HBOT / Transdermal Oxygen (OxyBand)/ TOWT

OxyBand’s Dressing is ambulatory and provides continuous treatment for up to 5 days and is backed by a strong IP portfolio.
Transdermal Wound Oxygen Therapy
RCT, Single-Blind Studies –
1. Burns (subjects served as their own control requiring two identical wounds)
2. Pressure Ulcers Treatment/Control Groups

• Study 1: Burn patients undergoing harvesting of two donor sites at the US Army Burn Center
• Randomized Treatment OxyBand (Transdermal Oxygen Dressing) or Standard of Care (Patients served as their own control)
• Patients were followed for 30-45 days to determine the time to re-epithelialization, cosmetic appearance, and pain during healing.
• Results showed average time to wound healing for OxyBand was 9.3 +/- 1.7 days, compared with SOC 12.4 +/- 2.7 days (p<0.001). Pain scores were significantly lower (p<0.001) at the OxyBand site compared to SOC site for all measurement points during the healing period.
• Study 2: 100 hospitalized adult with a stage II-IV pressure ulcer were recruited to this single blinded multi-center study and were randomly assigned
• All patients received the routine care of the study setting & intervention group received the addition of transdermal wound oxygen therapy.
• After 12 days of treatment, complete wound healing was assessed. Sixteen patients (16/50) in the interventional group and one patient (1/50) in the control group exhibited complete wound healing, as defined by complete epithelialization of the wound without drainage (p 0.001).

United States. Army Institute of Surgical Research, Fort Sam Houston, TX
OxyBand
Transdermal Oxygen System

- Similar to a Transdermal Drug Delivery Patch containing O2
- Capability of enhancing the wound microenvironment via the sustained delivering of oxygen substrate for an extended period of time (No Tank, Tubes or Generator)
- O2 diffuses across high permeability film, saturates the wound fluid, provides continuous supply for up to 5 to 7 days (depending on size of reservoir internal to is achieved with a single application.)
Results - Elevated pO2 - OxyBand vs. Film Dressing, Normobaric & After HBOT

- OxyBand Increases pO2 Pre & Post HBOT

- Graph showing pO2 (mmHg) over time with two lines representing OxyBand and Film Dressing

- HBOT treatment timeline

- UHMS Poster Presentation; An Oxygen Reservoir Dressing Sustains Elevated Wound pO2 After Hyperbaric Oxygen Treatment
  Harriet W. Hopf, MD¹, Gerit Mulder, DPM², Jay Duchnick, CHT³, Scott Barnhill, AS, SRS, RLATG
Topical Oxygen Device Type Reviewed by CMS for NCD
Evaluation of an Oxygen-Diffusion Dressing for Accelerated Healing of Donor-Site Wounds


A randomized, double-blind, placebo-controlled prospective, randomized, placebo-controlled, controlled, clinical trial to evaluate the effectiveness of a new oxygen-diffusion dressing (Cryopave) compared with standard gauze dressings in the care of burn wounds. Twenty-one patients with burn wounds were randomly assigned to receive treatment with the oxygen-diffusion dressing or standard gauze dressings. The primary endpoint was the healing time of burn wounds. The results of the study showed that the oxygen-diffusion dressing significantly reduced the healing time of burn wounds compared to standard gauze dressings. The study concluded that the oxygen-diffusion dressing is an effective and safe treatment for accelerating the healing of burn wounds.
Results

<table>
<thead>
<tr>
<th>Outcome</th>
<th>OxyBand</th>
<th>Xeroform</th>
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<tbody>
<tr>
<td>Healing Time</td>
<td>9.4±1.7 days (range 6-12 days)</td>
<td>12.4±2.7 days (range 8-20 days) No Infection</td>
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<tr>
<td>(Blinded Evaluation of Photographic Evidence)</td>
<td>No Infection Significantly Faster Healing w/ OxyBand</td>
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<tr>
<td>(p&lt;0.01)</td>
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<tr>
<td>Pain (0-10 Scale on Day)</td>
<td>Day 4, 0.6</td>
<td>Vs 1.6 (~ 3x more pain)</td>
</tr>
<tr>
<td>4,8,10,12)</td>
<td>Day 8, 0.4</td>
<td>Vs 1.4, (&gt; 3x more pain)</td>
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<tr>
<td>(p&lt;0.05)</td>
<td>Day 10, 0.3</td>
<td>Vs 0.8, (&gt; 2x more pain)</td>
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<tr>
<td></td>
<td>Day 12, 0.2</td>
<td>Vs 0.5 (&gt; 2x more pain)</td>
</tr>
<tr>
<td></td>
<td>Significantly Less Pain with OxyBand</td>
<td>Significantly More Pain with Xeroform</td>
</tr>
</tbody>
</table>

Kimberly F. Lairet, MD, Leopoldo C. Cancio, MD, Michelle L. Leas, RN, Chaya Galin, RN, David Baer, PhD, Evan M. Renz, MD Evaluation of an Oxygen Diffusion Dressing for Accelerating Healing of Donor Site Wounds. Journal of Burn Care and Rehabilitation 1997;18(4):353-5 United States Army Institute of Surgical Research, Fort Sam Houston, TX
OxyBand Research & Evidence

• Delivers Oxygen Up To 5 Days, Oxygen Transfer Study
• Delivers Oxygen into wounds (PO2 to 264 mmHg)
• Increases Wound O2 After HBOT - Complementary
• Versus Standard of Care (Randomized Controlled)
  Significantly Faster Healing, Less Pain
• Versus Placebo (Double Blind Randomized Controlled)
  Significantly Faster Healing, Less Inflammation, Pain
• Effective Healing, Diabetic & Venous Ulcers (Case Studies)
  Closure of Non Healing Wounds
• Improves Neutrophil killing of Pathogens
  Acinetobacter baumannii (In Vitro)
• Oxygen increases the efficacy of Silver efficacy
  Pseudomonas Aeruginosa & MRSA
• US Army USAISR Pre Clinical & Clinical Trial
• Chronic Case Studies
• Pressure Ulcer, Pressure Redistribution Study

“Healing time for donor sites of burn victims can be the difference between life and death. OxyBand outperformed the SOC with respect to significantly less (at least 25%) healing time and 3x less pain. Results are clinically as well as statistically significant.”

Kimberly F. Lairet, MD,
Leopoldo C. Cancio, MD, Evan M. Renz, MD,
David Baer, PhD US Army Institute of Surgical Research
Case Studies

Chronic Wound after 2 Year of Ineffective Treatment
Concrete Chemical Burn

Chronic 2 Year Wound  OxyBand- 30 Day  OxyBand- 90 Day

Ellis et al.