OxyBand Technologies: Local oxygen therapy and wound healing

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Abstract

BACKGROUND: Hyperbaric oxygen has been shown to be effective in improving healing in selected 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. Chronic wounds represent a significant problem for both patients and health care delivery systems, and the changing demographics of most developed societies imply that a dramatic increase in the incidence of chronic wounds will soon appear. The absence of a single therapeutic target in chronic wounds has made the treatment of these conditions almost entirely empiric in nature. It is common to develop a technology for chronic wounds and to test the efficacy in patients suffering burn injury. It is only recently that a conceptual link has been developed to describe how burns and chronic wounds may be sufficiently similar in nature to allow for the transfer of knowledge on therapies to occur between what would otherwise be considered conceptually distinct disease processes. That link is the presence of biofilms in both types of lesions. Recent data indicate that anaerobic bacteria are significant components of biofilms in both chronic wounds and burns. Local oxygen therapy carries the potential benefit of not only providing oxygen to allow for cellular migration into an otherwise non-healing area, but also presents a treatment that will be toxic to the bacteria largely responsible for the biofilms that inhibit healing.

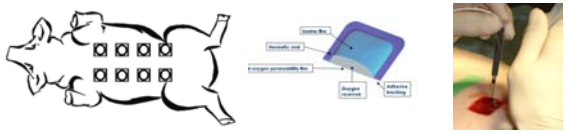
AIM: Develop a practical oxygen delivery system that is independent of any active source of oxygen and illustrate its ability to improve wound healing. The delivery system is an FDA approved (510k) device.

MATERIALS: All studies (in vitro, preclinical, clinical) used the FDA approved device (510k approval number K043063). The description of the device is taken from the approval:"OxyBand is a multilayer wound dressing that keeps out water, dirt and germs, and supplies oxygen to the wound. It is designed to be applied directly over clean skin or wounds for up to 5 days. A study has shown that upon attaching the dressing over a test plate, **oxygen levels rise steadily over the device area for the first few hours and then maintain at elevated levels through 5 days** as long as the dressing remains intact and secure around the perimeter."

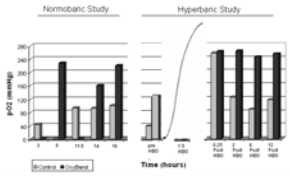
METHODS: (Detailed information on each method is available from OxyBand and contact information appears above.) Briefly, clinical case series studies were carried out at Univ Calif San Diego on recalcitrant wounds. A second clinical trial on laser induced injury and healing was carried out on 19 patients each receiving two wounds measuring 1x1 inch in size and 100 microns in depth. Each patient received both placebo and OxyBand in a randomized pattern. Preclinical testing was performed according to accepted guidelines using a porcine model with real-time oxygen measures. Full thickness wounds were used (as illustrated, next column) and the combination of hyperbaric oxygen and local oxygen delivery were monitored using standard oxygen measures. In vitro analysis (not illustrated) of the role of local oxygen delivery on enhanced bacterial killing by silver was measured using standard culture methods against multiple strains of MRSA and Pseudomonas species.

RESULTS: The results indicate that the use of the OxyBand Dressing was associated with healing in patients with longstanding lower limb ulcers. Re-epithelialization occurred in less than one month in all patients. Laser induced injury showed less pain, less erythema, and shorter healing times than placebo controls. Preclinical data support the concept of sustained delivery seen in vitro. Bacteria commonly associated with biofilm formation, i.e., Pseudomonas species and Methicillin resistant Staphylococcus aureus, demonstrate enhanced destruction by silver in the presence of local oxygen delivery.

Results: Preclinical studies

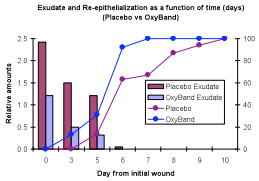


Preclinical studies were carried out using a porcine full thickness wound model (left image). Oxygen delivery using one of the OxyBand configurations was carried out into the wounds (center image). Oxygen measurements were made in situ for each wound as a function of time.(right image above, graph below)



Clinical Results

Randomized trial



Comparative oxygen levels as a function of local oxygen delivery

In a series of 19 patients, two wounds, each 1x1 inch and 100 microns deep were produced by laser and monitored for re-epithelialization (solid lines above) and exudate production (ordinal scale, solid bars above). Exudate production ended sooner for OxyBand and the rate of re-epithelialization was greater at 6 days for OxyBand than Placebo.

Case series

Diabetic Non- Healing Foot Wound
- treated unsuccessfully since Dec 2005
- full thickness, low exudating, history of mrsa, toe amputation
- reduced size by half in 1 week, fully epithelialized 2nd week

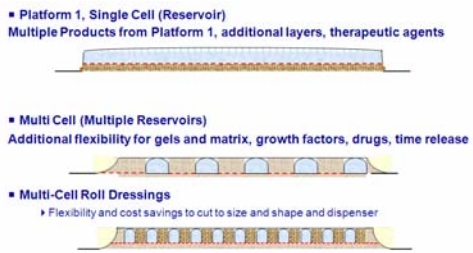
Case Studies:

Diabetic Non- Healing Foot Wound
- reduced size by half in 1 week, fully epithelialized the following week

Venous Chronic Leg Ulcer - right inner calf
- fully epithelialized in 2 weeks
- male with history of venous ulcers

Arterial Chronic Leg Ulcer
- fully epithelialized in 2 weeks
- female w/ yellow exudate

Next steps: Technology selection



Methods: Patented technology platforms include a variety of designs and production methods. Correlation with outcomes represents a logical next sequence in technology enhancement.

Summary

- In vitro data indicate that the technology provides oxygen in a continuous fashion for up to 5 days.
- Microbiological assays in vitro demonstrate enhanced antimicrobial effect of silver ions by the use of the OxyBand technology.
- Preclinical studies illustrate an enhanced delivery of oxygen in vivo after hyperbaric oxygen in a porcine model.
- OxyBand was associated with successful treatment of recalcitrant wounds in a case series of lesions of varied etiologies.
- A randomized acute wound study using laser induced lesions resulted in earlier re-epithelialization of induced wounds with decreased exudate and decreased pain with OxyBand vs placebo.

Conclusion

The *in vitro* and *ex vivo* evidence derived from these data indicate that local oxygen delivery can be beneficial by interacting with biochemical sequences involved in healing while interfering with bacteria capable of causing biofilms.

Representative References

Goldman RJ. Hyperbaric oxygen therapy for wound healing and limb salvage. Phys Med Rehab (2009) 1:471-489.

Wolcott RD, Cox SB, Dowd SE. Healing and healing rates of chronic wounds in the age of molecular pathogen diagnostics. J Wound Care (2010) 19:272-280.