

Efficacy of Topical Super Oxidized Solution Over Povidone Iodine for Lower Limb Diabetic Ulcers

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Abstract

Context: The Super oxidized solution is a new concept of wound management. It has anti inflammatory effect that damage single cell organism not multicellular organism, therefore host tissues are spared. *Aims:* To study the efficacy of topical SOS in Diabetic ulcers to observed Wound size, Time for appearance of healthy granulation tissue, Wound disinfection, Duration of hospital stay. *Settings and Design:* Prospective, cohort & single centred, experimental study. *Methods and Material:* 100 cases divided in to two groups for comparison between topical SOS and PI dressing for lower limb diabetic ulcers. *Statistical analysis used:* p values, student t test. *Results:* in SOS and PI group patients wound assessments done on day 1,9,15 and 21 days and various wound outcome variables were compared. Patients were in the age group of 51-60 years and 68% were male. There was rapid decrease in wound size in SOS group compared to PI group at day 21, and earlier appearance of granulation tissue in SOS group. Resolution of peri wound erythema and peri wound edema was earlier in SOS group compared to PI Group. There was shorter duration of hospital stay, earlier wound disinfection and more number of patients who underwent skin grafting before 21 days in SOS group. *Conclusions:* SOS with its moistening effects and cost effectiveness is safe, has faster response in wound healing and gives better efficacy as compared to the traditional Povidone Iodine solution for use as a

topical / irrigant solution in wound care and in management of lower limb diabetic ulcers..

Keywords: Wound Debridement; Diabetic Foot; Super Oxide Solution.

Introduction

Diabetes mellitus is a chronic disorder and affects large segments of population. Diabetic foot ulcer affects 10-15% of patients during their life and cause morbidity, hospitalisation, affecting the quality of life. Infected, non-healing ulcer is the major cause of non-traumatic lower limb amputation. It is estimated to be 40 times greater in the diabetics. Over 1 million amputations for diabetes related complications occur every year [1]. It has increased the cost of treatment, hospitalization and its management involves a multidisciplinary approach [2]. chronic wounds, inspite of daily dressing, will not heal. Thus to treat these is a constant challenge for the surgeon. The risk of amputation in a patient with diabetes is 15-40 times higher than that in a patient without diabetes. The prevention of diabetic foot is crucial, considering the negative impact on a patient's quality of life and the associated economic burden on the healthcare system [3].

Wound healing has a multifactorial etiology. Various treatment modalities have been discovered over the years in forms of different types of wound dressings. 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 [4]. Some commonly used dressing agents are collagen, gentian violet, benzoyl peroxide, EUSOL, acetic acid, silver sulfadiazine etc.

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Povidone iodine is the most commonly used topical wound care product. The Super oxidized solution (SOS) is a new concept of wound management. It has anti-inflammatory effect and produce an environment with an unbalanced osmolarity that damage single cell organism not multicellular organism, therefore host tissues are spared [5].

The present study was conducted to assess the efficacy of topical application of Super oxidized solution (SOS) as compared to Povidone iodine in healing process in lower limb diabetic ulcers, and prove that topical application of Super oxidized solution can be used as much better alternative option in the management of lower limb diabetic ulcers.

Aims & Objectives

To study the efficacy of topical SOS over PI in Diabetic foot ulcers in terms of decrease in Wound size, Time for appearance of healthy granulation tissue, Wound disinfection, Duration of hospital stay

Materials and Methods

Inclusion Criteria

All patients with diabetic foot ulcers of Wagners grade I, II, III, and also those with chronic lower limb ulcers in diabetics formed the subjects of this study.

Table 1: Age distribution

Age (in Years)	Group A	Percentage (%)	Group B	Percentage (%)	Total
15-20	1	2.0	0	0.0	1
21-30	3	6.0	3	6.0	6
31-40	10	20.0	5	10.0	15
41-50	5	10.0	6	12.0	11
51-60	16	32.0	20	40.0	36
61-70	13	26.0	15	30.0	28
71-75	2	4.0	1	2.0	3
Total	50	100	50	100	100

Chi-square value = 3.678, p value = 0.720 (Not Significant)

Table 2: Sex distribution

Sex	Group A	Group B	Total
Male	38 (76.0%)	30 (60.0%)	68
Female	12 (24.0%)	20 (40.0%)	32
Total	50	50	100

Chi-square value = 2.941, p value = 0.086 (Not Significant).

Table 3: Wagners grading of diabetic ulcer

Wound Grading	Group A	Group B	Total
Grade 1	27 (54.0%)	25 (50.0%)	52 (52.0%)
Grade 2	14 (28.0%)	15 (30.0%)	29 (29.0%)
Grade 3	9 (18.0%)	10 (20.0%)	19 (19.0%)
Total	50	50	100

Chi-square value = 0.164, p value = 0.921 (Not Significant).

Exclusion Criteria

Ulcers not considered to be related to diabetes eteology and patients with severe co morbid conditions were excluded from the study.

This is a prospective, cohort & single centred Experimental study done on 100 cases making them in to two groups for comparison between topical SOS and PI.

All the patients were subjected to thorough general examination and data recorded. The location and the charecters of all the parts of the ulcer noted The patients were divided in to two groups Group A and Group B.

Group A was dressed with oxum solution and Group B with 5% Betadine solution. The size of the wound was measured using graph paper and charting the ulcer in it on Day 1 of admission and again on day 9 and day 15. and the percentage of change in size noted. The floor of the ulcer was inspected daily and the time taken for the healthy granulations and time taken for resolution of periwound erythema, edema and infection was noted.

Ethical Commette Clearence has been obtained from NMC, nellore.

Results

The average percentage of decrease in wound size from day 1 to day 9 was 18.56% with SOS group

compared to 15.22% in Povidone Iodine group, which was statistically significant ($P < 0.004$). The average percentage of decrease in wound size from day 1 to day 15 was 30.83% with SOS group compared to 25.33% in Povidone Iodine group, and this was statistically significant ($P < 0.0001$). (Table 4).

Group A and Group B using independent samples t test. $P < 0.0001$.

The average percentage of decrease in wound size from day 1 to day 21 was 70.95% with SOS group compared to 54.29% in Povidone Iodine group, and this was statistically significant ($P < 0.0001$). (Table 5).

Table 4: Mean wound size (in cm²)

		N	Mean	Std. Deviation	t-value	p-value
Wsd_1	A	50	14.05	5.68	-1.798	0.076
	B	50	15.78	3.75		
	Total	100	14.92	4.86		
Wsd_9	A	50	11.59	5.08	-2.108	0.038
	B	50	13.40	3.33		
	Total	100	12.49	4.37		
Wsd_15	A	50	9.82	4.30	-2.671	0.009
	B	50	11.82	3.06		
	Total	100	10.82	3.84		
Wsd_21	A	50	4.19	2.20	-6.815	< 0.0001
	B	50	7.33	2.41		
	Total	100	5.76	2.78		
W1_9	A	50	18.56	6.75	2.986	0.004
	B	50	15.22	4.13		
	Total	100	16.89	5.82		
W1_15	A	50	30.83	6.61	4.331	< 0.0001
	B	50	25.33	6.08		
	Total	100	28.08	6.90		
W1_21	A	50	70.95	6.51	10.201	< 0.0001
	B	50	54.29	9.54		
	Total	100	62.62	11.67		

Table 5: Percentage of mean decreased in wound size

		N	Mean (%)	Std. Deviation	t-value	p-value
W1_9	A	50	18.56	6.75	2.986	0.004*
	B	50	15.22	4.13		
	Total	100	16.89	5.82		
W1_15	A	50	30.83	6.61	4.331	< 0.0001*
	B	50	25.33	6.08		
	Total	100	28.08	6.90		
W1_21	A	50	70.95	6.51	10.201	< 0.0001*
	B	50	54.29	9.54		
	Total	100	62.62	11.67		

Table 6: Days taken for appearance of healthy granulations

		Appearance of Granulation tissue (days)	
Group A	Mean \pm S.D	5.04 \pm 1.59	
	N	50	
Group B	Mean \pm S.D	6.78 \pm 2.23	
	N	50	

There was significant difference between Group A (SOS) and Group B (P) in the appearance of granulation tissue, $P < 0.001$. (Table 6).

Table 7: Mean duration of peri wound erythema resolution

		Day of Resolution of Periwound Erythema (days)	
Group A	Mean \pm S.D	4.72 \pm 1.51	
	N	50	
Group B	Mean \pm S.D	7.90 \pm 2.01	
	N	50	

There was significant difference between Group A (SOS) and Group B (P) in Peri wound erythema resolution, with $P < 0.001$. (Table 7).

Table 8: Mean duration of peri wound odema resolution

Day of Resolution of Periwound Edema (days)		
Group A	Mean ±S.D N	7.98 ± 2.31 50
Group B	Mean ±S.D N	12.26 ± 2.51 50

There was significant difference between Group A (SOS) and Group B (PI) for Peri wound oedema resolution, with P<0.001. (Table 8).

Table 9: Mean duration of wound disinfection

Day of Wound Disinfection (days)		
Group A	Mean ±S.D N	9.13 ± 2.53 50
Group B	Mean ±S.D N	12.63 ± 3.15 50

There was significant difference between Group A (SOS) and Group B (PI) in the duration for Wound Disinfection (Culture negative), with P<0.001. (Table 9).

Table 10: Mean duration of hospital stay

Mean duration of hospitalization (days)		
Group A	Mean ±S.D N	12.54 ± 2.88 50
Group B	Mean ±S.D N	16.12 ± 3.57 50

There was significant difference between Group A (SOS) and Group B (PI) on Duration of hospital stay, P<0.001 (Table 10).

Table 11: Organisms cultured from the ulcer

Organism on Culture sensitivity	Group A	Group B	Total
Staph aureus	14	11	25
Enterococci	5	7	12
Pseudomonas	7	5	12
Klebsiella	4	7	11
E.coli	4	6	10
Citrobacter	5	3	8
Streptococcus	5	3	8
Proteus	4	3	7
Acinetobacter	1	3	4
No growth	1	2	3

Table 12: Number of patients treated by Split Skin Graft

Split skin grafting	Group A	Group B
Yes	13 (26.00%)	4 (8.00%)
No	37 (74.00%)	46 (92.00%)
Total	50	50

Table 13: Pearson correlations

		AGE	Gran_day	Ery_day	Oedema	Disinf_day	Hosp_stay	Wsd_21
AGE	Pearson Correlation	1	-.071	-.031	-.051	-.057	-.067	-.098
	P value		.485	.757	.617	.583	.506	.333
Gran_day	Pearson Correlation	-.071	1	.769**	.715**	.214*	.600**	.303**
	P value	.485		.000	.000	.036	.000	.002
Ery_day	Pearson Correlation	-.031	.769**	1	.840**	.480**	.684**	.417**
	P value	.757	.000		.000	.000	.000	.000
Oedema	Pearson Correlation	-.051	.715**	.840**	1	.401**	.665**	.403**
	P value	.617	.000	.000		.000	.000	.000
Disinf_day	Pearson Correlation	-.057	.214*	.480**	.401**	1	.415**	.262**
	P value	.583	.036	.000	.000		.000	.010
Hosp_stay	Pearson Correlation	-.067	.600**	.684**	.665**	.415**	1	.232*
	P value	.506	.000	.000	.000	.000		.020
Wsd_21	Pearson Correlation	-.098	.303**	.417**	.403**	.262**	.232*	1
	P value	.333	.002	.000	.000	.010	.020	

** . Correlation is significant at the 0.01 level (2-tailed). * . Correlation is significant at the 0.05 level (2-tailed).

Procedures Done

Among both Groups, wound healed without surgical intervention was in 60 cases (Group A 33, Group B 27) and additional surgical intervention was done in 40 cases in both Groups. 16 cases underwent Debridement, 2 cases in Group A and 14 cases in Group B. 7 cases underwent Fasciotomy, 2 cases in Group A and 5 cases in Group B. 13 cases underwent Split Skin Grafting in Group A and 4 cases in Group B. (Table 11).

Granulation day (r value = 0.303, p value = 0.002), peri erythematous resolution day (r value = 0.417, p value = 0.000), periOedematous resolution day (r value = 0.403, p value = 0.000), Disinfection day (r value = 0.262, p value = 0.010) and Hospital stay (r value = 0.232, p value = 0.02) are having significantly positive correlation with wound size for 21 days. (Table 13).

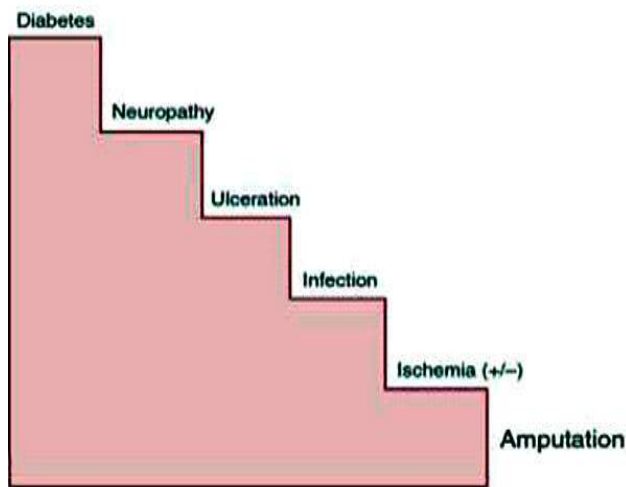


Fig. 1:

Discussion

Diabetic ulcers are challenging problem to every surgeon in day to day practice. Diabetes as one of the major cause of non-healing ulcers is increasing in prevalence now a days. Diabetics have a 15% higher risk for amputation than the general population due to chronic ulcers. The natural history of diabetes-related lower extremity amputation can be described as a stairway.

Wound healing in diabetes is impaired by factors that are both extrinsic and intrinsic to the wound and its biology. Extrinsic factors include repeated trauma or mechanical stress applied to a foot that has been rendered insensitive due to neuropathy as well as ischemia as a result of macro- or micro vascular disease.

An important role has been attributed to factors intrinsic to the biology of the chronic wound in diabetes. It has been postulated that hyperglycemia itself has a deleterious effect on wound healing through the formation of advanced glycation end

products (AGEs) which induce the production of inflammatory molecules (TNF- α , IL-1) and interfere with collagen synthesis.

An altered immune function may also contribute to poor wound healing in patients with diabetes. Decreased chemo taxis, phagocytosis, bacterial killing, and reduced heat shock protein expression have been implicated in the early phase of wound healing in diabetes.

Dressings

Most foot infections do not require extensive incisions and debridement, yet the principles must always be remembered. Dressings are used to serve the following purposes.

- Contain wound drainage.
- Debride a wound.
- Protect an area from trauma.
- Protect an area from contamination.
- Promote proper wound healing.

The basic equipment necessary for bedside foot care are

- Sterile debridement set containing
 - Sharp scissors for debriding.
 - Blunt ended needle wound probe.
 - Smooth forceps.
- Sterile toenail clippers.
- Sterile gauze dressings.
- Tube gauge, paper tape, culture tube
- Antiseptic agents like Povidone iodine, SOS, vasaline guage and Normal saline.

Povidone Iodine as Dressing Agent

Povidone iodine is a stable chemical complex of polyvinyl pyrrolidone (and elemental iodine. *Ingredients of PI*: 9.0% to 12.0% available iodine, calculated on a dry basis. Concentrations of 7.5% to 10.0% in solution, spray, surgical scrub, ointment, and swab dosage forms.

Mechanism of Action of PI

- Free iodine, slowly liberated from PVP-I complex in solution, kills eukaryotic or prokaryotic cells through iodination of lipids and oxidation of cytoplasmic and membrane compounds.
- Broad range of microbicidal activity against: Bacteria, Fungus, Protozoa, yeast, molds and virus.
- Slow release of iodine from the PVPI complex in solution minimizes iodine toxicity towards mammalian cells.

Advantages

- Broad spectrum antiseptic for topical application of minor cuts, grazes, burns, abrasions, blisters and as surgical scrub.
- As pre- and post-operative skin cleaning agent.
- Used for traumatic ulcers, decubitus ulcers, stasis ulcers dressing.
- For treating candidal, trichomonal or mixed vaginitis.

Disadvantages

- Irritation at the site of application, toxicity, staining of surrounding tissues.
- Tendency to kill human cells
- Deficiencies overcome by use of PVP-I, in which the iodine is in complexed form and the concentration of free iodine is very low.

The product thus serves as an iodophor and the sensitization rate to the product is only 0.7%.

Super Oxidized Solution as Dressing Agent

In 2004, European approval was obtained (CE KEMA - Medical Device Class IIb) and FDA approval was obtained in 2005 for the Super Oxidized Solution as a dressing method. It moistens, irrigates, debrides, and reduce microbial load of acute and chronic wounds of diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, and minor irritations of the skin. No reaction or complication has been reported in literature.

SOS is used for treatment of infectious skin defects or ulcers, mediastinal irrigation after open-heart surgery, and treatment of peritonitis and intraperitoneal abscess. Super-oxidized solutions have also been recommended for hand washing in medical personnel.

Mechanism of Action

Superoxidized solution may form part of a wound care regimen for acute or chronic wounds. It has a triple mode of action that significantly improves wound healing.

1. *Infection control:* It acts as bactericidal fungicidal, virucidal, Sporicidal and rapidly reduces microbial load, thus prevents and reduces infection and also reduce the odour of wounds by reacting with dying material.
2. *Inflammation control:* Anti-inflammatory and anti-allergenic effect via mast cell stabilisation.
3. *Stimulation of wound healing:* Promotes fibroblast migration and increases capillary perfusion.

Super oxidized Solution have shown to be both safe and efficient as a wound care product that moistens,

lubricates, debrides and reduces the microbial load of various types of lesions. 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) non flammable and noncorrosive. Super oxidized Solution (SOS) is effective in reducing bacterial load, enhancing local blood supply, accelerating development of neo vascularity and provide a wound environment that is hostile to opportunistic organisms. Although super oxidized solution is an extremely effective agent in wound management, it will not replace administration of good wound care practices.

The concept of wound healing with super oxide solution is a novel and effective mode of treatment. The efficacy of super-oxide solution in different types of wounds was found to be superior to the conventional method of treatment with Povidone iodine.

A major concern when using super-oxidized solutions is the potential induction of DNA oxidation, accelerated aging, and genotoxicity

Ingredients of SOS

Oxidized solution (H₂O), sodium hypochlorite 35.7mg/L (NaOCl), Hypochlorous acid 25.2mg/L (HOCl), Hydrogen peroxide (H₂O₂), Ozone (O₃), Chlorine dioxide (ClO₂), Sodium hydroxide (NaOH), Sodium Carbonate (Na₂CO₃) and Sodium chloride 110.6mg/L (NaCl).

- Osmolarity - 13 mOsm /kg
- Super oxidized water (999.8%)
- Hypotonic solution
- Sodium hypochlorite is a solution preservative.

Advantages

- *Indications for Use:* It is intended for mechanical cleaning of dirt and debris from skin, abrasions, cuts, and minor irritations.
- *Professional Use:* Wound cleaner for mechanical cleaning and debriding acute and chronic wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, pre and post surgical wounds, first and second degree burns, grafted wounds and donor sites.
- *Patient Population:* Patients with acute or chronic wounds.
- *Environment of Use:* Hospitals, nursing homes, wound clinics and pre and post hospitals.

Age and Sex Distribution

In our study mean age of patients was similar when compared to the study conducted by Dr. K.B.S.

Prabhakar et al., Dr. Satish Kumar et al. and Dr.V. AnithaLavanya et al. In our study male patients are predominant and this is comparable to Dr. K.B.S. Prabhakar et al., Dr. V. AnithaLavanya et al, Dr. Satish Kumar et al. and Dr. Luca Dalla Paola et al. studies.

Grading of Ulcer

Our study is similar to Dr. Satish Kumar et al. [7] study which is done on 70 patients with diabetic ulcers more number of patients had Grade I ulcers followed by grade II and III ulcers.

Wound Size

The average percentage of decrease in wound size from day 1 to day 9 was 18.56% with SOS group compared to 15.22% in Povidone Iodine group. The average percentage of decrease in wound size from day 1 to day 15 was 30.83% with SOS group compared to 25.33% in Povidone Iodine group.

The average percentage of decrease in wound size from day 1 to day 21 was 70.95% with SOS group compared to 54.29% in Povidone Iodine group. Dr. S.S. Meera et al. [8] done a similar study which showed decrease in the wound size of about 70% and 80% at day 22 and day 29 in super oxide solution group and 50% and 65% in betadine group respectively.

In a study conducted by V. Kapur et al. [9], in diabetic foot ulcer and chronic leg ulcers patients on day 21 cases treated with SOS showed average reduction in wound size of 70% and 50% in betadine group. In our study mean percentage of decreased in wound size was high at day 21 (70.96%) when compared to 56% in study conducted by Dr. Satish Kumar et al. [7].

Appearance of Granulation Tissue

In our study, granulation tissue appeared earlier in SOS group (5.04±1.59 days) when compared to control PI Group (6.78±2.23 days). In current study granulation tissue appeared in ≤ 5 days in SOS group 76% as compared to 36% in PI group. So SOS group had high percentage when compared to Dr. Satish Kumar et al. [7] study (69%).

Dr. Ashok Anand [10] in his study showed that 88% had granulation by day 5 in SOS group compared to 80% in PI group and by day 10 there was granulation in all patients. Dr. S.S. Meera et al. [8] study SOS group developed healthy granulation tissue earlier than Povidone group.

Resolution of Periwound Erythema

In the current study, there was earlier resolution of periwound erythema in Group A (SOS) 4.7±1.5 days as compared to Group B (PI) 7.23±1.76 days.

Resolution of Periwound Edema

In our study there was earlier resolution of periwound edema in Group A (SOS) 7.8±2.01 days as compared to Group B (PI) 11.3±2.3 days. Our study is similar to study conducted by V. Kapur et al. [9], which shows early granulation and rapid epithelisation in SOS group when compared to betadine group. The mean follow up of 21 days shows that average reduction in wound size and peri wound odema/erythma in SOS group was 70% as compared to 50% in betadine group. This study is similar to study conducted by Dr. S.S. Meera et al. [8] which shows that average decrease in periulcer edema and erythema about 70% at 22 days 90% at 29 days super oxide solution and 55% and 75% respectively.

Time Taken for Improvement in Wound Infection

The mean duration for day of wound disinfection (Culture negative) was earlier in Group A (SOS) 9.13±2.53 days as compared to Group B (PI) 12.63±3.15 days. Our study is similar to Chittoria RK et al., Dr. S.S. Meera et al., Dr. Satish Kumar et al., Dr. vanitha kapoor et al. and Dr. Chiara Goretti et al study. In Dr. S.S. Meera et al. [8] study the mean duration for day of wound disinfection in SOS group was 10±5 days compared to 25±5 days in Povidone iodine group.

Organisms Cultured from the wound: In our study, Staph aureus was the commonest organism on culture Sensitivity and is similar to the study conducted by VanithaKapur et al., Chittoria RK et al. and Dr. Satish Kumar et al.

Duration of Hospital Stay: The mean duration of hospitalization was 12.54±2.88 days in Group A (SOS) which included Skin grafting in 13 cases as compared to 16.12±3.57 days in Group B (PI), showing shorter hospital stay in patients treated with SOS. In the present study mean duration of hospitalization in SOS group was 12.54 days and is earlier when compared to 16.4 days in Dr. Satish Kumar et al. [7] study. In Dr. Miranda Altamirano et al. [11] study on superficial partial, deep partial and full thickness burns hospital stay was reduced by 50% in oxum group v/s control group.

Procedure Done: In current study in 60 cases (Group A 33, Group B 27 cases) no intervention was done and in remaining cases additional Surgical intervention like debridement, Fasciotomy and Split Skin Grafting was carried out. Out of 40 cases, the 13 patients in SOS group were take nearlier for SSG before 21 days compared to 4 cases of PI group, which is statistically significant. ($p = 0.017$).

In Dr. Luca Dalla Paola [6], study the mean healing time was lower in the SOS group (45±14) days compared to (58±20) days in PI group. Wolvos TA [12] 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.

Gutierrez AA [13] in his study to explore various applications of super oxidized solutions concluded that the moistening effects and minimum toxicity found with the use of this super oxidized solution made it a good choice for wound care management and that this non antibiotic technology appears to offer a broad new paradigm for the prevention and treatment of acute and chronic wounds.

Conclusion

Super oxidized solution when compared to Povidone Iodine for diabetic foot ulcers is better with high statistically significance in terms of

- Earlier appearance of granulation tissue
- Earlier resolution of peri wound erythema
- Earlier resolution of peri wound edema
- Early wound disinfection
- Rapid decrease in wound size
- Patients are taken for SSG early.
- Shorter duration of hospitalization

Hence we recommend SOS for regular diabetic wound dressings.

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Conflicts of Interest

Nothing

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