

# **The Effectiveness of Neutral Ph, Super-oxidized Solution for the Treatment of Infected Diabetic Foot Wounds**

**Objective:** Foot ulcers are common in diabetic patients, and most become infected, thereby increasing the risk of amputation. Successful treatment requires a comprehensive program of metabolic control, wound debridement, and antibiotics. The role of topical antimicrobials remains undefined. Dermacyn<sup>®</sup> is a stable, pH-neutral super-oxidized solution (nSOS) that contains oxochlorine compounds and is highly active against numerous microorganisms.

**Study Design:** We evaluated the clinical efficacy and microbial load reduction of topical therapy with nSOS or saline in diabetic patients with mild foot infections. This randomized trial enrolled 100 patients (81 men and 19 women) with either type I or type II diabetes and solitary infected foot ulcers 2 cm to 15 cm in diameter. Patients were randomized into two groups and were instructed to bathe their wounds in either 20-50 mL of nSOS or normal saline for 4–5 minutes once a day for 16 weeks. Debridement was performed as needed. Cultures were obtained from the base of the wounds on days 1, 7, and 21 of the treatment period. Off-loading was achieved in all patients. Patients were evaluated weekly by an examiner who was blinded to the solution the patient was using for wound cleansing. All 100 patients completed the 16-week study. At entry, the most common isolates in both groups were *Staphylococcus aureus* and *E. coli*.

**Results:** A 5-log reduction in bioburden was documented at some point in 38 patients (76%) in the study group, whereas only 16 patients (32%) in the saline group achieved a 2-log reduction in bioburden ( $p=0.01$ ). In addition, better growth of granulation tissue was noted at the base of the ulcers in patients in the study group than in those in the saline group (8 cm<sup>2</sup> versus 2 cm<sup>2</sup>,  $p=0.05$ ). At the conclusion of the trial, the wounds had healed in 39 patients (78%) in the nSOS group versus only 20 patients (40%) in the saline group ( $p=0.05$ ).

**Conclusion:** This study demonstrates for the first time that nSOS is superior to saline for treating mildly infected foot wounds in diabetic patients and that mechanical eradication of bacteria is not the sole explanation for its efficacy.

