

MANAGEMENT OF VENOUS LEG ULCERS WITH TWO ACTIVE WOUND DRESSINGS. RESULTS OF A RANDOMIZED CLINICAL TRIAL

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Objective: The Nano-OligoSaccharide Factor (NOSF) is a new compound aiming to promote wound closure mainly through inhibition of MMPs activity. This factor is incorporated within a lipido-colloid matrix (TLC-NOSF matrix) and locally released in the wound. The objective of this study was to document the performance of the NOSF relative to a matrix containing collagen and oxidized regenerated cellulose (ORC) effect, in the local management of venous leg ulcers (VLU).

Methods: This was a 12-week, open, 2-arm multicentre randomized study. Patients were selected if the area of their VLU (ABPI ≥ 0.80) was ranged from 5 to 25 cm² with a duration ≥ 3 months. In addition to receiving compression bandage therapy, patients were randomly allocated to either NOSF-matrix or ORC treatment for 12 weeks. The VLU's were assessed on a weekly basis and wound tracings were recorded. Percentage wound relative reduction (%RR) was the primary efficacy criterion. Secondary objectives were wound absolute reduction (AR), healing rate (HR) and % of wounds with $\geq 40\%$ reduction compared to baseline.

Results: 117 patients were included (57 NOSF-matrix and 60 ORC). Fifty six percent of the VLU were present for >6 months, 61% were recurrent, 68% were stagnating despite appropriate cares. Mean wound area at baseline was 11.2 ± 7.4 cm². At the last evaluation, a superiority of NOSF-matrix effect compared to ORC was concluded ($p=0.0059$ for superiority test). The median of the wound area reduction was of 61.1% and 7.7% in the NOSF-matrix and control groups respectively (PP analysis) or 54.4% vs. 12.9% in ITT analysis. In the oldest and largest VLU's, a strong promotion of healing effect was particularly observed in the NOSF-matrix group when compared to the control group.

Conclusion: NOSF-matrix is a very promising option for the local management of chronic wounds, especially for venous leg ulcers with poor healing prognosis.