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Introduction

Locally acting, well-tolerated treatments for digital ulcers (DUs) in patients with systemic sclerosis (SSc) are needed (Figure 1).



Figure 1: DUs in SSc

Objectives

- The primary aim of the study was to assess the safety, feasibility and tolerability of a novel light treatment for SSc-related DUs.
- Our secondary aim was to tentatively assess treatment efficacy.

Method

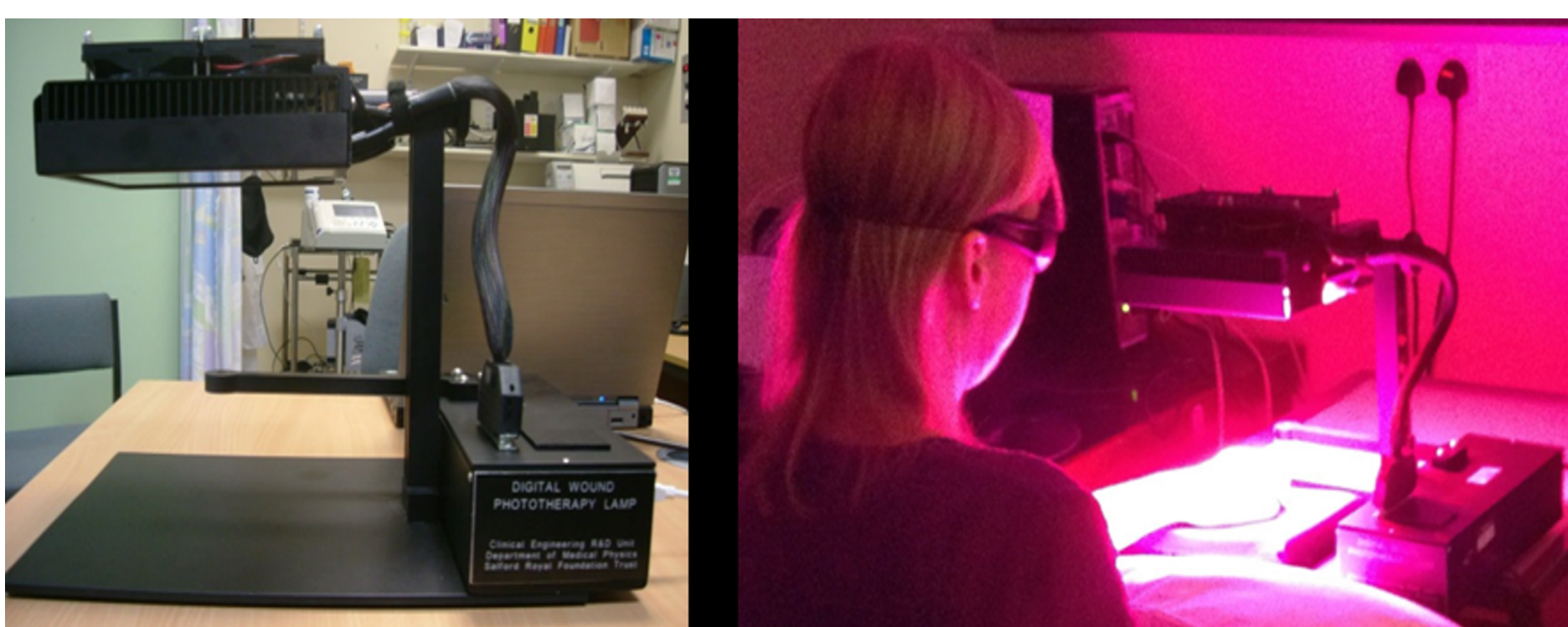


Figure 2: The light-based treatment device

- A custom built device (Figure 2) was constructed consisting of infrared (850nm), red (660nm) and blue (450nm) LEDs.
- Treatment was administered twice weekly for three weeks, with follow-up at weeks 4 and 8.

Method (outcomes)

- Adverse events were documented.
- Data on patient opinion about the time to deliver, feasibility (“not feasible”, “indifferent”, “feasible”), and pain VAS, 0–100) were collected.
- Patient and clinician assessment of severity of DUs (VAS, 0–100) was documented.
- An independent assessor graded change in appearance of DUs from photographs (–2 to +2).
- Perfusion (pre and post) treatment was measured by Laser Doppler imaging (LDI) (Figure 3).

Results 1

- 14 DUs in 8 patients were studied.
- 46 light treatments were successfully administered, with no adverse events.

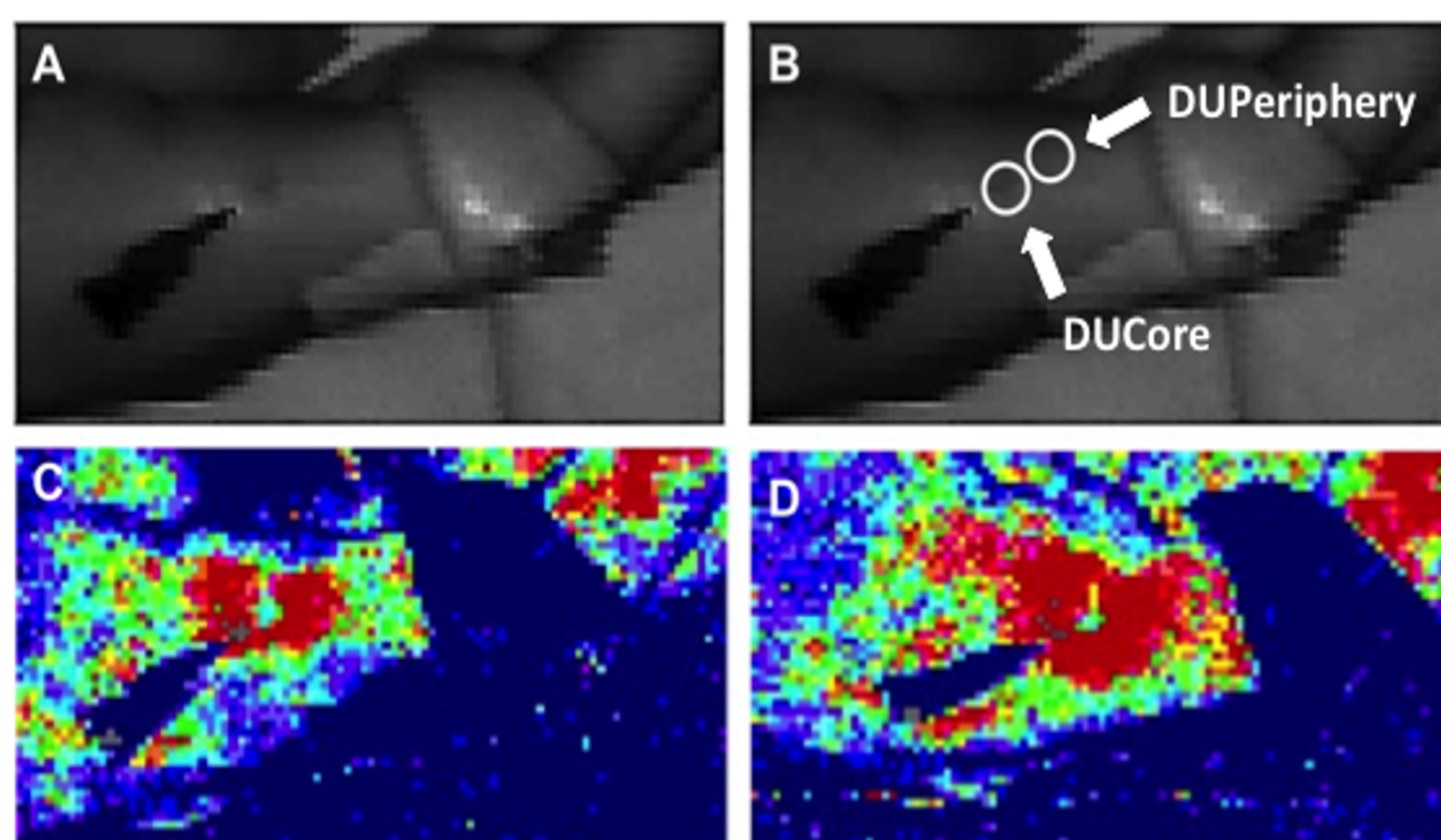


Figure 3: LDI. There is increase in DU perfusion with treatment compared (D) to baseline (C), in particular to the ischaemic centre (DUCore). Corresponding grey scale images top row.

Results 2

- There were no adverse events.
- All patients believed that light treatment was “feasible” and “took just the right amount of time”, with a low associated mean pain VAS of 1.6 (SD 5.2).
- Patient and clinician DU severity (Figure 4) improved during the study (mean change in VAS –7.1 and –5.2; both $p \leq 0.001$).
- Mean change in appearance of DUs per week was 0.14 (95% CI 0.0–0.3) ($p=0.01$).
- There was a significant increase in mean perfusion (Figure 3), in particular, at the DU centre (0.32, 95% CI 0.13–0.52; $p=0.0013$).

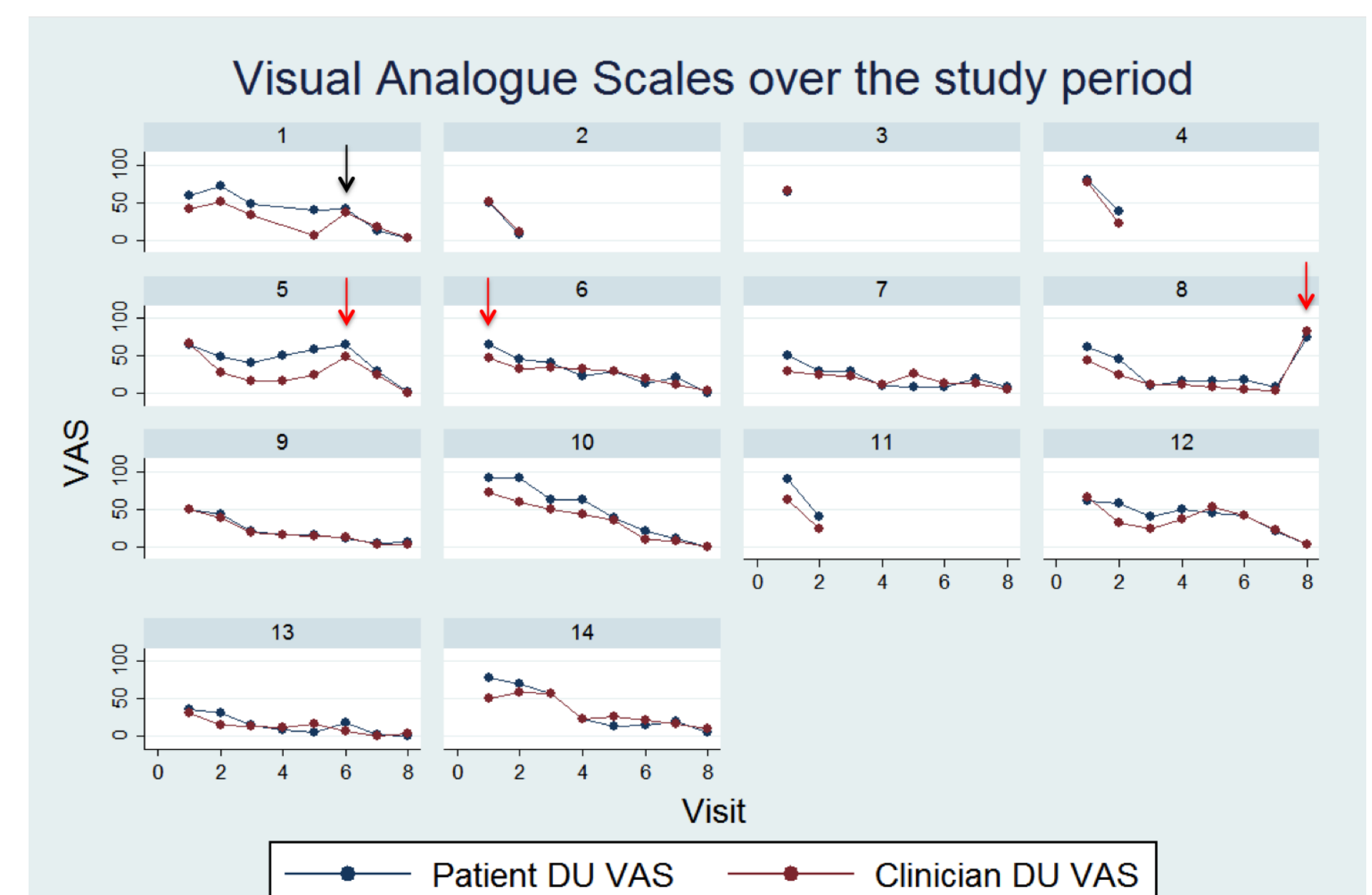


Figure 4: Patient (blue) and clinician (red) DU opinion.

Conclusion

- Light treatment for DUs in SSc is safe, feasible, and well tolerated.
- There was an early tentative suggestion of efficacy.
- Future research is warranted to develop light-based treatment as a locally acting therapy for DUs in patients with SSc, and other common types of skin ulcers.