Topical Oxygen Therapy™ (TO2):

Topical Oxygen (TO2) Therapy is a low–pressure oxygen therapy which applies oxygen directly to the wound site at 1.03 atmospheres of pressure. It is a safe, effective and non-invasive therapy for treating open wounds in any setting.

How does TO2 Work?

A Simple Protocol:
- 90 Minutes Per Treatment
- 4 Consecutive Days
- 3 Days Rest
- Repeat Cycle Until Wound Is Healed

Patient Criteria
- Open, debrided, moist wound
- Oxygen cannot penetrate wound area completely covered by eschar or slough. There must be some open areas for oxygen to penetrate for healing process
- Suggested ABI (Ankle Brachial Index) > .4
- Antibiotic/IV Treatment if active osteomyelitis at wound site
- Antibiotic Treatment of aerobic infections at wound site
- Patient receiving home treatments must be able to perform TO2 therapy independently or with the help of a family member or caregiver

FDA Approved Indications for Use:
- Skin ulcerations due to diabetes, venous insufficiency post surgical infections and gangrenous lesions
- Pressure ulcers
- Skin grafts
- Burns
- Frostbite
- Amputations/infected stumps

For More Information Contact:
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Chronic and non-healing wounds tend to exhibit low oxygen tensions. It is generally believed that wound healing is impaired when the tissue pO2 (partial pressure of oxygen) drops to 30mmHg (millimeters of mercury) or less. Thus, many open wounds do not get the oxygen required for healing.

In the past, it was believed that oxygen therapy had to be administered systemically (100% oxygen breathed at an increased pressure of 2-3 atmospheres) to produce positive outcomes. In the past, this line of thinking partly stemmed from the lack of clinical understanding and the misrepresentations of oxygen therapy administered locally. However, new studies have been able to establish the efficacy of TO2 and resolve some of it’s previously unexplained success.

A 2005 study used topical oxygen for wound healing in pigs (as their tissue closely resembles human tissue). This study showed that within four (4) minutes the tissue pO2 of superficial wound tissue increased over 40mmHG with the application of topically applied pure oxygen1.

Additionally, recent studies have proven that through TO2 Vascular Endothelial Growth Factor (VEGF) content is increased at elevated oxygen tensions2 (about four to six hundred mm Hg). This range represents the oxygen tension to which the macrophage layer of tissue is exposed when oxygen is applied topically to a wound.

A link has also been established demonstrating the efficacy of oxygen-sensitive genes and oxygen-derived reactive species in facilitating wound contraction and closure3. It is clear that molecular oxygen not only serves as a fuel to provide energy to the regenerating tissue but that oxygen-derived products produced by the body facilitate wound vascularization.

One of these oxygen-derived products is hydrogen peroxide, which has also been shown to stimulate the expression of the angiogenic factor VEGF4.

It is becoming clear that when oxygen is delivered topically to the wound, oxygen derived by-products are produced. Many of these by-products play an integral role in the closure of difficult wounds.

The Differences Between TO2 and Systemic Hyperbaric Oxygen (HBO)

The main differences between TO2 and systemic hyperbaric oxygen (HBO) are the pressures and the method of O2 delivery.

- HBO is delivered systemically (breathed) at an increased pressure of 2-3 atmospheres. This method relies on the vascular system to deliver the super-oxygenated blood to the wound site.
- Topical Oxygen TO2 delivers oxygen directly to the wound site under slightly increased pressure (1.03 atmospheres).

**Problem:** As we know, many patients with chronic wounds have poor blood flow and the vascular system may be compromised at the wound site so that the super-oxygenated blood may never reach the wound.

HBO – Systemic HBO adds additional O2 into the bloodstream and raises vascular blood oxygen levels in the body; patients receive oxygen in a specialized chamber under high pressure (about 2-3 atmospheres of pressure). The concept is that the additional O2 will be carried in the bloodstream, through the body’s vascular and microvascular (capillary) system, to the base of the wound, to help promote healing. This is true, **IF** the patient’s vascular and microvascular systems are intact. However the problem with so many chronic wounds is that there is POOR VASCULARITY. Very simply put, if the vascular and microvascular systems are COMPROMISED, the delivery of additional O2 via Systemic HBO is also compromised.

TO2 – The advantage of TO2 is that the delivery of O2 to the wound base (the cellular level where it is needed) IS NOT dependent on the body’s vascular system. Topical HBO delivers additional O2 directly to the wound site under low pressure. As long as the wound is OPEN and DEBRIDED of heavy eschar or necrotic tissue, and MOISTENED with saline before starting, by using TO2, the O2 penetrates the cell membrane and is presented to the wound cells. The tissue takes up a small percentage of the O2. TO2 TEMPORARILY raises the pO2 levels in the wound tissue at the cellular level for 90 minutes each treatment. When the O2 is taken away after each treatment, the pO2 level falls rapidly.

- The cells perceive this sudden change in pO2 levels produces hypoxia, which causes a signaling mechanism that “turns on” growth factors, and starts angiogenesis (production of new blood vessels).

**Additional advantages of TO2 Therapy are:**

TO2 is a Home Based Therapy (the patient does not need to travel to a specialized facility).
TO2 is a natural and NON Invasive alternative (recommend trying TO2 before surgery, amputation, etc)
TO2 is user-friendly (most patients can perform the therapy by themselves or with help of a family member, once in-serviced by a GWR Rep).

Nutrition, good vascularity and O2 are the fundamentals to wound healing. TO2 is not a Silver Bullet but is an essential component to a comprehensive approach to wound healing.
Why You Should Consider Using TO2 For Your Patients

In-home Therapy:
TO2 is conveniently applied in the comfort of the patient’s own home. This eliminates the need for costly ambulatory care and transportation and can help maximize patient compliance.

Utilization:
TO2 can be utilized in conjunction with other common wound care modalities. The patient will continue to see his or her doctor on a regular basis while treating.

Disposable:
GWR Medical’s devices are discarded after each use. Thus eliminating the risk of cross contamination and any time intensive cleaning.

Positive Results for the Doctor’s Practice

- Doctor continues to see patient weekly or bi-weekly for debridement and to monitor progress.
- GWR is provider of services and insurance billing.
- Doctor is providing a convenient and effective wound care therapy.
- Doctor will heal his or her patients more quickly, avoiding future complications (infections, amputations).
- Doctor will retain patient and not lose him or her to another provider.
- Doctor will be known as a progressive wound healer.
- New patient volume can increase.

How a Patient Gets Started (simplified)

1. The Doctor’s office or the ISR must fax:
   a. Completed and signed Certificate of Medical Necessity / Patient Information Form (CMN/PIF) into GWR
   b. NEW YORK MEDICAID – Completed TOWT Prescription and Clinical Information forms, Prior Approval Request form and LMN
   c. Current Doctor notes and, upon GWR request
   d. Letter of Medical Necessity (LMN).
2. GWR Billing Specialists will verify Insurance Coverage.
3. Patient Account Reps will advise ISR if patient is authorized based on Insurance Verification.
4. If authorized the Patient Account Rep will identify the patient treatment start date.
5. Product and oxygen will be delivered directly to the patient’s home for the duration of the therapy. Only GWR makes the arrangements for the product and the oxygen.
6. The ISR or a contracted homecare nurse will in-service the patient and take the initial wound picture.
7. GWR will bill the patient’s insurer. There are no financial risks to the doctor or the patient. GWR does all the insurance work.
8. GWR follows patient progress from start to finish with patient’s doctor.