

BIOMODULATION INDUCED BY FLUORESCENT LIGHT ENERGY VERSUS STANDARD OF CARE IN VENOUS LEG ULCERS: A RETROSPECTIVE STUDY

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OBJECTIVE OF THE STUDY

EUREKA study has confirmed the efficacy and safety profile of Fluorescent Light Energy (FLE) in treating hard to heal wounds. To supplement this study, a matching analysis compared 46 venous leg ulcers (VLU) patients treated with standard of care (SoC) in real-life conditions vs wounds treated during the EUREKA study with both FLE and SoC.

METHOD

- 5-year retrospective review identifying patients matching the 10 VLU patients enrolled in the EUREKA study, by the wound care center in Pisa.
- The matching list was established following specific criteria : wound age at the first treatment visit, wound size, patients' age, patients' gender, same SoC for the 2 groups
- The center identified 46 patients matching these criteria for the ten (10) Eureka VLU patients.
- The list of 46 matching wounds was reviewed and approved by an independent statistician.

RESULTS

On average, the EUREKA group had older wounds than the matching wounds at baseline, as well as a higher prognostic factor of poor wound healing, despite all efforts to recruit patients with wounds that matched the EUREKA VLUs.

- **Wound closure rates:** at week 16, higher wound closure rates were observed in the EUREKA group: 40% of the wounds were considered as fully closed by investigators. This percentage was only 7% in the matching group.

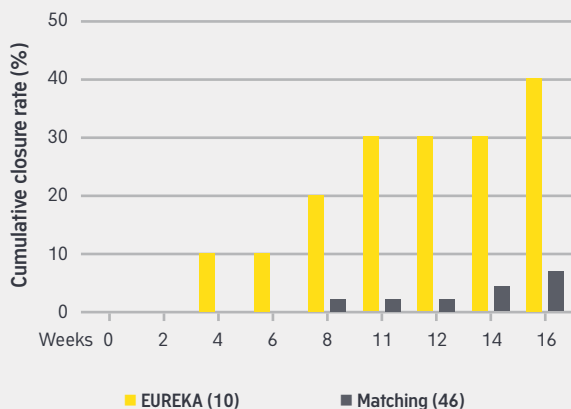


Fig. 1. Cumulative wound closure rates at 16 weeks, all groups

- **Wound breakdown:** in the EUREKA group, no wound that closed during the 16-week evaluation reopened vs 25% in the matching group treated with SoC only.

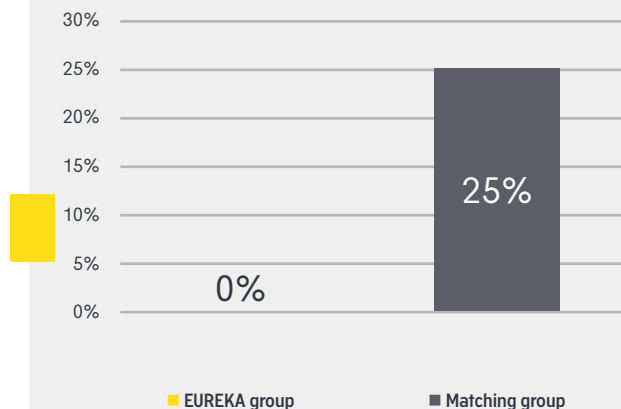


Fig. 2. Percentage of wound breakdown at week 16 (% of closed wounds)

- **Mean times to wound closure:** a Kaplan-Meier analysis was used to estimate the mean time of wound closure for all wounds. Estimated mean time of wound closure was in favor of the VLUs treated in the EUREKA study compared to the wounds of the matching patients treated with SoC.

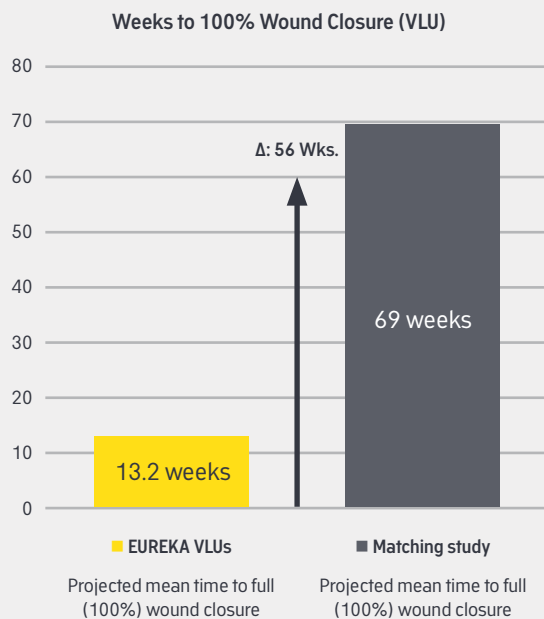


Fig. 3. Estimated mean time to wound closure (all wounds, Kaplan Meier analysis).

- **Relative wound area regression (RWAR)** was higher for the EUREKA group than for the matching group at both 6 and 16 weeks.

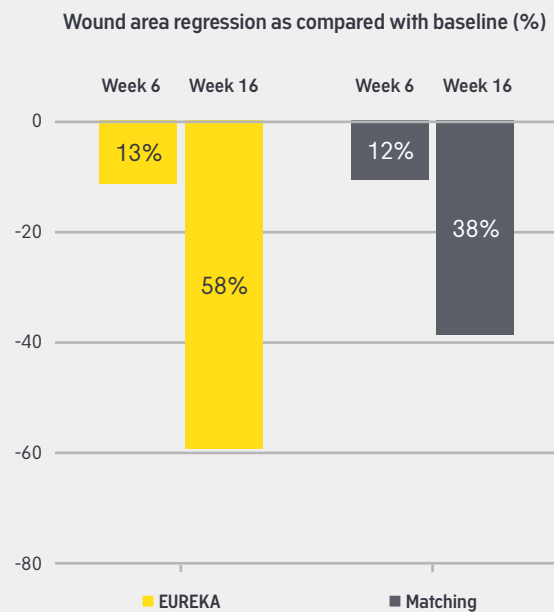


Fig. 4. Median relative wound area regression (RWAR) for the two groups, at week 6 and 16 of treatments.

- **Safety profile:** None of the patients of the EUREKA group developed an infection that required antibiotics during the EUREKA study period, compared with 37% of the patients of the matching group during treatment period.

CONCLUSIONS

Although EUREKA patients presented more severe VLUs compared with the 46 matching wounds, the EUREKA wounds showed better results, on many clinical outcomes:

- Higher rate of wound closure
- Faster closure: shorter time to achieve wound closure
- Higher rate of RWAR at weeks six and 16
- No wound breakdown after wound closure during the same observation period in the two groups (week 16)
- Higher safety profile (no infections). This might be explained by the ability of FLE to modulate the anti-inflammatory responses and control bacterial colonization and growth.

These findings support EUREKA results in patients with VLUs which showed that the system was well-tolerated and efficacious.