Topical Oxygen Wound Therapy (TOWT)

GWR Medical, Inc.
2016
GWR Topical Oxygen Devices

- FDA Cleared
- One-time Use, Portable, Disposable Devices
- All Patient Settings

O₂Sacral

- Clinician Prescribed
- Protocol
  - 90 minutes
  - 4 consecutive days
  - 3 days rest

O₂Boot
Topical Oxygen Therapy

FDA Cleared Indications:

- Diabetic Wounds
- Venous Stasis Ulcers
- Pressure Ulcers
- Burns
- Post Surgical Infections
- Frost Bite
- Skin Grafts
- Amputations
Contra-indications

- Inadequate perfusion to support Healing
- Wounds completely covered with eschar
- Wounds with fistulae or deep sinus tracks where wound cannot be probed
- Non-Compliant Patients
Topical Oxygen vs. Systemic Hyperbaric Oxygen (HBO)

- **Topical Oxygen**
  - Oxygen applied directly to open wounds at a low pressure of 1.03 atmospheres.

- **Systemic Hyperbaric Oxygen**
  - Administered systemically in large chambers at a high pressure of 2.5 atmospheres.
  - Relies on vascular system to deliver $O_2$ to wound
    - Problem: Poor vascularity of wound tissue limits $O_2$ diffusion into wound tissue
Topical Oxygen in Wound Care

Chronic Wounds:

- Tissue $pO_2 < 30$ mmHg
- Cell metabolism slows - becomes “dormant”
- Body fails to recognize “dormant” tissue as wound to be healed
- Normal wound healing cascade does not proceed
Topical Oxygen Technology

- **Current Paradigm**: Oxygen must be administered systemically in large chambers at a high pressure of 2.5 atmospheres.

- **Topical Oxygen**: Oxygen applied directly to open wounds at a low pressure of 1.03 atmospheres.
Dermal excisional wound healing in pigs following treatment with topically applied pure oxygen


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Abstract

Hypoxia, caused by disrupted vasculature and peripheral vasculopathies, is a key factor that limits dermal wound healing. Factors that can increase oxygen delivery to the regional tissue, such as supplemental oxygen, warmth, and sympathetic blockade, can accelerate healing. Clinical experience with adjunctive hyperbaric oxygen therapy (HBOT) in the treatment of chronic wounds have shown that wound hyperoxia may increase granulation tissue formation and accelerate wound contraction and secondary closure. However, HBOT is not applicable to all wound patients and may pose the risk of oxygen toxicity. Thus, the efficacy of topical oxygen treatment in an experimental setting using the pre-clinical model involving excisional dermal wound in pigs was assessed. Exposure of open dermal wounds to topical oxygen treatment increased tissue \( pO_2 \) of superficial wound tissue. Repeated treatment accelerated wound closure. Histological studies revealed that the wounds benefited from the treatment. The oxygen treated wounds showed signs of improved angiogenesis and tissue oxygenation. Topically applied pure oxygen has the potential of benefiting some wound types. Further studies testing the potential of topical oxygen in pre-clinical and clinical settings are warranted.

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Dermal Injury day 0, TO$_2$ 3hrs/day on days 1-7.
Fig. 2. Wound-bed \( pO_2 \) measurements in pigs treated or not with topical oxygen. The dermal wound model is described in this figure. \( pO_2 \) measurement was performed non-invasively using Oxy-Lite (Oxford-Optronix). An \( O_2 \) electrode was specially designed for our application (\( pO_2 \) assay at 2 mm depth) by the vendor. A real-time measurement of \( pO_2 \) in response to topical oxygen application is shown. The arrow indicates the time of initiation of topical \( O_2 \) treatment.
TOPICAL OXYGEN THERAPY INDUCES VASCULAR ENDOTHELIAL GROWTH FACTOR EXPRESSION AND IMPROVES CLOSURE OF CLINICALLY PRESENTED CHRONIC WOUNDS


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Study Conclusions

• O2 and its reactive derivative, Hydrogen Peroxide, are known to induce VEGF

• O2 induces VEGF in endothelial cells and macrophages and increases VEGF protein expression in wounds
Study Conclusions

• Collagen deposition is fundamental step in wound healing which provides the matrix for angiogenesis and tissue remodeling

• Adequate tissue oxygenation is crucial to support collagen synthesis

• Hence increasing wound oxygenation results in increased collagen deposition and tensile strength
Chandan K. Sen, PhD – The Ohio State University

- “Topical Oxygen Induces Vascular Endothelial Growth Factor Expression and Improves Closure of Clinically Presented Chronic Wounds” -- *Clinical and Experimental Pharmacology and Physiology* (2008), Blackwell Publishing

- “Dermal Excisional Wound Healing in Pigs Following Treatment with Topically Applied Pure Oxygen” *Mutation Research* (2005), Elsevier B.V

Necrotic Ulcer

- Sixty-one year old with a non healing necrotic ulcer in gluteus area extending into genital area.
  - Prior treatments included chemical and surgical debridement, wet to dry dressings, numerous topical ointments, off loading and whirlpool
  - Wound completely healed in 24 weeks.
Diabetic Ulcer

- Patient is a 76 year-old with a non-healing diabetic ulcer on her right great toe.
  - Prior treatments include wet to dry dressing, Silvadene, antibiotics, off-loading and debridement.
  - Wound completely healed after 20 weeks of TO$_2$ Therapy
Post-Op

• Patient is a 45 year-old with a non healing post operative wound on foot.
  – Prior treatments include Silvadene, wet to dry dressings, off-loading, antibiotics, debridement and Wound VAC.
  – Wound completely healed 16 weeks after beginning TO$_2$ Therapy
Diabetic Ulcer

• Patient is a 67 year-old with a non healing diabetic ulcer under the arm.
  – Prior treatments include various topical dressings and ointments, surgical debridement and antibiotics.
  – Wound completely healed after 8 weeks of TO$_2$ Therapy
• Patient is a 66 year-old with a non healing gangrenous post operative wound.
  – Prior treatments include Betadine, wet to dry dressings, off-loading, antibiotics and debridement.
  – Wound completely healed 16 weeks after beginning TO$_2$ Therapy
Decubitus Ulcer

- 45-year old paraplegic with sacral decubitus ulcer
  - Prior therapies: wet to dry saline dressings
  - Expected time to complete healing utilizing wet to dry dressings was 1 to 2 years
  - Wound completely healed after 31 weeks of TO\(_2\) therapy
  - No other modalities or dressings used in conjunction with TO\(_2\) treatments
• Forty-two year-old with 2 Burns from scalding water to the right arm.
  – Prior treatments include Silvadene, wet to dry dressings and oral antibiotics
  – Wounds completely healed in two weeks.
Post-op Wound

- 60-year old male, insulin dependent, morbid obesity
  - Failed split thickness graft on sternum measuring 20 cm X 19 cm x 5 cm with 3 cm undermining in both directions
  - Wound treated with gentamicin soaked sponges for 2 months with no results
  - TO$_2$ therapy started February 17, 1998
  - Patient received total of 18 weeks of TO$_2$ therapy before discontinuing therapy due to hypergranulation
  - Patient then continued with normal wound care until complete healing