Continuous Diffusion of Oxygen for the Treatment of a Chronic Recalcitrant Venous Stasis Ulcer

Objective

Demonstrate the efficacy of utilizing Continuous Diffusion of Oxygen (CDO) for the treatment of recalcitrant venous stasis ulcer's as a compliment to topical wound dressings that are utilized to maintain adequate moisture balance to the wound bed.

Background

Lower extremity venous disease (LEVD) is synonymous with chronic venous disease. Chronic Venous Insufficiency (CVI) refer to leg related manifestations of venous hypertension and functional abnormalities of the venous system (edema, skin changes, ulceration).¹ Venous ulcers are the most common lower extremity ulcers, accounting for 70% to 90% of all leg ulcers.² These lesions develop as a result of skin and tissue changes caused by CVI and the associated ambulatory venous hypertension. Management of patients with venous ulcers must include measures to optimize wound healing through reduction of edema, prevention of complications, and appropriate topical therapy to promote healing.³ Once the wound is healed the priority shifts to long-term disease management and prevention of recurrence. The main treatment is the application of compression, either in the form of compression bandages or hosiery. Dressings are usually applied beneath the compression to aid healing, comfort and to control exudate. Wounds heal quicker in a moist environment and dressings are used to absorb excess fluid or retain fluid in an otherwise dry wound in order to achieve a 'moist wound environment'. CDO therapy was developed to enable the continuous treatment of wounds through the localized diffusion of oxygen directly into the wound site. To achieve continuous treatment, the device which delivers the therapy is easily portable and capable of delivering oxygen continuously to the wound site. Although the concept of localized diffusion of oxygen directly into wounds is not a novel technique, the manner in which the TransCu $O_2^{\mathbb{R}}$ delivers the oxygen is unique to the market.

Method

Multiple adjunctive therapies were applied to the wound over a seven year period including negative pressure wound therapy, compression, hyperbaric therapy and advanced dressings resulting in chronic non-healing (stalled) wound. CDO Therapy at 8 ml/hr was added along with a moisture balancing dressing (consisting of calcium alginate and/or foam dressing) depending on amount of exudate, compression was attempted but patient was not adherent and did not tolerate consistently. The cannula was place on the wound bed and covered with calcium alginate and or a foam dressing. The patient had weekly physician visits and between physician visits the wife changed the dressing at home. Dressing were changed approximately three times a

Case Study

A 58 year old male with chronic venous stasis ulcer for approximately seven years. Past medical history revealed years of wound care without significant progress. Venous duplex ultrasound had revealed severe reflux in the great saphenous vein to the distal calf. Endovenous laser ablation of the great saphenous vein with a adjuvant sclerotherapy of various tributary veins was performed in past. Heavy smoker (2 packs per day). BMI 21.7.

Results and Discussion

The patient responded well to the CDO therapy, especially considering the high age of the wound (seven years). The wound bed showed signs of angiogenesis and the appearance of the wound and surrounding tissue improved over time. The wound healed fully in 269 days after having been open for over seven years.

The use of oxygen to treat wounds has recently undergone significant changes which enable the efficacious and safe delivery of oxygen directly to the wound bed. Recent published clinical studies which used intermittent diffusion of oxygen therapy have shown the following significantly positive effects of using diffusion of oxygen therapy:4-6

W. Brent Gillespie, DPM San Antonio, TX; Cassie Gray, RN, BSN-WCN, Mark Niederauer, PhD, and Shelly Monnens, APRN-BC, FNP, MSN, RN, CWOCN, CWS, FACCWS, EO2 Concepts[®]



Day 0 - 5.0 x 5.2 X 0.2 cm



Day 31 - 4.7 x 4.7 x 0.2 cm





Day 255 - 0.4 x 0.5 x 0.1 cm



4 cm 5 cm 6 cm 7 cm 8 cm 9 cm 10 cm 11 c -------

Day 136 - 3.9 x 4.3 x 0.1 cm



2 cm 3 cm 4 cm 5 cm 6 cm 7 cm 8 cm 9 cm Day 192 - 2.2 x 2.5 x 0.1cm



Two weeks Post CDO Therapy

- Faster wound closure
- Improved wound closure success rate
- Pain reduction
- Reduction in MRSA infection
- Increased VEGF expression and angiogenesis
- Reduced Venous Stasis recurrence

Our results using Continuous Diffusion of Oxygen therapy are similar to those for intermittent diffusion of oxygen therapy with regard to efficacy. However, CDO therapy has significant advantages over intermittent therapies such as HBO or TO, including ease of application (can be applied in any setting), continuous treatment of wound, full patient mobility during treatment, no known safety issues or risks, and lower cost. Wounds treated successfully thus far include venous stasis ulcers, pressure ulcers, diabetic foot ulcers, gangrenous ulcers, wound bed preparation for skin grafting, full and split thickness skin grafts, radiation burns, dehiscent surgical wounds and diabetic amputation wounds, among others. With regard to the safety of the device and technology, it is considered to be safe with no known risks to the patient. There have been no reported adverse effects or reactions associated with the use of CDO therapy in the literature.

Conclusions

Advances continue to be made in many areas of wound care, including technique, dressings and advanced treatment modalities. After multiple attempts to heal this wound with a variety of adjunctive therapies including: topical agents, NPWT, HBO, and surgery over a 7 year time frame which resulted in repeated failures. CDO Therapy was administered and the wound healed in 269 days. There are currently three types of therapies being used clinically for delivering oxygen to treat wounds: Hyperbaric Oxygen (HBO), Topical Oxygen (TO) and Continuous Diffusion of Oxygen (CDO). Each of these technologies uses a unique method to deliver oxygen, which also affects how the oxygen is used by the body to effect wound repair. HBO is currently the most widely used and commonly accepted form of oxygen therapy for wounds, yet TO has recently shown significant advances in technology supported by good clinical trial data.⁷⁻⁹ The newest oxygen therapy, CDO, can deliver continuous therapy, allows for full patient mobility, has good scientific evidence and is building a credible body of clinical evidence. The use of oxygen therapy for treatment of wounds is a viable option and should be considered as part of any formulary for advanced wound treatment.

CDO therapy has been shown to be safe and efficacious on a wide variety of wounds. Overall, our findings are in line with a significant body of experimental data suggesting that increasing oxygen supply to chronic wounds improves wound healing.

References

- 1. Meissner MH. Pathophysiology of varicose veins and chronic venous insufficiency. In Hallet JW Jr. et al, editors: Comprehensive vascular and endovascular surgery, Philadelphia, 2009, Mosby.
- 2. Myers, BA. Venous Insufficiency Ulcers, 249-278, Upper Saddle River, New Jersey, 2008, Pearson Prentice Hall.
- 3. Moffat C et al. Compression therapy in leg ulcer management. In Morrison M et al, editors: Leg ulcers: a problem based learning approach, Edinburgh, 2007, Elsevier.
- 4. Gordillo GM, Roy S, Khanna S, Schlanger R, Khandelwal S, Phillips G, Sen CK. Topical Oxygen Therapy Induces VEGF Expression and Improves Closure of Clinically Presented Chronic Wounds. Clin Exp Pharmacol Physiol. 2008; 35: 957-964.
- 5. Tawfick W, Sultan S. Does Topical Wound Oxygen (TWO2) Offer an Improved Outcome Over Conventional Compression Dressings (CCD) in the Management of Refractory Venous Ulcers (RVU)? A Parallel Observational Comparative Study. Eur J Vasc Endovasc Surg. 2009; 38(1): 125-32.
- 6. Blackman E, Moore C, Hyatt J, Railton R, Frye C. Topical Wound Oxygen Therapy in the Treatment of Severe Diabetic Foot Ulcers: A Prospective Controlled Study. Ostomy Wound Manage. 2010 Jun; 56(6): 24-31.
- 7. Sen CK. Wound Healing Essentials: Let There Be Oxygen. Wound Rep Reg 2009; 17: 1-18.
- 8. Gordillo GM, Sen CK. Evidence-Based Recommendations for the Use of Topical Oxygen Therapy in the Treatment of Lower Extremity Wounds. Intl J Lower Extremity Wounds 2009; 8: 105-111.
- 9. Schreml S, Szeimies RM, Prantl L, Karrer S, Landthaler M, Babilas P. Oxygen in Acute and Chronic Wound Healing. British J Dermatology 2010; 163: 257-268.