



WOUND HEALING

SUCROSE OCTASULFATE DRESSING VERSUS NEUTRAL DRESSING IN PATIENTS WITH DIABETIC FOOT ULCER: RESULTS OF A PROSPECTIVE, EUROPEAN, RANDOMISED, DOUBLE-BLIND, CONTROLLED TRIAL ('EXPLORER')

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Background: According to most recent guidelines, no treatment added to optimal Standard of Care (SOC) including efficient off-loading has shown any clear benefit in the management of diabetic foot ulcer (DFU).

Objective: Efficacy of a sucrose octasulfate (TLC-NOSF) wound dressing versus a neutral dressing (TLC) in addition to the same standard of care, in patients presenting with a neuro-ischaemic DFU, was then assessed in neuro-ischaemic DFU, through a European RCT conducted in five countries (UK, France, Spain, Italy and Germany).

Materials and Methods: This double-blind RCT was conducted in 43 centres in patients presenting with a non-infected DFU (grade IC/ IIC, Texas Classification), and a surface area > 1cm². The primary outcome was the wound closure rate by week 20 in the ITT population (binary logistic analysis, completed with sensitivity analysis). Secondary outcomes included time to closure and adverse events occurrence (infection, notably).

Results: A total of 240 patients were randomised and received either the treatment dressing (n=124) or the control dressing (n=114). At Week 20, wound closure occurred in 34 patients (30%) in the control group and in 60 patients (48%) in the treatment group (adjusted odds ratio 2.60 [95% CI 1.43 to 4.73], p=0.002) and the estimated mean time to closure was 60 days (95% CI 47-75) longer in the control dressing group than in the sucrose octasulfate dressing group (180 vs 120 days, p=0.029).

Post-hoc analysis were also undertaken, considering parameters that may influence the





tissue repair process (wound duration, wound location...), always showing favorable outcomes for the sucrose-octasulfate dressing, whatever the characteristics of the treated wound.

Conclusions: Sucrose octasulfate dressing is significantly more effective than neutral dressing, in addition to good standard of care, in the management of neuro-ischaemic DFUs, and specifically when treatment is initiated early in the wound evolution.

