TREATING VENOUS LEG ULCERS WITH SUCROSE OCTASULFATE LIPIDOCOLLOID DRESSING (TLC-NOSF): CLINICAL OUTCOMES FROM TWO RANDOMIZED CLINICAL TRIALS.

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AIM

The last decade, many procedures have been developed in order to improve the healing prognosis of the venous leg ulcers, the most prevalent chronic wounds in western countries. Among these procedures, a sucrose octasulfate dressing (TLC-NOSF), which presents metallo-proteases inhibiting properties and stimulates angiogenesis, has been developed and then assessed in two large controlled randomized trials, to establish its benefits in these chronic wounds.

METHOD

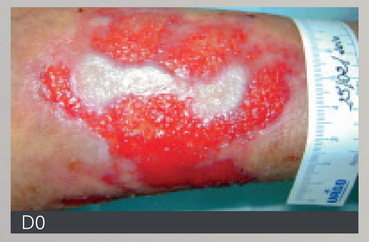
Two european prospective, multicentre, controlled randomised clinical trials were carried out in VLUs; the first one was open label versus oxidised regenerated cellulose (ORC matrix) and a second one, conducted under a double blind design. Patients were randomly assigned and treated during 12 and 8 weeks respectively, with a biweekly investigator's assessment (with clinical, planimetric and photographic records). The primary outcome in both trials was the relative Wound Area Reduction (WAR, in %), and the secondary objectives were absolute WAR and percentage of wounds with >40% surface area reduction compared with baseline.

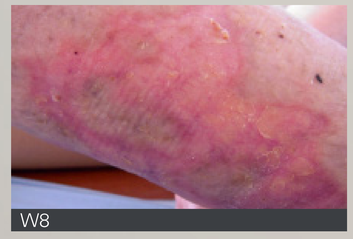
RESULTS

117 and 187 patients were randomly allocated to treatment groups, in each trial, respectively. Baseline patients' and wounds' characteristics were well balanced between the two groups, in both trials, with a high level of compression therapy compliance (91% and 96% respectively). In both studies, the median WAR was significantly higher in the TLC-NOSF group ; 54.4% vs 12.9% (p=0.0286) and 58.3% vs 31.6% (p=0.002) in the tested and the control groups, respectively. All secondary outcomes were in favor of the sucrose octasulfate dressing, and a good safety profile was documented for this tested dressing, in both trials.

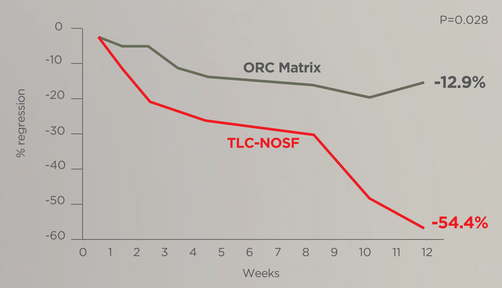
CHALLENGE STUDY: complementary analyses

Complementary analyses were undertaken to document the relative WAR when considering parameters of poor healing prognosis such as the recurrence of the leg ulcer, the duration of the ulcer of more than 1 year, or an initial surface area greater than 10 cm^2. Whichever subgroup is considered, the superiority of the TLC-NOSF dressing is documented as having a very homogeneous effect. The neutral dressing group, however, shows more disparity for wounds of different conditions.

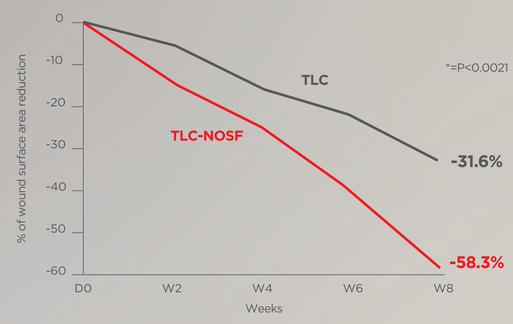


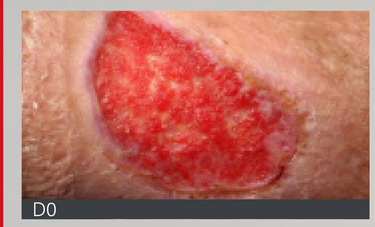


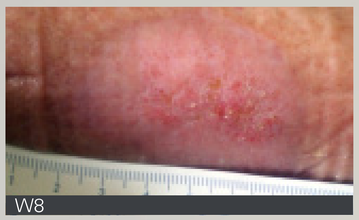
WHAT RCT[1]: wound area reduction



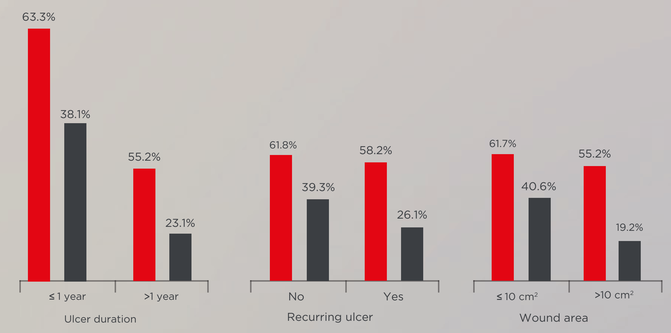
CHALLENGE RCT[2]: wound area reduction







Relative wound area reduction (WAR) ; CHALLENGE Study subgroup analysis



Inclusion criteria

- Adult patient who has provided written consent for his participation
- Patient who can be monitored by the same investigator throughout the 8 weeks of treatment
- Patient who agreed to wear compression, along with the study dressing, every day
- Ulcer with a surface area of between 5 cm^2 and 50 cm^2
- Ulcer that has been prese nt for between 6 and 36 months
- Venous or mixed leg ulcer (ankle brachial pressure index: 0.8 < ABPI < 1.3)
- No dark necrosis on the wound bed
- Leg ulcer that is at least 3 cm away from another wound
- Patient compliant to an effective compression system therapy
- Non-infected leg ulcer

CONCLUSIONS

The two RCTs undertaken with the TLC-NOSF lipidocolloid dressing have documented positive and concordant outcomes for this tested dressing, suggesting a strong promotion of the healing process in the VLUs, as recently reported in the NICE Guidance (January 2019) based on this sucrose octasulfate dressing procedure, in addition to improvement of Quality of Life and cost savings for the payers.

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(2) Meaume S, Bohbot S, Dompmartin A et al. A randomized, controlled, double-blind prospective trial with a Lipido-Colloid Technology-Nano-OligoSaccharide Factor wound dressing in the local management of venous leg ulcers. Wound Repair Regen. 2012 Jul-Aug;20(4):500-11