The OxyBand
Transdermal Oxygen System

- Transdermal Drug Delivery Patch containing O2
- O2 diffuses across high permeability film, saturates the wound fluid, provides continuous supply
- Feel of conventional dressings or transdermal patch
OxyBand
How Does it Work?

- A therapeutic advanced oxygen reservoir device with the capability of delivering sustained oxygen substrate for an extended period of time (up to 5 days) to enhance the wound microenvironment and the benefit is achieved with a single application.
- OxyBand is applied over the wound and provides medical grade oxygen from the reservoir to the wound.
- Oxygen diffuses across a permeable membrane and is occluded from escaping into the atmosphere.
Chronic Wounds & Hypoxia

Chronic wounds are thought to fail to progress through the phases of healing in an orderly and timely fashion due to one or more defects in the healing cascade, including excessive bio burden, uncontrolled inflammation, the presence of stagnant or senescent cells, the lack of essential cytokines or metabolic factors, and inadequate tissue perfusion resulting in tissue hypoxia and deficient oxygen substrate.

The ability to improve tissue oxygenation in chronic wounds hastens healing. Oxygen enhances white cell bacterial killing and bio burden reduction, stimulates cellular metabolic activity, enhances angiogenesis and promotes fibroblast and epithelia cell proliferation.

- Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
Sustained delivery of oxygen over 5 days from an advanced reservoir system inside.

From concept to commercial product
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
- Definitive Army USAISR Pre Clinical & Clinical Trial

“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. Lairret, MD, Leopoldo C. Cancio, MD, Evan M. Renz, MD, David Baer, PhD US Army Institute of Surgical Research

Significantly Faster Healing & Significantly Less Pain, No Infection
Does OxyBand Increase Dissolved Wound Oxygen (pO2)?

- Hopf et al.,
- Will OxyBand worn in normobaric conditions increase pO2?
- Worn during HBOT result in elevated levels of PO_2 after HBOT?
Methods

- IACUC approval
- 2 pigs (HBOT and control)
- Anesthesia
  - During HBOT
    - Diazepam and ketoprofen
  - Otherwise
    - Isoflurane in oxygen (intubated)
- 8 standardized full thickness wounds per pig
- Wounds covered with thin Film or OxyBand dressing
Specifics - Methods

- $\text{O}_2$ measured within wound exudate
- polarographic micro-electrodes
  - MI-730 and OM-4 oxygen monitor,
    - Micro-Electrodes, Inc, Bedford NH
  - Type K thermocouple 5SC-TT-
    - K-36-36 and HH1A monitor,
      - Omega Engineering, Stamford CT

- 2-3 mm depth wounds
- 2hr  8hr  16hr  after OxyBand & (control)
- 15m  2hr  12hr  after HBOT – OxyBand & Control
- HBOT=90 min at 2ATA
Results - Elevated pO2 - OxyBand vs. Film Dressing, Normobaric & After HBOT
Conclusion

- $pO_2$ was higher in OxyBand vs. control at baseline
- Even given high inspired $O_2$
- $pO_2$ (control) remained elevated for <2 h after HBOT
- $pO_2$ (OxyBand) remained elevated at least 12 h after HBOT
- HBOT (post 12 h not measured)

Synergies of systemic HBOT and prolonged local oxygen

- An Oxygen Reservoir Dressing Sustains Elevated Wound $pO_2$ After Hyperbaric Oxygen Treatment
  Harriet W. Hopf, MD\textsuperscript{1}, Gerit Mulder, DPM\textsuperscript{2}, Jay Duchnick, CHT\textsuperscript{3}, Scott Barnhill, AS, SRS, RLATG
**Evidence Based - Clinical Trials RCT - OxyBand vs. Standard Care**

**Oxy-Band™ vs. Standard of Care Tegaderm™ Dressings**

(Wound Diameter)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Day 1</th>
<th></th>
<th>Day 3</th>
<th></th>
<th>Day 7</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OxyBand</td>
<td>TegaDerm</td>
<td>OxyBand</td>
<td>TegaDerm</td>
<td>OxyBand</td>
<td>TegaDerm</td>
</tr>
<tr>
<td>(N) Number of wounds</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Mean Wound Diameter</td>
<td>5.00</td>
<td>5.00</td>
<td>2.95</td>
<td>4.32</td>
<td>1.51</td>
<td>2.65</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound area ((\pi \times r^2 = \text{mm}^2))</td>
<td>19.63</td>
<td>19.63</td>
<td>6.83</td>
<td>14.65</td>
<td>1.79</td>
<td>5.51</td>
</tr>
<tr>
<td>% Diameter Reduction from Day 1</td>
<td>41%</td>
<td>14%</td>
<td>70%</td>
<td>47%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Wound Area Reduction from Day 1</td>
<td>65%</td>
<td>25%</td>
<td>91%</td>
<td>72%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of Wound Area Remaining</td>
<td>35%</td>
<td>75%</td>
<td>9%</td>
<td>28%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*All Day 3 and Day 7 primary endpoints demonstrated statistical significant differences (p < .001)*
Results showed a significant difference in healing time of 30%
RCDB Study: OxyBand Vs. Placebo (air filled)
Significant Difference in the number of days to healing

% of Subject Wounds Fully Epithelialized

All OxyBand Wounds Healed By Day 7 Vs. Placebo By Day 10

Day 3: OxyBand 26%, Placebo 0%
Day 4: OxyBand 26%, Placebo 0%
Day 5: OxyBand 53%, Placebo 0%
Day 6: OxyBand 100%, Placebo 37%
Day 7: OxyBand 100%, Placebo 84%
Day 8: OxyBand 100%, Placebo 100%
Day 9: OxyBand 100%, Placebo 100%
Day 10: OxyBand 100%, Placebo 100%
OxyBand & Surgical Wounds
Donor Sites, Post-op, SSI

Example of donor site (skin harvesting) procedure.

Typical appearance of OxyBand dressing on a donor site.

USAISR Clinical Trial – Colonel Leopold Cancio MD (Photo)
Injured US Army Soldier requiring at least two identical donor sites
Objective of the DOD Research

- Primary objective, determine if autogenous donor sites heal faster with OxyBand than Control
  - Control Group = Xeroform dressing
- Secondary objective, determine whether the antimicrobial efficacy of silver is affected by higher oxygen levels.
- OxyBand also evaluated increased % O2 on PMN bactericidal killing of Acinetobacter
METHODS: Prospective, randomized, patient-controlled study of burn patients undergoing harvesting of two donor sites. Patients were followed for 30-45 days to determine the time to re-epithelialization, cosmetic appearance, and pain during healing. Subjects were adult burn patients with less than 30% TBSA (total body surface area) burn admitted to the US Army Burn Center who required excision and grafting of their wounds. 20 patients were enrolled, of which 17 completed the study. Patients underwent harvest of split thickness skin graft in the usual fashion with one donor wound dressed with OxyBand and the other dressed in Xeroform gauze. Wounds were inspected and photographed on postoperative days 4, 8, and then every 2 days until the donor wounds were healed, as determined by a staff surgeon or associate investigator.

RESULTS: The average time to wound healing for OxyBand was 9.3 ± 1.7 days, compared with Xeroform 12.4 ± 2.7 days (p<0.01). Pain scores were significantly lower (p<0.01) at all the OxyBand site compared to the Xeroform site for all measurement points during the healing period (postoperative days 4-12). There was no difference in the cosmetic outcome of the wounds at 30-45 days postoperatively. CONCLUSIONS: This study revealed a significant 3-day decrease in the time to healing compared to a placebo.

OBJECTIVE: Assess the effectiveness of a new oxygen diffusion dressing (OxyBand) compared to standard Xeroform gauze dressings. Time to healing was the major endpoint. Pain scores and cosmetic outcome were also assessed.

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Published Prospective RCT
US ARMY (USAISR)

Kimberly F. Lairet, MD, Leopoldo C. Cancio, MD, Michelle L. Leas, RN, Chaya Galin, RN, David Baer, PhD, Evan M. Renz, MD United States Army Institute of Surgical Research, Fort Sam Houston, TX Evaluation of an Oxygen Diffusion Dressing for Accelerating Healing of Donor Site Wounds
## Results

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

Kimberly F. Lairet, MD, Leopoldo C. Cancio, MD, Michelle L. Leas, RN, Chaya Galin, RN, David Baer, PhD, Evan M. Renz, MD United States Army Institute of Surgical Research, Fort Sam Houston, TX Evaluation of an Oxygen Diffusion Dressing for Accelerating Healing of Donor Site Wounds
Conclusion

"This study revealed a decrease in the time to healing and patient reported pain OxyBand versus the Xeroform dressing. Accelerating the healing process and reducing pain save limbs and lives which is critical.”

Kimberly F. Lairet, MD, Leopoldo C. Cancio, MD, Michelle L. Leas, RN, Chaya Galin, RN, David Baer, PhD, Evan M. Renz, MD United States Army Institute of Surgical Research, Fort Sam Houston, TX Evaluation of an Oxygen Diffusion Dressing for Accelerating Healing of Donor Site Wounds
The Effect of Higher Levels of O2 (80%) on the Efficacy of Silver To Kill Bacteria (in vitro)

Conclusion

The results of the present study demonstrate 80% Oxygen combined with Silver (Silver Nitrate) is more effective as an antimicrobial against MRSA and Pseudomonas in vitro, than Silver (Silver Nitrate) at either hypoxic (5%) or ambient air (21%) levels of Oxygen. These results suggest there is an additive effect of higher levels of Oxygen to Silver Nitrate in treating MRSA and Pseudomonas. The clinical significance of these results could be very important in the treatment of infected and chronic wounds which are often hypoxic. The results suggest a combination treatment of Silver and high levels of oxygen may perform better as an antimicrobial than silver alone. More studies are needed to determine clinical results and with other wound pathogens.
Effect of Oxygen Tension on Neutrophil Mediated Killing of Acinetobacter baumannii

**Abstract**

More Oxygen = Less Bacteria

The effect of altering Oxygen Tension on Neutrophil Mediated Killing of Acinetobacter baumannii

**Results**

![Graph showing the effect of oxygen tension on neutrophil-mediated killing of Acinetobacter baumannii.](image-url)

**Conclusion**

Oxygen level significantly impacts the effectiveness of neutrophil-mediated killing of Acinetobacter baumannii. Higher oxygen levels lead to decreased killing efficiency, as indicated by the graph. Further studies are needed to elucidate the molecular mechanisms underlying this phenomenon.

**Representative References**

OxyBand Summary of Evidence

- Provides oxygen delivery to wounds
  - 5 days
- Increases wound pO2
- Absorbs fluids
- Sterile barrier to outside contaminants
- Reduces cost
- 3 Clinical Trials have shown significantly faster healing, reduced pain and no infection
- Cleared by the FDA
New Re-imbursement rules
- Penalties for surgical site infection
- Penalties for Chronic wounds
- Bundled payments for care
- Improved outcomes for less $
Clinical Experience
Specific Wound Types

- Surgical Wounds
  - Post operative, Donor Sites, SSSI
- Venous Insufficiency
- Diabetic Foot Ulcers
- Pressure Ulcers
Chronic Wound after 2 Year of Ineffective Treatment
Concrete Chemical Burn

Chronic 2 Year Wound  OxyBand- 30 Day  OxyBand- 90 Day
Multiple Case at UCSD showed OxyBand healed chronic wounds
Example below, Diabetic Wound.
Patient already had one toe amputated – two years non healing
After 2 OxyBand Dressing Treatments, One Week, Wound Healed

Before Treatment

After Treatment
OxyBand Treated Chronic Pressure Ulcer On Heel – Ellis et al.

Heel Day 1

Heel Day 10
The Future

- Additional Clinical Experience
  - Diabetic Foot Protocol
  - Pressure Ulcer Protocol
Pressure Ulcer Protocol

- Pressure Ulcer Prevention
  - Additional Cost of Care
  - Prolonged Hospitalizations
  - Financial Penalties
  - Medical Legal Exposure

- Oxyband uniquely designed to impact Pressure Ulcers
  - Providing Oxygen Substrates to Hypoxic Injury
  - Pressure Redistribution-Relief
  - Prevent Conversion Partial to Full Thickness Wound
The Future

- Additional Clinical Experience
  - Diabetic Foot Protocol
  - Pressure Ulcer Protocol
- Compliment to HBOT
- Adjunctive to Cellular & Tissue Based Products (CTPs)
- Indwelling Devices
- Regenerative Medicine
"Oxygen is itself regenerative. Cells in the presence of higher sustained oxygen regenerate. Wound healing is a regenerative process. The USAISR OxyBand Donor Site Study published results demonstrate the benefits of OxyBand in healing of autogenous donor sites which is regenerative healing. 100% healing in significantly less time than standard of care. The results demonstrate OxyBand is a regenerative device."

-Dr. Anthony Atala, MD
Director of the Wake Forest Institute of Regenerative Medicine &
Director of the Armed Force Institute of Regenerative Medicine,
Chairman of Urology Baptist Wake Forest Medical Center
OxyBand
Customizable Delivery Device

PRODUCTS TO ADDRESS THE MARKETS

OxyBand Intellectual Property

- Donor Sites
- Burns
- Venous & Pressure Ulcers
- Incisions

Oxy Band

- Abrasions
- Post-Surgical Therapeutic Wound Care
- Diabetic Wound Care

Multi-cell Oxy-wraps

- Partial Thickness Wounds
- Lacerations
- Retinal & Macular Disease
- Cosmetics

Gel

Cell application heals burn

Foams

Oxy Cells

Kit with existing dressing

User Filled

Army Dressing

Antimicrobial

Alginates
OXYBAND WOUND DRESSING

- Oxygen generating gel launched for the military
- Value as cosmetic because oxygen stimulates collagen
- Oxygen penetrates skin
- Oxygen heals

**OXYBAND™**
The healing power of oxygen

- Future Standard of Care
- All Surgeries
- Reconstruction
- Chronic Wounds
- Military Medicine
- Regenerative Medicine

Oxygel, finding the healing you need