

## SUPEROXIDISED SOLUTION IN THE MANAGEMENT OF LOWER LIMB ULCERS: OUR EXPERIENCE

SatishKumar R<sup>1</sup>, Narayanaswamy T<sup>2</sup>, Madhushankar L<sup>3</sup>, Nikshita N<sup>4</sup>

### HOW TO CITE THIS ARTICLE:

SatishKumar R, Narayanaswamy T, Madhushankar L, Nikshita N. "Superoxidised solution in the management of lower limb ulcers: our experience". Journal of Evolution of Medical and Dental Sciences 2013; Vol. 2, Issue 44, November 04; Page: 8483-8489.

**ABSTRACT: BACKGROUND:** The management of wounds is fundamental in the practice of surgery. The prevalence of leg ulceration is approximately 1% to 2%, and is slightly higher in the older adult population. Lower limb ulcers have a multifactorial etiology, more commonly seen in diabetics. Superoxidised solution is a new concept in wound management, it is an electrochemically processed aqueous solution with neutral pH, non toxic, non-irrigating, no rinse dermal wound irrigant. **AIMS:** Superoxidised solution was used on Lower Limb Ulcers to observe; Wound disinfection, Decrease in wound size, Appearance of Granulation tissue and Duration of Hospital stay. **SETTINGS & DESIGN:** This prospective study was conducted at Kempegowda Institute of Medical Sciences & Research Center on a study population of 100 patients from September 2011 to September 2012. Sampling Design is purposive sampling. **MATERIAL AND METHODS:** Study group included 100 patients above 18yrs of age, traumatic ulcers and diabetic ulcers. Informed consent was taken, routine and specific investigations, swab culture and sensitivity taken. Assessments were done on Day 1, 5, 9, 12, 18, 21. **CONCLUSION:** Superoxidised solution is safe and effective in lower limb ulcers, and we found it to be efficient with significant improvement in appearance of granulation tissue and epithelization and reduction in duration of hospital stay.

**KEYWORDS:** Diabetic ulcer, Superoxidised solution, lower limb ulcers

**INTRODUCTION:** Wound management during the early Egyptian civilization resembles current approaches. The Egyptians may have been the first, unknowingly, to employ the "moist wound healing" principle.

The Words quoted by Luodon and published in 1805<sup>1</sup> very much summarize leg ulcer management, "ulcers on the leg form a very extensive and important class of disease, the treatment of such cases is generally looked upon as an inferior branch of practice an unpleasant and inglorious task where much labour must be bestowed and little honour gained"<sup>1</sup>.

The management of wounds is fundamental in the practice of surgery. The prevalence of leg ulceration is approximately 1% to 2%, and is slightly higher in the older adult population.<sup>2</sup> Annual foot ulcer incidence among patients with diabetics is 2-3%, and documented U.S. and U.K. prevalence ranges from 4 to 10%<sup>3</sup>.

Wound healing has a multifactorial etiology. Various treatment modalities have been discovered over the years in forms of different types of wound dressings. Some commonly used dressing agents are povidone iodine, EUSOL, acetic acid, silver sulfadiazine etc. An ideal wound care product in addition to controlling the infection should also protect the normal tissues and not interfere with the normal wound healing.

Super oxidised solution is a new concept in wound management, it is an electrochemically processed aqueous solution with neutral pH, non toxic, non-irrigating, no rinse dermal wound

# ORIGINAL ARTICLE

---

irrigant used in humans for wound care treatment including postoperative (post- surgical) wound care. Super oxidized solutions are electrochemically processed aqueous solutions manufactured from pure solutions which is rich in reactive oxygen species with neutral pH and longer half life (>12 months). It is FDA approved.

**Ingredients:** Oxidized solution (H<sub>2</sub>O), sodium hypochlorite 35.7mg/L(NaOCl), Hypochlorous Acid 25.2mg/L(HOCl), Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), Ozone (O<sub>3</sub>), Chlorine dioxide (ClO<sub>2</sub>), Sodium hydroxide (NaOH), Sodium Carbonate (Na<sub>2</sub>CO<sub>3</sub>) and Sodium chloride 110.6mg/L (NaCl).

Osmolarity - 13 mOsm /kg , ORP >800mV, super-oxidised water (999.8%), pH 6.27.8, Hypotonic solution , Sodium hypochlorite is a solution preservative.

**Mechanism of Action:** Superoxidised solution is Bactericidal, Fungicidal, Virucidal and Sporicidal. During the electrolysis process, solutions molecules are broken, ions and free radicals are formed. They rapidly react and denature proteins of bacterial cell wall, have anti-inflammatory effect, produce an environment with an unbalanced osmolarity that damages single cell organism. Damage is a direct result of the osmolarity difference between the concentrations of the ions in the solution versus the concentration of the same ions in the cell. Multicellular organisms are not prone to such osmolarity changes, therefore host tissues are spared. Once the single cell membrane is damaged, the ions in the product denature the bacterial proteins as well<sup>4</sup>

As wounds are a great burden on the Healthcare system, hence the need for the study.

**MATERIAL AND METHODS:** The inclusion criteria of the study group was 100 patients above 18yrs of age, traumatic ulcers and diabetic ulcers. We have excluded patients under 18 years of age, with arterial ulcers, venous ulcers, trophic ulcers malignant ulcers, decubitus ulcers, osteomyelitis, patients on cytotoxic drugs and immunocompromised patients.

Consecutive Patients with Lower Limb Ulcers attending Kempegowda Institute of Medical Sciences & Research Center, General Surgery Department, were screened and selected for study after satisfying the inclusion criteria. 100 patients were included in the study.

Informed consent was taken, routine and specific investigations, such as haemogram, blood sugar, renal function tests, liver function tests, total protein, swab culture and sensitivity and x-rays when indicated was taken.

Patients were put on antibiotic coverage according to culture and sensitivity. Insulin and oral hypoglycemic agents were given for diabetics for blood sugar control. Assessments were done on Day 1, 5, 9, 12, 18, 21 and the observations were noted in the written proforma.

Various tools were used to assess the efficacy of superoxidised solution which included appearance, wound, Appearance of granulation tissue and Epithelialization, periwound erythema, periwound edema, Organism Isolated/Growth on culture sensitivity, if any procedures done (skin grafting, mechanical debridement).

**RESULTS:** The study was conducted in 100 patients.

1). Demographic data: 71 patients (71%) were males and 29 (29%) were females. The age at presentation in the males ranged from 26 to 86 years, with a mean age of 52.25 years (SD 14.50). In females it ranged from 35 to 81 years with a mean age of 54.65 years (SD 10.24). (table 1)

Age	Male	Female	percentage
18-30	2	-	2%
30-40	6	2	8%
40-50	19	5	24%
50-60	20	12	32%
60-70	13	6	19%
70-80	9	3	12%
>80	2	1	3%
Total	71	29	
Mean $\pm$ SD	52.25 $\pm$ 14.50	54.65 $\pm$ 10.24	

**Table 1: Demographic data**

2). Number of diabetics: This study included 70 patients with type I and type II diabetes out of which 52(73.2%) were males and 18(62%) were females, thus comprising a significant number in the study group.

	Male	Female
Diabetes	52(73.2%)	18(62%)

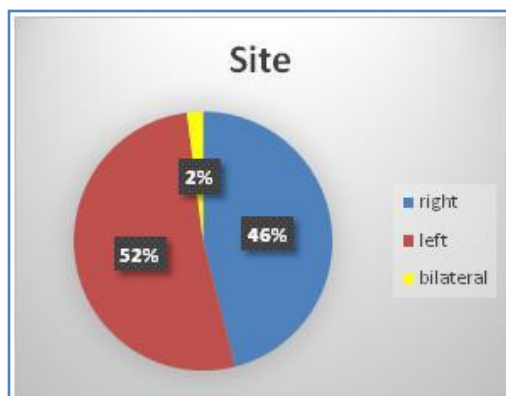
**Table 2: Number of Diabetic patients**

3). Site of ulcer:

Right lower limb- 46%

Left lower limb- 52%

Bilateral - 2%



**Table 3: Affected Limb**

Position of ulcer: Ulcers most commonly involved the dorsum of the foot, and the other areas as mentioned in Table 4, either alone or together with other sites.

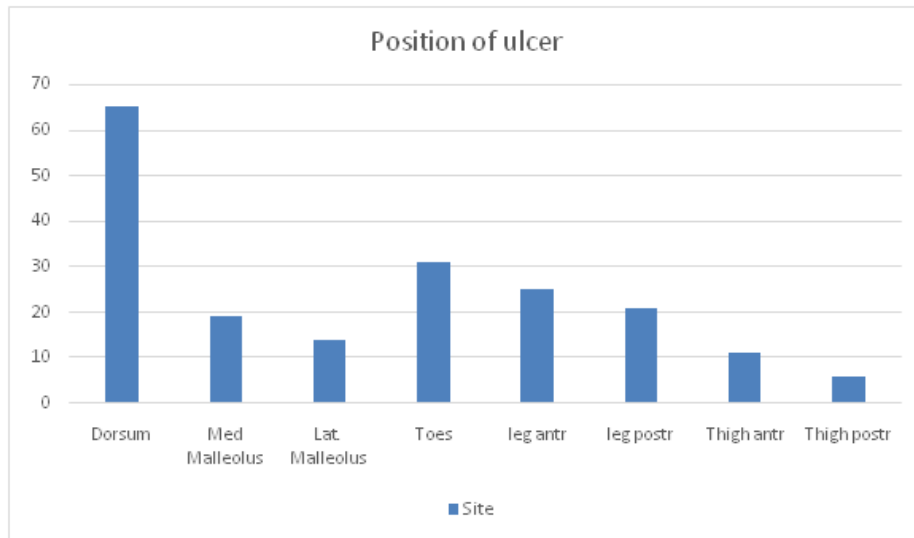


Table 4: Position of Ulcer

4). Severity of diabetic foot ulcers are graded according to Meggit-Wagner classification<sup>9</sup>

Out of 70 Diabetic Patients,

39 Patients had Grade 1- Superficial Diabetic ulcer,

23 Patients had Grade 2 Ulcers with Extension involving, tendon / fascia

8 patients had Grade 3 Ulcer with abscess

5). Percentage decrease in wound size: The wound size was documented at the assessment days and an average reduction in wound size tabulated. We found a 32% reduction in wound size at day 12 and about 56% at day 21. (Table 3)

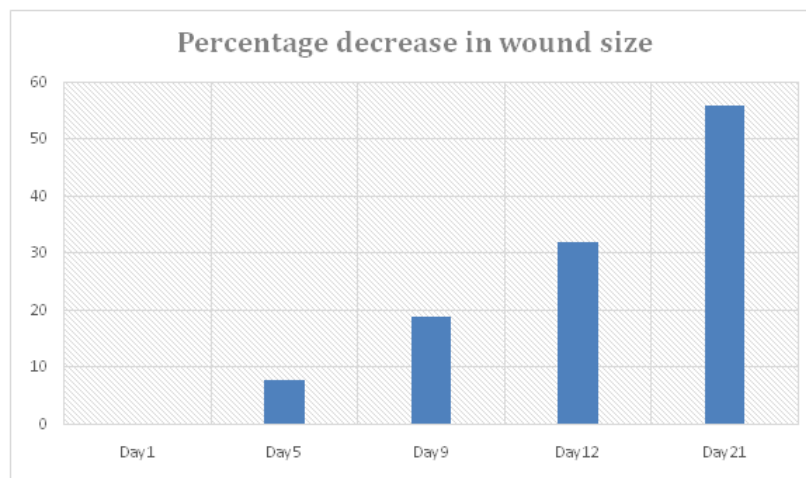


Table 5: Percentage decrease in wound size

6). Appearance of granulation tissue: In 69% of patients we noticed appearance of granulation tissue by day 5.

# ORIGINAL ARTICLE

---

7). Epithelization: 65% patients had epithelization by day 12.

8). Commonest organism on culture: Growth on culture was positive in 68 patients. Staph aureus was the commonest organism on culture sensitivity (41 cases). 2 or more organisms were seen in some patients. 28% patients had no growth on culture taken on day 9. (Table 4).

Growth on culture	Number of cases
Staph aureus	42
E.coli	21
Pseudomonas	20
Klebsiella	15
Enterococci	13
Proteus mirabilis	11
Streptococci	5

Table 6: Growth on culture

9). Procedures done:

Surgical debridement was done in 26 cases.

Disarticulation of toes was done 12 cases.

Split skin grafting-23 patients out of which 8 cases had undergone debridement.

Split skin grafting was done in 11 patients by day 15 and in 12 patients by day 21.

10). Duration of hospital stay: Average duration of hospital stay in 100 patients was 16.4 days.

**DISCUSSION:** Out of 100 patients included in the study, 71 were male and 29 female patients. 70% of the patients were diabetic. Around 56% reduction in wound size was noticed at 3 weeks, with early appearance of granulation tissue by day 5 in 69% patients. Staph aureus was the commonest organism on culture sensitivity. Average duration of stay in the hospital is 16.4 days, 23 patients underwent skin grafting by 21 days. We noticed early appearance of granulation tissue (avg. day 5) and epithelization (avg. day 12) and wound disinfection was achieved in 28% patients by day 9.

Superoxidised solution is safe and effective in lower limb ulcers, and we found it to give better efficacy as compared to other topical agents. It promotes rapid healing without damaging the normal tissue.

We noticed significant improvement in appearance of granulation tissue and epithelization. In our study we noticed reduction in duration of hospital stay. No adverse events/complications were noted.

Gutierrez in his study to explore various applications of superoxidised solutions concluded that the moistening effects and minimum toxicity found with the use of this superoxidised solution made it a good choice for wound care management<sup>5</sup>

Many studies have proven its safety and efficacy and showed no complications were noted.<sup>[6,7]</sup>

Wolvos TA concluded that Superoxidized solution could be used to treat a variety of wounds from simple to extremely complex. It can be used as the wound irrigation solution at simple dressing changes, and it can serve as the solution to moisten the gauze used to dress the wound.<sup>8</sup>

# ORIGINAL ARTICLE

---

**CONCLUSION:** Superoxidised solution is safe and effective for the management of lower limb ulcers. It has no toxicity and its moistening effect makes it an effective topical solution for wound care.

## REFERENCES:

1. The Inquirer (1805). What are the comparative advantages of the different modes proposed for the treatment of ulcerated legs? *Edinburgh Medical and Surgical Journal*, I, 187-193. This is a very lucid account of opinion in 1805 on the treatment of leg ulcers.
2. Mekkes JR, Loots MAM, Van Der Wal AC, Bos JD. Causes, investigation and treatment of leg ulceration. *Br J Dermatol*. 2003, 148: 388-401.
3. Reiber GE, Boyko E, Smith DG: Lower extremity ulcers and amputations in individuals with diabetes. In *Diabetes in America*, 2nd ed. Harris MI, Cowie CC, Stern MP, Boyko EJ, Reiber GE, Bennett PH, Eds. Washington, DC, U.S. Govt. Printing Office, 1995, p. 409-427 (NIH publ. no. 95-1468).
4. Oxum Product Monograph.
5. Gutierrez Andres A. The science behind stable super oxidized water exploring the various applications of super-oxidized solutions in clinical experience with a new and stable superoxidized water in wound treatment, advanced wound care with stable, superoxidized water. Supplement to January 2006 *Wound (A compendium of Clinical Research and Practice)* Page 7-10.
6. Dalla Paola L, Brocco E, Senesi A et al (2005) Use of Deracyn, a new antiseptic agent for the local treatment of diabetic foot ulcers. *J Wound Healing* 2:201.
7. Chittoria RK, Yootla M, Sampatrao LM, Raman SV, The role of super oxidized solution in the management of diabetic foot ulcer: our experienced Department of Plastic Surgery, Sri Venkateswara Institute of Medical Sciences, Tirupati, Andhra Pradesh, India.
8. Wolvos Tom A.-A look at how combination therapy can optimize wound healing in Clinical Experience With A New And Stable Super-Oxidized Water In Wound Treatment, Advanced Wound Care with Stable, Superoxidized Water. Supplement to January 2006 *Wounds (A Compendium Of Clinical Research and Practice)* Page 11-13.
9. Wagner, F., Levin, M., & O'Neal, L., 1983. Supplement: algorithms of foot care. In *The Diabetic Foot*. 3rd ed. St. Louis, MO, CV. Mosby, 1983, p. 291- 302.



# ORIGINAL ARTICLE



## AUTHORS:

1. SatishKumar R.
2. Narayanaswamy T.
3. Madhushankar L.
4. Nikshita N.

## PARTICULARS OF CONTRIBUTORS:

1. Professor & Unit Head, Department of General Surgery, Kempegowda Institute of Medical Sciences & Research Centre, Bangalore.
2. Associate Professor, Department of General Surgery, Kempegowda Institute of Medical Sciences & Research Centre, Bangalore.
3. Assistant Professor, Department of General Surgery, Kempegowda Institute of Medical Sciences & Research Centre, Bangalore.

4. Post Graduate, Department of General Surgery, Kempegowda Institute of Medical Sciences & Research Centre, Bangalore.

## NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. SatishKumar R.,  
Professor & Unit Head,  
Kempegowda Institute of Medical Sciences &  
Research Centre, K.R. Road, V.V. Puram,  
Bangalore – 560004.  
Email – satikramaiah62@gmail.com

Date of Submission: 12/10/2013.

Date of Peer Review: 15/10/2013.

Date of Acceptance: 26/10/2013.

Date of Publishing: 29/10/2013