

EFFICACY AND SAFETY OF A NOVEL SUPER-OXIDIZED SOLUTION (SOS) IN MANAGING POST-SURGICAL LESIONS OF THE DIABETIC FOOT – A PROSPECTIVE, RANDOMIZED CLINICAL TRIAL.

We evaluated the efficacy and safety of SOS in the management of infected lesions of the diabetic foot after surgical debridement.

All the diabetic patients with post-surgical infected lesion $> 5 \text{ cm}^2$, attending our foot clinic during 2006 were randomized to receive local SOS treatment (Group A = 20 pts) or standard local treatment with povidone iodine (Group B = 19 pts), in addition of metabolic control, systemic antibiotics and offloading. At baseline and at weekly control visits lesional area, clinical signs of infection, microbiological sampling, new debridements and adverse events were recorded blindly to the local treatment. Endpoints at week 24 included healing rate, healing time, time for sterilization of the lesions, number of debridements and of adverse events.

85% of Group A patients healed in 24 weeks vs 53% of group B ones ($p<.01$); healing time was 10.5 ± 1.3 wks Group A vs 16.5 ± 1.7 wks Group B ($p<.01$), time for sterilization was 5.5 ± 2.1 wks Group A vs 16.2 ± 6.6 wks Group B ($p<.01$), further debridements were carried out in 3 patients of group A and in 9 of group B ($p<.05$), no differences were observed in the adverse events occurrence (2 in group A vs 3 in Group B).

SOS local treatment proved to be as safe as and more effective than povidone iodine in the management of wide post-surgical infected lesions of the diabetic foot.