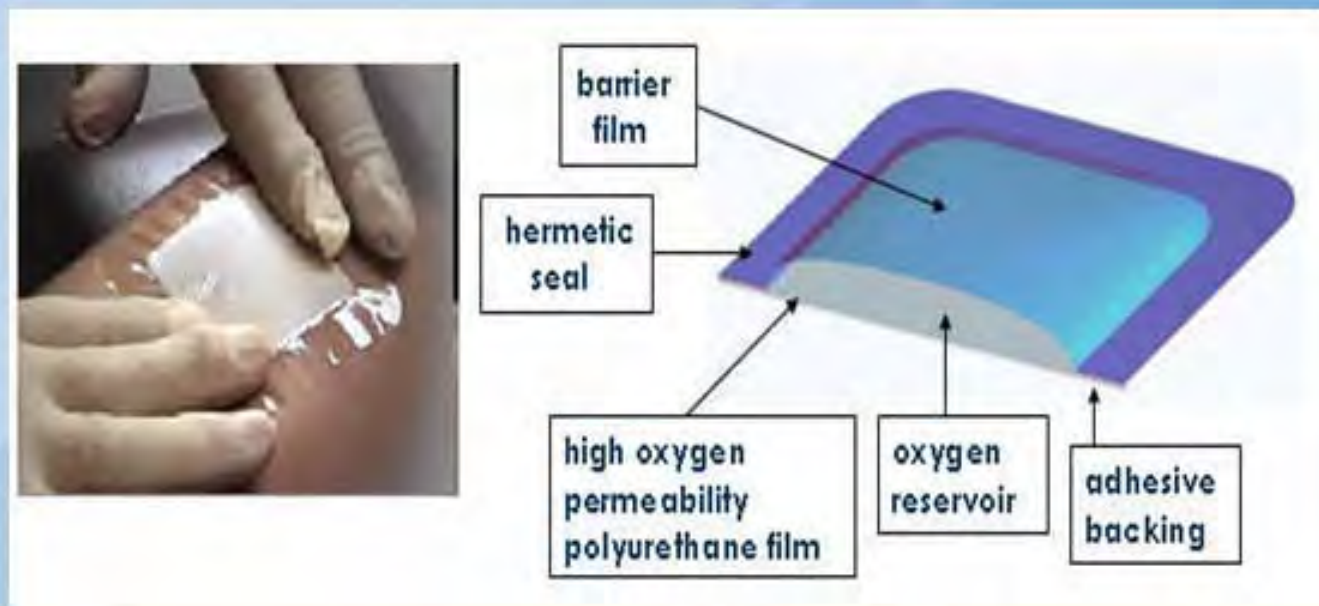


# The OxyBand Transdermal Oxygen System

- Transdermal Drug Delivery Patch containing O<sub>2</sub>
- O<sub>2</sub> 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

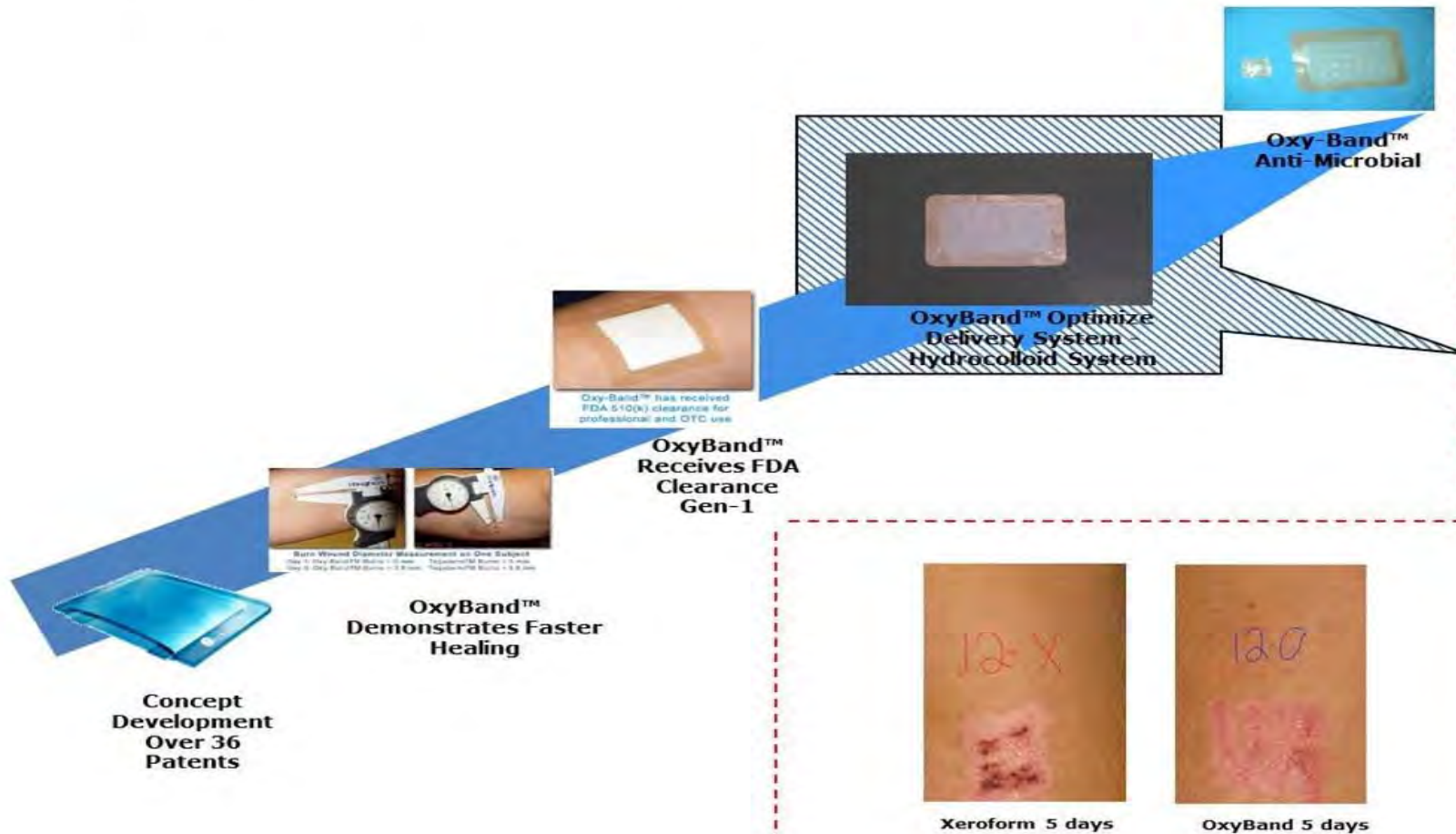
- Chronic wounds are thought to fail to progress through the phases of healing in an orderly and timely fashion due to one or more defects in the healing cascade, including excessive bio burden, uncontrolled inflammation, the presence of stagnant or senescent cells, the lack of essential cytokines or 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 (PO<sub>2</sub> to 264 mmHg)
- Increases Wound O<sub>2</sub> 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. Lairet, 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 (pO<sub>2</sub>)?

- Hopf et al.,
- Will OxyBand worn in normobaric conditions increase pO<sub>2</sub>?
- Worn during HBOT result in elevated levels of PO<sub>2</sub> after HBOT?





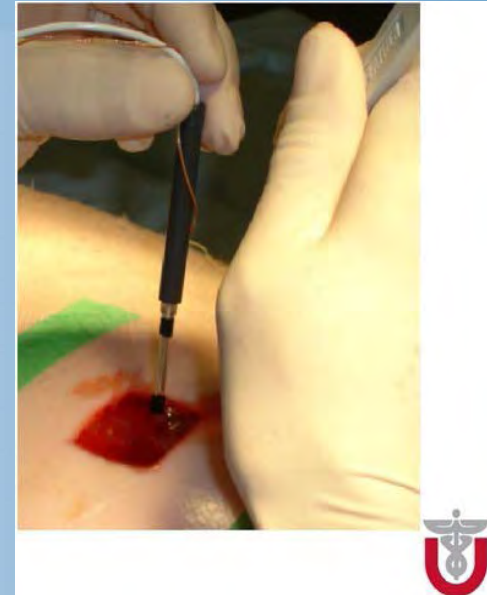
# Methods

- 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

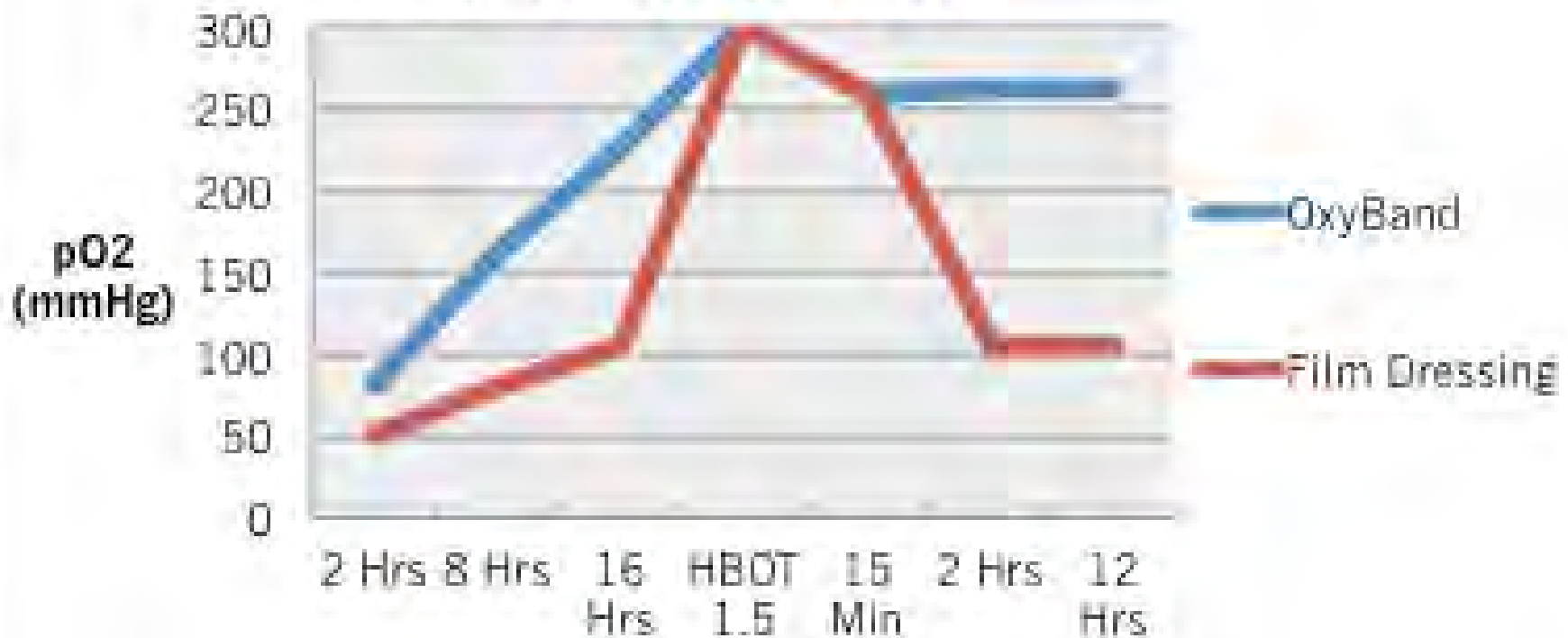
- O<sub>2</sub> measured within wound exudate
- polarographic micro-electrodes
  - MI-730 and OM-4 oxygen monitor,
    - Micro-Electrodes, Inc, Bedford NH
  - Type K thermocouple 5SC-TT-
    - K-36-36 and HH11A monitor,
      - Omega Engineering, Stamford CT
- 2-3 mm depth wounds
- 2hr 8hr 16hr after OxyBand & (control)
- 15m 2hr 12hr after HBOT – OxyBand & Control
- HBOT=90 min at 2 ATA





# Results - Elevated pO<sub>2</sub> - OxyBand vs. Film Dressing, Normobaric & After HBOT

## OxyBand Increases pO<sub>2</sub> Pre & Post 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 (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<sup>1</sup>, Gerit Mulder, DPM<sup>2</sup>, Jay Duchnick, CHT<sup>3</sup>, Scott Barnhill, AS, SRS, RLATG**

# Evidence Based - Clinical Trials RCT - OxyBand Vs. Standard Care

Oxy-Band™ vs. Standard of Care Tegaderm™ Dressings  
(Wound Diameter)

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

\*All Day 3 and Day 7 primary endpoints demonstrated statistical significant differences ( $p < .001$ )



# RCDB Clinical Trial Results

## OxyBand Vs. Placebo – Air Filled Dressing

**Photograph 1:**  
Epithelialization of Wounds; OxyBand™ Vs. Placebo



Photo 1A: OxyBand™ Treated



Photo 1B: Placebo Treated

**Photograph 2:**  
Wound Exudate Levels; OxyBand Vs. Placebo



Photo 2A: OxyBand™ Treated

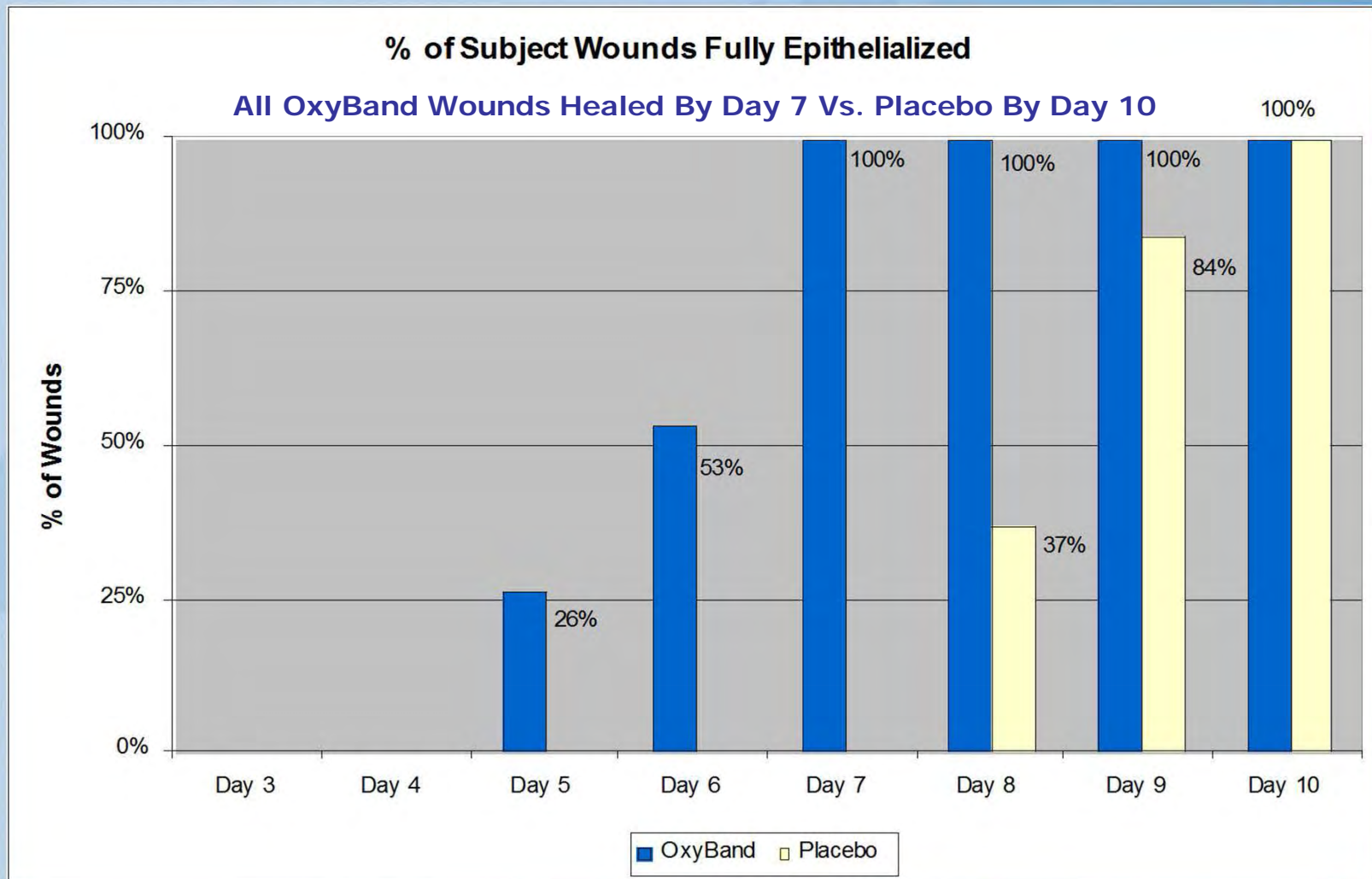


Photo 2B: Placebo Treated

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



# 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 % O<sub>2</sub> on PMN bactericidal killing of Acinetobacter



## Abstract

**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.

**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 burn surgeon or associate investigator. Pain scores at each site were also collected at these visits (rated by patients on a scale from 0-10). After both wounds were healed, patients were seen at a 30-45 day visit to photograph the wounds a final time.

**RESULTS:** The average time to wound healing for OxyBand was 9.3 +/- 1.7 days, compared with Xeroform 12.4 +/- 2.7 days (p<0.001). Pain scores were significantly lower (p<0.01) at 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 with

## Introduction

### Clinical Problem:

- Thermal injury; 10% of combat casualties from the current battlefield (OIF, OEF) have burns (Schmidt et al., Am Burn Assn 2012)
- Many of these patients require excision and skin grafting
- In patients with major burns (>20%), wound healing is the key to survival (Nitzschke et al., Am Burn Assn 2012)
  - Successful wound healing → survival
  - Unsuccessful wound healing (wound failure) → death
- Donor site healing is often the limiting factor. Inability to reharvest donor sites prevents a rapid pace of wound closure



### Technology:

- OxyBand™ dressing (OxyBand Technologies, Woodbury, MN) was developed to provide local delivery of high concentrations of oxygen to healing wounds
- Directionally permeable, gas-emitting reservoir
- Like hyperbaric oxygen, without cost and risk
- Studies on standardized laser burn wounds showed faster healing time compared to a placebo
- 510K-approved by the FDA

## Objective

### Objective:

• To evaluate the OxyBand's efficacy in comparison with our usual donor site dressing on time to healing (90% confluent epithelialization, in judgment of staff surgeon)

• Secondary endpoints: pain, cosmesis, ease of application

**Hypothesis:** The mean healing time for wounds treated with the OxyBand dressing will be less than the mean healing time for wounds treated with the Xeroform dressing

## Methods

### Subjects:

- Adult burn patients with total burn size (TBSA) < 30%
- In need of excision and grafting
- Without critical illness or healing disorder (e.g.: ongoing mechanical ventilation, vasoactive medications, diabetes, peripheral vascular disease, corticosteroids, coagulopathy)

### Study design:

- Prospective, single-center, randomized, controlled, open-label
- Subjects served as their own controls, with comparison of simultaneously harvested donor sites on the opposite sides of the body (e.g., both anterior thighs)

### Donor harvest:

- Minimum 4 inches by 2 inches x 2 sides
- Goal depth 10/1000 inch; Zimmer air-powered dermatome

### Study dressing:

- OxyBand dressings supplied by the manufacturer
- Secured to intact skin around the donor site by the adhesive edge of the dressing
- Replaced if non-adherent or leaky
- Removed and site photographed on days 4, 8, and every 2 days till healed

### Control dressing:

- Xeroform gauze (3% bismuth tribromophenate and petrolatum) on fine mesh gauze
- Trimmed as healing occurred underneath
- Bacitracin applied to assist with separation, beginning on post-operative day 14

Photo assessment: Blinded staff surgeon reviewed photos on days 30-45 and subjectively judged which side had better cosmetic outcome

Statistics: A power analysis concluded that 17 patients, providing 34 matched donor sites, would be required to demonstrate a difference in healing time with a confidence level of 95%. Data were analyzed using SAS. Continuous and score variables were compared by Wilcoxon Test. All tests for significance were two-tailed with  $\alpha = 0.05$ .



Example of donor site (skin harvesting) procedure.



Typical appearance of OxyBand dressing on a donor site.



Application of Xeroform dressing to a donor site.

### Comment:

- Uniform wound depth
- Scheduled procedure with patient's own consent
- Well-established healing rate
- Can use identical paired sites
- Rate of healing provides an objective measure of dressing efficacy
- Decreased infection risk as a confounding factor compared to traumatic injuries

## Results

- 20 patients were enrolled; 17 completed the study
- Of the 3 who did not, 2 did not require 2 donor sites at time of surgery and 1 was lost to follow-up (after completion of successful healing)
- Of the 17 patients:
  - Mean TBSA = 9.1%
  - Mean age = 35 years
  - 7 military and 10 civilians
  - 14 males and 3 females
- Mean time to wound healing for OxyBand =  $9.4 \pm 1.7$  days (range 6-12); for Xeroform =  $12.4 \pm 2.7$  days (range 8-20) (p<0.01).
- No infections
- 2 patients had blisters at final follow up visit at both sites
- Pain: lower in OxyBand site on all post-operative days (days 4, 8, 10, 12) (p<0.05 for all timepoints)
- No difference in cosmetic appearance of final photos

## Conclusions

In an open-label, prospective, randomized controlled trial of 2 donor site dressings, the OxyBand oxygen-diffusing dressing outperformed the Xeroform dressing with respect to healing time and pain. The reduction in healing time with the OxyBand dressing of 25% was clinically as well as

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## Acknowledgements

This study was approved by the Institutional Review Board of Brooke Army Medical Center, protocol ISR #H-09-008, BAMC #1.2009.080. USAISR performed this study as part of a Cooperative Research and Development Agreement (CRADA) with OxyBand, with funding from the U.S. Army Medical Research and Materiel Command Clinical Trials Task Area. OxyBand received additional funding from the U.S. Army Medical Materiel Agency (USAMMA). The authors gratefully acknowledge the support of Ms. Patricia M. Dubhill and Mr. Gregory Houser of USAMMA; of USAISR Clinical Research Nurse Coordinators, to include Cathy Rauschendorfer, RN, Elsa Coates, MS, RN, CCRN, and Bryan Jordan, RN, MSN; of surgeons Dr. Jonathan Lundy and Dr. Rodney Chan for reviewing photographs; and of ISIR Statistician Mr. John Jones. The opinions or assertions contained herein are the private views of the authors, and are not to be construed as official or reflecting the views of the Department of the Army or Department of Defense.

# 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

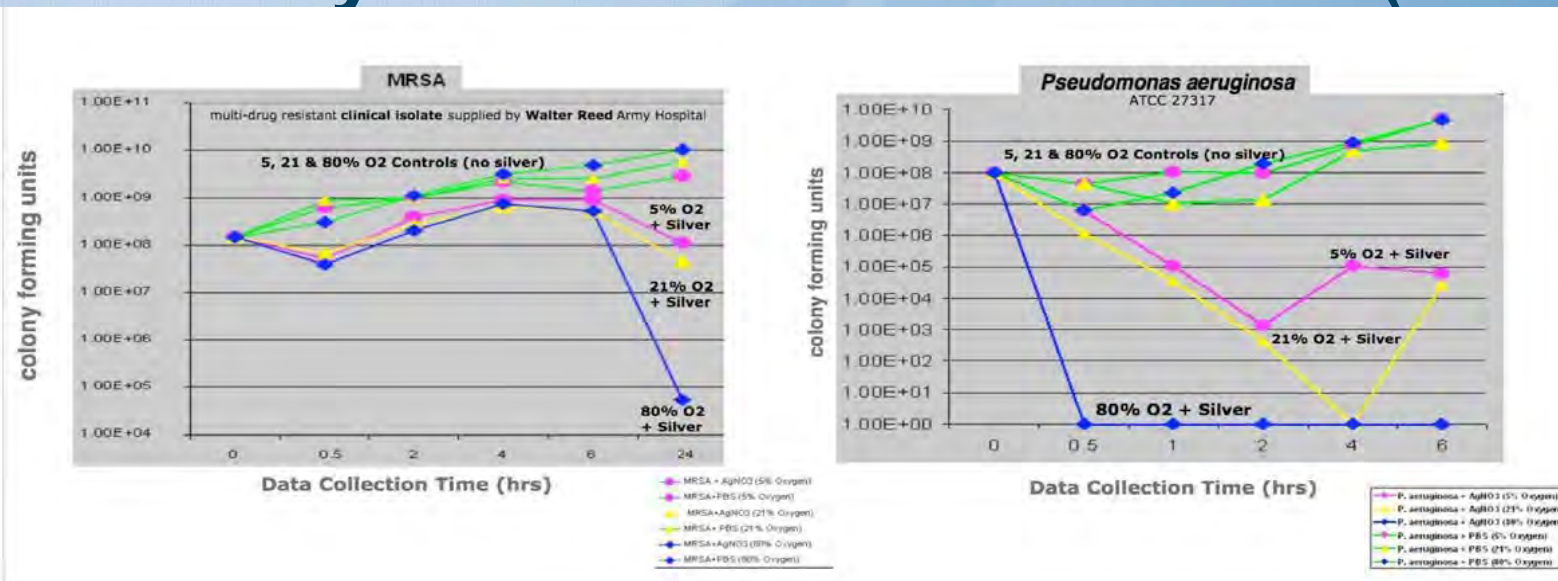
Outcome	OxyBand	Xeroform
<b>Healing Time</b> (Blinded Evaluation of Photographic Evidence) <b>(p&lt;0.01)</b>	<b>9.4 ± 1.7 days (range 6-12 days)</b> <b>No Infection Significantly Faster Healing w/ OxyBand</b>	<b>12.4 ± 2.7 days (range 8-20 days) No Infection</b>
<b>Pain (0-10 Scale on Day 4,8,10,12)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

# 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."



# The Effect of Higher Levels of O<sub>2</sub> (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*

Mark Rollins, MD, PhD; Joseph Torina, MD, University of California San Francisco School of Medicine, San Francisco, CA and OxyBand Technologies Inc., San Francisco, CA; Amie Franklin, PhD, OxyBand Technologies Inc., San Francisco, CA; Stanley Poulos, MD, Plastic Surgery Specialist, Marin General Hospital, Greenbrae, CA



## ABSTRACT

An *in vitro* study was conducted to determine whether increased oxygen tension (presently oxygen provided by OxyBand™) would increase neutrophil mediated killing of Acinetobacter baumannii. OxyBand™ has been shown to increase oxygen tension (increase and maintain elevated levels of dissolved oxygen) in wounds (FOU) for full thickness wounds for extended periods of time. A recent *in vivo* study demonstrated OxyBand™ elevated PO<sub>2</sub> in full thickness wounds to 285–385 mmHg for weeks (over 30 days) in the study was completed (compared to 95 mmHg in wounds treated with NEGOT and covered with a film dressing that provided a PO<sub>2</sub> level of 0–150 mmHg).

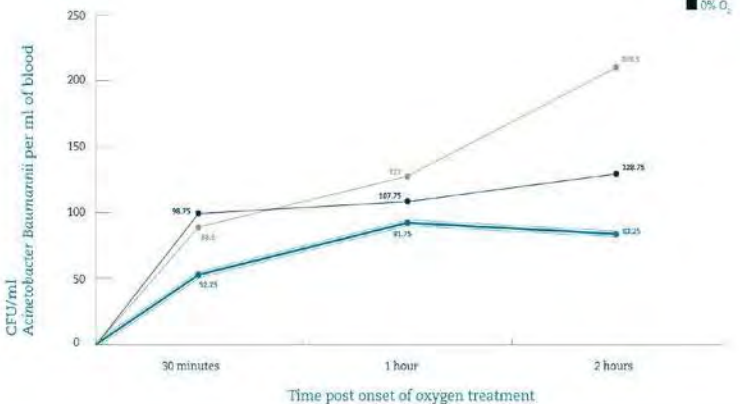
*Acinetobacter baumannii* was grown as a single clone of consistently associated and associated pneumonia infections with Acinetobacter baumannii on commonly vegetative medium (Difco) in a military personnel, particularly soldiers returning from Iraq and Afghanistan with burns and wounds caused by explosives. Studies have shown that the use of Acinetobacter baumannii respiratory substrates that neutrophils are highly sensitive to the high hydrogen ion concentration of the Acinetobacter baumannii pathogen and decline to bacteria level after clearance of the infection. Depletion of neutrophils using monoclonal antibody (MAB) or prior to infection resulted in an acute lethal infection that was associated with enhanced bacterial burden in the lungs (CFU) and extrapulmonary dissemination to the spleen.

The study presented in this paper was designed to determine the effect of increasing the killing of Acinetobacter baumannii by increasing oxygen tension *in vitro*. The question to be answered was whether killing of Acinetobacter baumannii by neutrophils would be proportional to total oxygen content in vitro.

Results from the *in vitro* study confirm that FOU (Acinetobacter baumannii) in an oxygen dependent fashion. Levels of oxygen provided by OxyBand™, showed across FOU and showed increase in neutrophil mediated killing of Acinetobacter baumannii. Results suggest there is a beneficial effect of increasing oxygen tension on neutrophil mediated killing of Acinetobacter baumannii. From these data a clinical trial of treatment and control wounds is warranted.

OxyBand Technologies Inc. has developed OxyBand™ – a ready to deploy liquid oxygen delivery system to a wound that requires up to several weeks and can be used for prolonged periods in a single FOU (wound). The delivery system is a FDA approved (128) device which has demonstrated ability to increase wound healing with less pain, and without infection. Preliminary studies demonstrate that OxyBand™ maintains low oxygen levels over a several weeks in wounds on neutrophil mediated killing of up to 30 days. It can be manufactured in a way that including small enough to be carried in a backpack, and large enough to treat wounds on vegetative body surface area. OxyBand™ if it is well-tolerated in preventing or treating infection/contamination with Acinetobacter and possibly MRSA, will have a demonstrable potential for widespread military use.

## More Oxygen = Less Bacteria The Affect of Increasing Oxygen Tension on Neutrophil Mediated Killing of *Acinetobacter baumannii*



## BACKGROUND

Hypoxic oxygen can be shown to affect the immune response in several clinical conditions. Similarly, local oxygen delivery has been shown to provide a stimulus to healing in a manner similar to hyperbaric oxygen. The exact mechanism of effect remains an open question for both technologies, differences affecting wound healing rate and depth of cure. Chemistry links to depth represent a significant problem for both patients and military and civilian health care delivery systems. Combined some of the most advanced technologies of most developed countries imply that a dramatic increase in the incidence of wounds including infected and chronic wounds is occurring.

**OxyBand™ Studies & Demonstrated Results:**  
All studies *in vitro* (proliferation, healing) and *in vivo* (open wounds) showed increased wound healing, OxyBand™ is a multi-layer wound dressing that keeps air out, dirt out, germs out, and keeps oxygen to the wound. It is designed to be applied directly over a wound for up to 30 days. A study has shown that oxygen levels rise steadily over a wound site for the first few hours and then increase at elevated levels through 5 days or longer in the dressing mechanism and repeat as needed.

The present study evaluated the efficacy of increasing levels of oxygen tension in OxyBand™ to prevent and treat AOB infection by examining the oxygen-dependence of neutrophil-mediated killing of Acinetobacter baumannii *in vitro*.

**Study Methods:**  
Acinetobacter baumannii were cultured and grown in a variety of growth media to optimize growth rate, viability and metabolic characteristics. Human neutrophils (PMNs) were then isolated using a Histopaque gradient. Cell viability and data reproducibility, viability and bactericidal activity were determined. An experiment was built to allow for control of temperature and oxygen concentrations while exposing PMNs and bacteria for various lengths of time to measure their bactericidal activity.

After determining the growth rate of Acinetobacter baumannii and neutrophil phase concentrations in broth, the chamber was built to mix the PMNs and bacteria. This involved constructing a humidified environment where the partial pressure of oxygen could be varied from 100 mmHg (atmospheric) while maintaining a constant temperature of 37°C. The chamber was designed to allow constant stirring to ensure good mixing and enable rapid gas exchange between the liquid environment of the PMNs and the gas environment of the chamber. Additionally, the apparatus allowed researchers rapid access to remove bacterial samples at various time points without disturbing the environment. After the chamber was designed, well and treated PMNs were added to the bacterial suspension, and then the viability and bactericidal activity were tracked. Samples were taken from the reaction at various time points and at various oxygen tensions to determine viability and the bactericidal efficacy of PMNs in this environment. After adapting the protocol for Acinetobacter the protocol was repeated 3 times.

## RESULTS

Table 1 shows a trend toward higher oxygen tension affecting the PMN killing of Acinetobacter baumannii at 100% O<sub>2</sub> (the data shows 98.75 CFU/ml with 100% oxygen vs 206.5 at a greater reduction in CFU of Acinetobacter baumannii with 0% oxygen at 30 minutes, after 1 hour and after 2 hours).  
These data confirm that PMNs kill Acinetobacter baumannii in an oxygen dependent fashion. Results suggest there is a beneficial effect of increasing oxygen tension on neutrophil mediated killing of Acinetobacter baumannii. From these data a clinical trial of treatment and control wounds is warranted.

## DISCUSSION

Wounds and burn wounds are common sequelae of military personnel, whether an active duty or veteran. Many injuries cause major functional morbidity and mortality, and the morbidity from even minor injuries may be high, particularly if the wound is not treated. Infection of superficial wounds, particularly burn wounds, with Acinetobacter baumannii has become a significant problem that delays return of military personnel to active duty – or to access of daily living. Acinetobacter is frequently resistant to multiple antibiotics. Typical infections need to require hospitalization, and there have been reports of mortality with OxyBand oxygen. However, oxygen appears to enhance bactericidal activity.

Oxygen is important in wound healing, and there is a need to find technology to deliver sustained concentrations of hyperbaric oxygen. OxyBand™ has been shown during *in vitro* and *in vivo* trials to increase PO<sub>2</sub> and reduce bacterial load. In full thickness wounds over time, we achieved the speed of epithelialization in partial thickness wounds compared to placebo and standard of care, reduce contamination and decrease pain.

This investigation was initiated to determine whether increasing oxygen concentrations could reduce bacterial kill rates for Acinetobacter baumannii that has become important in combat wounds. These *in vitro* results correlated with prior findings about the use of oxygen provided by OxyBand™ versus standard of care.

## CONCLUSION

The study presented demonstrates from a basic science standpoint that oxygen plays a critical role in increasing the killing of bacteria such as Acinetobacter baumannii. From a clinical standpoint, with significant military relevance, the study demonstrates that oxygen therapy, OxyBand™, may be useful in treating or preventing infections by bacteria such as Acinetobacter baumannii in wounds and combat wounds. OxyBand™ is an easy to apply liquid oxygen dressing that can deliver high levels of oxygen for up to 30 days. It requires no external oxygen source and can be used for prolonged periods in a single FOU (wound). Preliminary studies demonstrate that in wounds on vegetative body surface area, a wound sufficient to require neutrophil mediated killing for up to 30 days, it can be maintained in a way that including small enough to be carried in a soldier's backpack, and large enough to treat wounds over significant body surface area. OxyBand™ may be beneficial in preventing or treating infection/contamination with Acinetobacter and MRSA, it will have a demonstrable potential for widespread military use. It is small enough to replace the dressing currently required for all troops, and should have significant military utility in healing superficial wounds (thermal and chemical), burn, rope burns, scrapes, and de-gluing injuries, for example and returning to and preventing active duty.

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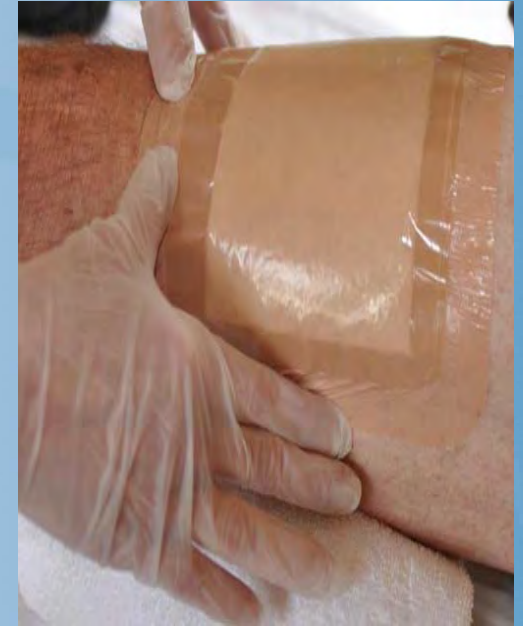
Further information see Rollins



# OxyBand


## Summary of Evidence

- Provides oxygen delivery to wounds
  - 5 days
- Increases wound pO<sub>2</sub>
- 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-imburement rules**
  - **Penalties for surgical site infection**
  - **Penalties for Chronic wounds**
  - **Bundled payments for care**
  - **Improved out comes for less \$**



# Clinical Experience

# Specific Wound Types

- Surgical Wounds
  - Post operative, Donor Sites, SSSI
- Venous Insufficiency
- Diabetic Foot Ulcers
- Pressure Ulcers

## Case Studies – Ellis et al.

### Chronic Wound after 2 Year of Ineffective Treatment Concrete Chemical Burn



Chronic 2 Year Wound



OxyBand- 30 Day



OxyBand- 90 Day



# UCSD – Mulder et al.

- 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

# 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

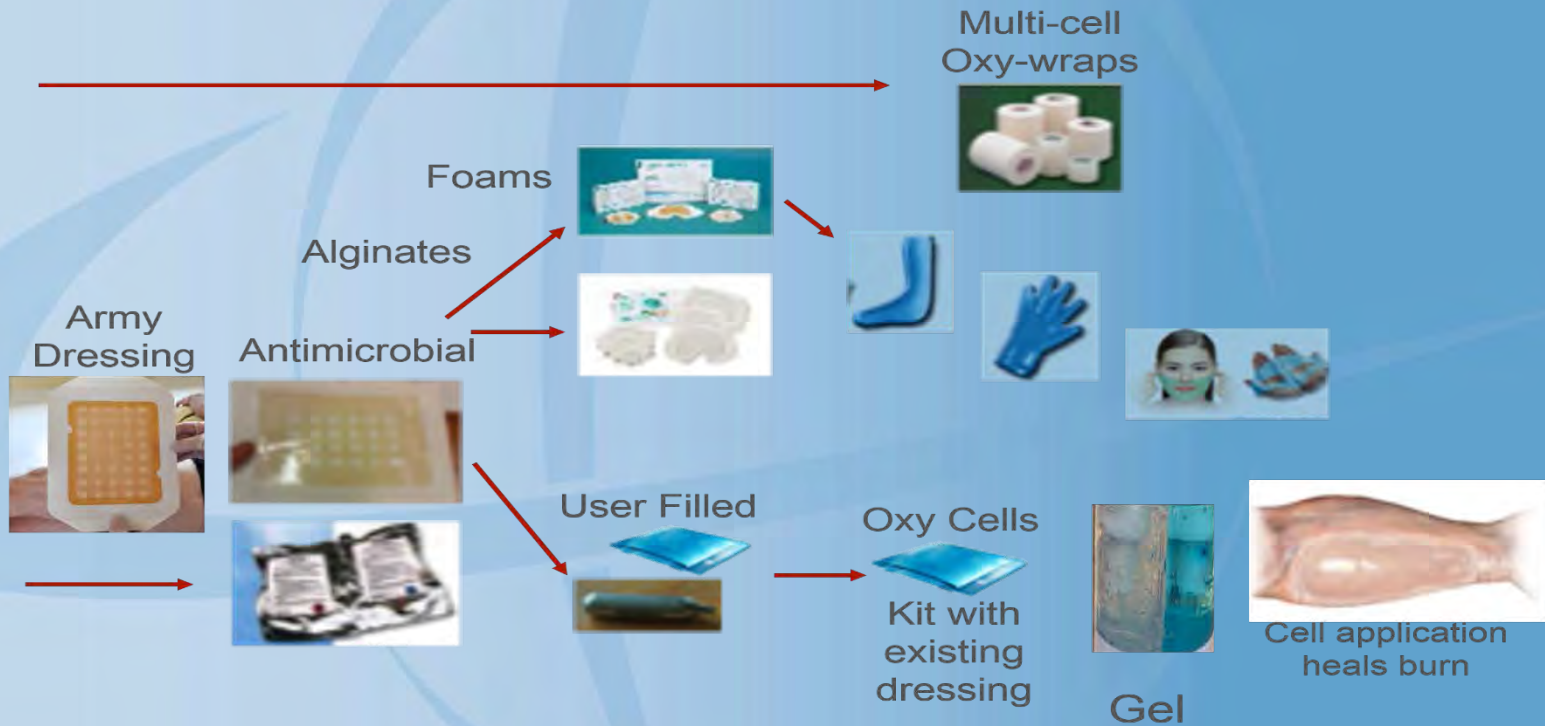


# OxyBand

## Customizable Delivery Device

### PRODUCTS TO ADDRESS THE MARKETS

OxyBand Intellectual Property



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

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

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

# OXYBAND WOUND DRESSING

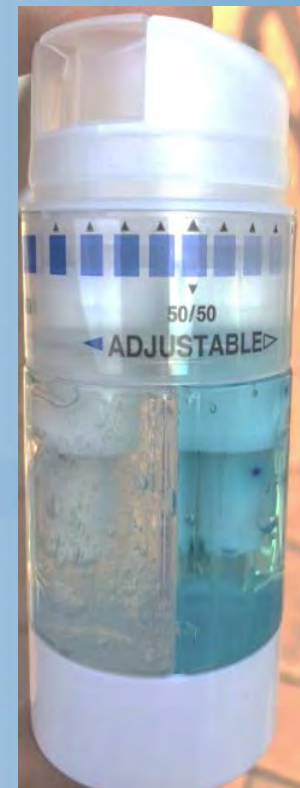
- Oxygen generating gel - future product
- Value as cosmetic because oxygen stimulates collagen

- 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