

Super-Oxidized Solution (SOS) Therapy for Diabetic Foot Ulcers

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OBJECTIVE

To evaluate the epithelialization rates of chronic, non healing diabetic limb ulcers treated topically with a commercially available, neutral pH- nSOS (Microcyn®) or saline solution.

BACKGROUND

The efficacy of a pH neutral-superoxidized solution (nSOS) for the treatment of diabetic foot infections has been suggested in two previous studies (Dalla Paola 2006, Goretti 2007). Improved control of the infection, reduction in the use of antibiotics and a faster wound healing were all found in the group treated with nSOS. Unfortunately, the control groups received betadine which -due to its cytotoxicity- could have biased the results in favour of nSOS. Thus, a pilot study was conducted to evaluate the effect a commercially available, topical nSOS (Mycrocyn®) versus topical 0.9% saline solution in the treatment of chronic, diabetic limb ulcers.

PATIENTS & METHODS

This was open label, non randomized study of consecutively enrolled adult patients with type I and II diabetes mellitus and chronic ulcers >5cm. All patients had diabetes for more than 10 years and a working diagnosis of neuropathy was made by vibratory and monofilament tests.

Standard of care included off-loading techniques, change of alginate dressings and metabolic control. JetOx, a hydroperfusor equipment, was used for the delivery of nSOS or saline solution to the wounds. This system uses oxygen at high pressure to propel the solutions for cleansing and debriding wounds without inducing pain. The pressure depends on the opening of the fluxometer which, at 8 to 10 liters per minute, generates an exit pressure of 8 - 10 mmHg. The wounds were cleaned with JetOx and 50 mL of the solution once every week. At home, lesions were irrigated with 30-50 mL every day, until complete closure.

RESULTS

Table 1: Patient Demographics

Factor		Test (MCN) N=40	Control (Saline Solution) N=40
Gender	Male n (%)	18	19
	Female n (%)	22	21
Age, years* Mean		58.42	54.19
Duration of DM , years Mean ± s.d.		14 ±6	12 ± 5
Ulcer size/cm ² Mean ± s.d.		9.2 ± 2	8.7 ± 1.5
PVD with Phono (n)		32	34
Neuropathy ** n (%)		40 (100)	40 (100)

*Age data available for n=40 control patients and n=40 test patients

MCN, Microcyn 60; Saline solution, 0.9% NaCl solution; PVD, peripheral vascular disease

Table 2: Sites Affected in 80 patients for whom information was available

Location	Number	%
Leg	25	31.25
Foot (unspecified)	17	21.25
Ankle	3	3.75
Hindfoot	10	12.5
Forefoot	8	10.0
Hallux	7	8.75
Toes	10	12.5

Table 3: Healing Time of Ulcers in Diabetic Patients

	nSOS (Microcyn)	Saline Solution
n	40	40
Median (days)	35	60
Min (days)	17	45
Max (days)	43	75

DISCUSSION

Yahagi et. al. (2000) showed that only neutral pH super-oxidized solution (nSOS), but not regular saline solution or acidic SOS, could induce a faster wound healing in clean ulcers in rats. This has been explained as a direct effect of nSOS on wound healing, not necessarily related to its antimicrobial activity (e.g. Bongiovanni, J Vasc Ultrasound, 2006). The present study also suggests that, in comparison to saline solution, nSOS induces a faster wound healing in chronic, non healing ulcers of diabetic patients. Controlled studies await to be conducted to evaluate this issue.

REFERENCES

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