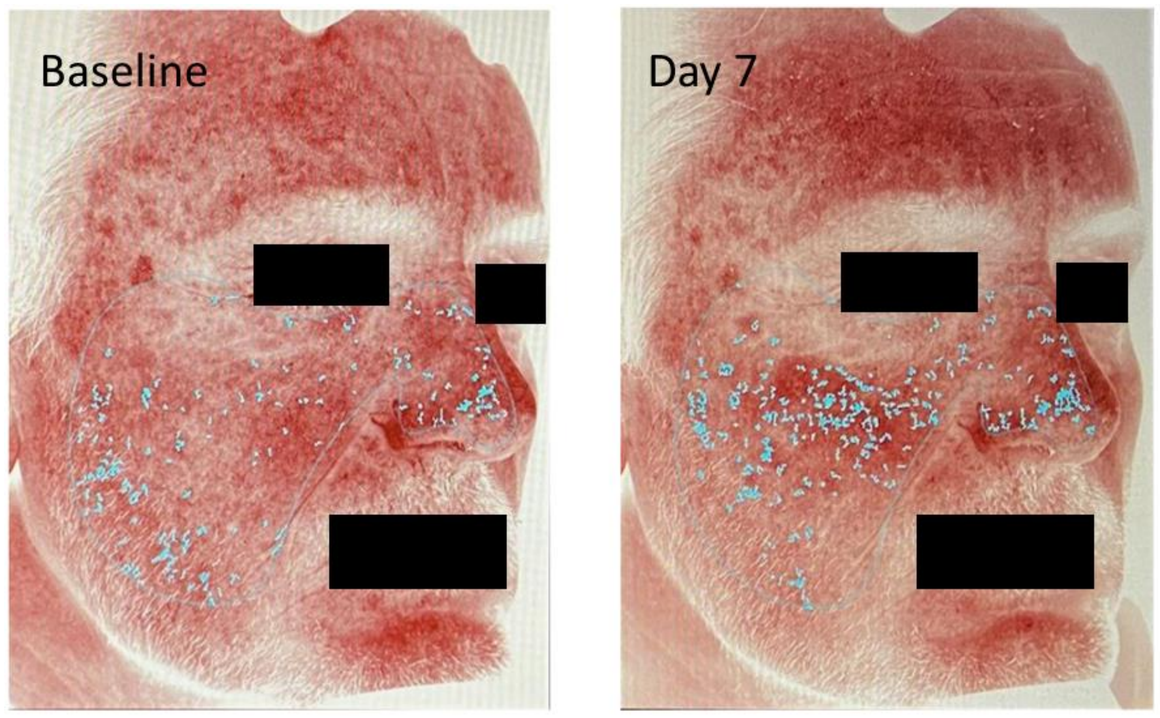
Patients

- A total of 26 patients completed the study.
- All patients were Caucasian with Fitzpatrick skin type 2-3, mean age (range) of 68 (58-81) years, and 15 (58%) patients were female.
- All patients presented sun-damaged skin, but no visible AKs.

Tolerability

- All patients developed mild erythema after application of tirbanibulin being visible on Day 7.
- At Day 7, VISIA® measurements of the erythematous skin revealed higher values of redness by 8% points and roughness of the skin of 7% points.
- At Day 57 there was no visible erythema.
- This erythema profile is aligned with the erythema evolution reported in the previous trials with tirbanibulin.[2,3]
- Thus, representing the mild LSR to tirbanibulin unmasking very early stages of subclinical AK as a symptom of sun damage (**Figure 2**).

Figure 2 VISIA® measurements of erythema at baseline and at Day 7



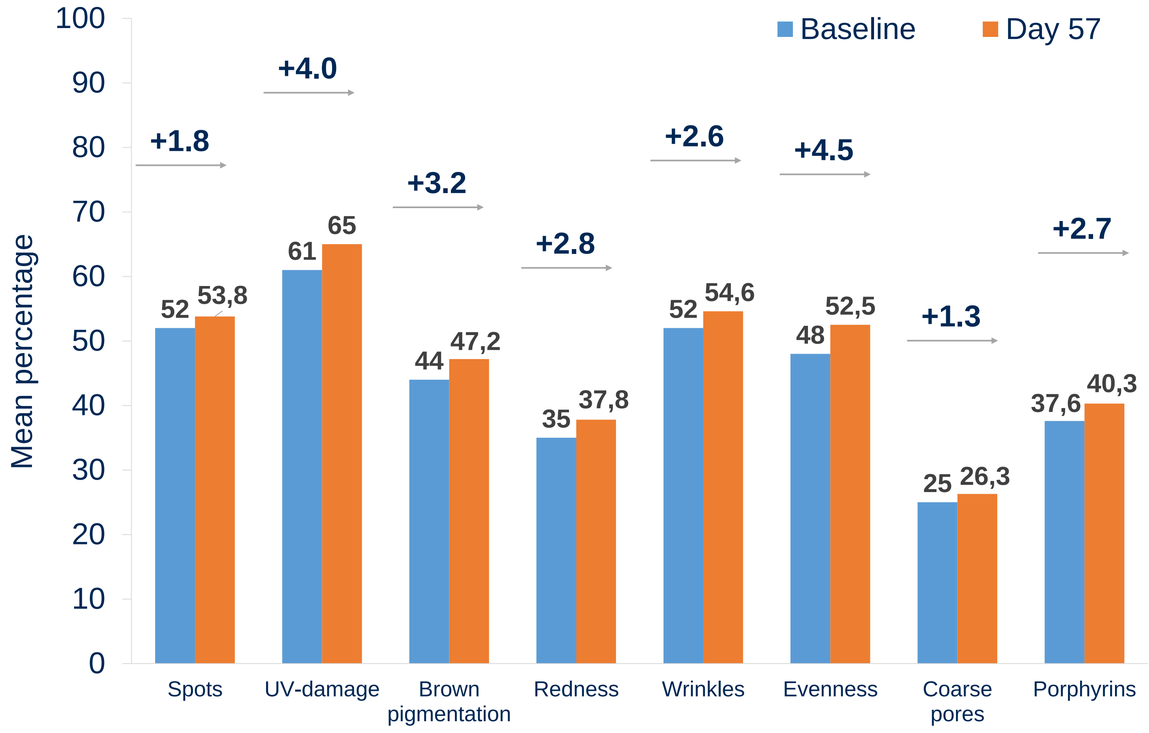
Efficacy

- At Day 57, VISIA® measurements revealed improvement in all qualities of the skin in measured percentage points: spots: + 1.8, UV-damage +4, brown pigmentation +3.17, redness +2.8, wrinkles +2.46, evenness +4.5, coarse pores +1.32, porphyrins +2.73, revealing enhancement of sun-damaged-skin qualities (**Figure 3**).

Safety

- No safety concerns were observed.

Figure 3. Skin quality at baseline and at Day 57



Conclusions

- These results confirm tirbanibulin to be effective, safe, and well tolerated in adult patients with facial sun damage.
- Tirbanibulin showed enhancement of 8 skin qualities measured by the VISIA® system: spots, UV-damage, brown pigmentation, redness, wrinkles, evenness, coarse pores, and porphyrins.
- VISIA® can contribute to the characterization of sun damage severity and the monitoring of tirbanibulin treatment.

References

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3. Blauvelt A, et al. Phase 3 Trials of Tirbanibulin Ointment for Actinic Keratosis. N Engl J Med 2021;384(6):512–20. DOI: 10.1056/NEJMoa2024040.

Potential or actual conflicts of interest

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