



O₂Misly™ Wound Treatment System when added to the Standard of Care in the Treatment of Non-Healing Foot Ulcers.



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Background / Purpose

Non-healing foot ulcers, especially diabetic, present a difficult clinical challenge and impose a significant socio-economic impact. Approximately 2.4 million diabetic foot ulcers are diagnosed each year in the U.S, many progressing to lower limb amputation. It is estimated that the U.S. spent \$10.9 billion for treatment of diabetic foot ulceration and related amputations in 2001.

It is well known that maintenance of an optimum wound bed environment enhances wound healing. Preparation of the chronic wound bed often requires debridement of material normally generated in the wound base such as slough, eschar, edema fluid, colonizing bacteria and necrotic tissue, collectively referred to as the "bio-burden," that stimulates the release of pro-inflammatory biochemical factors, which when generated in excess negatively impact wound progression.

Standard of wound care involves cleansing at each dressing change with normal saline, or non-cytotoxic wound cleanser recommended to decrease bacterial load. Tissue oxygenation associated with adequate perfusion is also vitally important in successful wound healing. The premise that increased oxygen tension in the wound bed is necessary to support and maintain the proliferative phase of cellular growth, collagen synthesis, and angiogenesis, accelerate microbial oxidative killing and epithelization is well established.

O₂Misly™ is a medical device technology that offers combination adjunctive therapy to the standard of care in the treatment on non-healing ulcers. It provides O₂ infused under tension in a closed chamber blended with a mist containing the clinician's choice of solution. The IRB approved protocol allowed for the use of an antimicrobial solution. The investigators utilized concentrated ionic silver. Ionic silver is fungicidal and bactericidal to a broad spectrum of bacteria. It can reduce bio-burden and is not cytotoxic.

The purpose of the study is to determine if the O₂Misly™ Wound Treatment System can reduce wound volume, accelerate healing rates and is safe and effective.

Materials / Methods

Patients enrolled in this IRB approved protocol had to have non-healing foot ulcers that had failed previous standard of care therapies.

Sample size 31 patients (38 ulcers)

Age range: 34-80
Males: 26 Females: 5

Type of wounds: 29 diabetic neuropathic

Range of time of open wound: 1.5 – 96 months
Range of wound size: 18mm³ to 9100mm³ wound volume measurement

Type of wounds: 9 non- neuropathic

Range of time of open wound: 1 – 48 months
Range of wound size: 24mm³ to 650mm³ wound volume measurement

Visits per week: 2

Treatment time per visit: 1 hour
Oxygen / mist cycles per treatment: 4

Mist time per cycle: 10 minutes

Mist density: 98%
Mist temperature: 77f
Concentration of ionic silver: 300ppm ionic silver solution

Oxygen time per cycle: 5 minutes

Oxygen pressure: ~2mm above atmosphere
Oxygen flow rate: 10 l/m

Treatment time range: 2 – 12 weeks

Average patient treatment time: 42 days = 6 weeks

Minimum # of treatments: 2

Maximum # of treatments: 65

Statistical Analysis: Meta Analysis. SAS 9.1 (procpower)

Demographics

Patient and Wound Characteristics

Characteristic	Neuropathic		Non-neuropathic	
N of patients	23		8	
N of ulcers	29		9	
Gender	21 Males	2 Females	5 Males	3 Female
Patient age (y)	Mean: 61	Range: 40-80	Mean: 64	Range: 34-80
Wound age (m)	Mean*: 24	Range: 1.5-96	Mean**: 20	Range: 1-48
Wound size (mm ³)	Mean: 1181	Range: 18-9100	Mean: 318	Range: 24-650

* based on 15 patients reporting values, ** based on 4 patients reporting values

Conclusion

Comparisons of O₂Misly™ and Standard Therapies

Statistic	Comparison		
	All Wounds	Neuropathic Wounds	Neuropathic Worst-Case
O ₂ Misly 12-w healing rate	76.7%	74.4%	51.6%
Standard 12-w healing rate	24.2%	24.2%	24.2%
Difference	52.5%	50.2%	27.4%
95% Confidence Interval	36% - 69%	33% - 67%	7% - 48%
p-value	< 0.0001	< 0.0001	0.004
O ₂ Misly 20-w healing rate	90.7%	87.2%	62.4%
Standard 20-w healing rate	30.9%	30.9%	30.9%
Difference	59.8%	56.3%	31.5%
95% Confidence Interval	48% - 71%	42% - 69%	12% - 51%
p-value	< 0.0001	< 0.0001	0.001

This investigation demonstrated that O₂Misly™ is an adjunctive therapeutic modality which combines the benefits of oxygen under tension with the benefits of an antimicrobial mist in a closed system to reduce wound volume and accelerate healing rates when added to standard of care of non-healing foot ulcers.

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