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A PROSPECTIVE CASE SERIES EVALUATING THE SAFETY AND EFFICACY OF THE KLOX BIOPHOTONIC SYSTEM IN VENOUS LEG ULCERS

NIKOLIS, GRIMARD *ET AL.* 2016

INTRODUCTION

Venous leg ulcers (VLUs) affect a significant proportion of the elderly population and cause significant morbidity, while seriously affecting patients' quality of life. Hereby, an open-label study design used to investigate the **safety** and **efficacy** of the Lumiheal® Fluorescent Light Energy (FLE) system in patients with VLUs is reported.

RESULTS AND DISCUSSION

- 9 patients were enrolled and evaluated for efficacy (57–87 years).
- Patients were treated for a maximum period of 16 weeks or until wound closure.
- The response rate obtained was 77.8%; 44.4% achieved complete wound closure.
- Time to closure was, on average, 127.5 days.
- At 1-month, wound size had decreased, on average, by 33%, and by 50% at 2 months.
- Patients achieving complete wound closure progressed to a 64.5% surface area reduction within the first 60 days.
- Perilesional skin was also examined: 62.5% improved significantly during the treatment period to the point that a skin graft would be tolerated.

Fig. 1. Venous leg ulcers of 3 patients at baseline (A) and at last observation (B).

No cases that developed a clinical infection requiring systemic antimicrobial therapy during the treatment.
All aspects of quality of life (social life, well-being, and physical symptoms and daily living) improved over time.

SAFETY

No treatment-emergent-related serious adverse events were reported throughout the study.
Compliance with study visits was excellent. Overall, 93.2% of study visits were conducted as per protocol.

CONCLUSIONS

The FLE system performed well when compared with other treatments in terms of wounds closure rates and time.
The treatment regimen led to a high rate of compliance. Due to its easy application, this medical device has all the required characteristics to become a treatment of choice in the management of chronic VLUs.
For more information and before/after pictures, visit the original publication.

Nikolis *et al.,* 2016. Chronic Wound Care Management and Research, 3:101-111.