The Efficacy of an Oxygen Reservoir Dressing, OxyBand™ on Accelerating Wound Healing
A Randomized Controlled Double Blind Clinical Trial

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Abstract

The efficacy of an oxygen (O_2) reservoir wound dressing, OxyBand™, on accelerating wound healing was compared to a placebo air filled dressing in a randomized controlled double blind trial (RCDT). Healing, 100% Epithelialization, pain, redness and inflammation were measured on standardized burn wounds of healthy volunteer subjects. A previous study comparing the efficacy of OxyBand™ to a standard dressing, Tegaderm™. OxyBand treated wounds had a significantly greater reduction in mean wound diameter by 40% on day three (including the day of the laser procedure) 40% and on day seven by 3.49 mm + 0.27 at $p < .001$ on day 7 compared to the Tegaderm™ treated wounds with a reduction 5.00 to 2.65 mm in diameter. The present clinical study was an RCDT trial that compared OxyBand™ dressing (95 ± 5% O_2) to a placebo (identical dressing) an air filled (21% O_2) on standardized on 38, 1" by 1" wounds of subjects who served as their own control. OxyBand treated wounds healed significantly faster than placebo treated wounds with less pain redness and Exudate. The mean time to healing for all OxyBand treated wounds was 6.2 days ± 0.9 compared to placebo treated wounds with a mean healing time of 8.8 days ± 0.7. Accelerating healing is critical in healing burns, combat wounds and other wounds. OxyBand treated wounds were also perceived to be less pain.

Introduction

Research in oxygen and wound healing has shown that oxygen is essential for tissue repair including angiogenesis, collagen synthesis, epithelialization, wound contraction, and to prevent infections. Research in animals and in humans has demonstrated that the basic physiology of wound healing is oxygen dependent, and several aspects of the healing process are accelerated with higher oxygen levels. For example, collagen synthesis is enhanced under hyperoxic conditions. Angiogenesis, on the other hand, appears to be stimulated by both a hypoxic tissue gradient, with new capillaries extending in the direction of lower oxygen concentration, and by hyperoxic conditions.

Oxygen treatment in the form of hyperbaric oxygen (HBOT) has become a standard treatment for non healing wounds. Topical oxygen treatment has not become standard because until the clinical studies described in this poster there were not reported results from randomized controlled double blind trials on topical oxygen. Topical oxygen if effective in wound healing, would be more cost effective, accessible, and not pose the same risks that are associated with HBOT. The RCDT described compared the efficacy of OxyBand™ to Placebo in accelerating wound healing, reducing pain, redness and exudate. A previous study demonstrated that OxyBand™ accelerated wound healing compared to Tegaderm™.

Methods

Nineteen male and female healthy volunteers received standardized 100 micron and 25 micron thermal coagulation, 1" by 1" laser burns on the upper aspect of the left and the right arm. Subjects served as their own control. Wounds on the right or left arm of each subject was dressed by random assignment with either the OxyBand™ dressing (95% oxygen ± 5% oxygen) or the placebo dressing (air filled, 21% oxygen).

Wounds were evaluated by two board-certified plastic surgeons experienced in wound care, assisted by two trained nurse practitioners on day 3, 5, 6, 7, 8, 9 & 10. Wounds were also evaluated for redness and exudate on a scale of 1-5. Subjects were asked to assess their own pain on a scale of 1-5 and wounds. Percent epithelialization by two plastic surgeons (0% to 100%) and photographed. After evaluation of scar appearance at 30 days, the study was unblinded.

Results and Discussion

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 1B: Placebo Treated

Photograph 1, A & B, shows wounds on both arms of a subject on day 4, day 1 counted as the day of surgery, as example, the wound randomly assigned OxyBand™ is 95% epithelialized and the placebo treated wound is not epithelialized to the same extent. Photograph 2, A & B, show the OxyBand treated wound of another subject with significantly less exudate than placebo treated wound on day 2. The visual Table 1 presents the mean scores for epithelialization (1% - 100%), exudate (1 – 5 point scale), redness (1 – 5 point scale) and pain (1 – 5 point scale) for all nineteen subjects who completed the study. Subjects reported significantly less pain with OxyBand™ treated wounds and had significantly less redness and exudate than placebo treated wounds. The primary endpoint for the study was 100% epithelialization. By day five, 5 out of 19 OxyBand treated wounds reached 100% Epithelialization (Table 2). By day 6 this number increased to 10 and by day 7, all of the OxyBand treated wounds were 100% epithelialized. No placebo treated wounds were 100% epithelialized on day 7. Placebo treated wounds reached 100% epithelialization on day 10. A significant difference was found between the time to 100% Epithelialization at $p<.001$ OxyBand™ wounds were 100% epithelialized in a 6.2 days ± 0.9 compared to placebo treated wounds which were 100% epithelialized in ™ 8.8 days ± 0.7. These results support the results from the previous study comparing the efficacy of OxyBand™ wound dressing to a standard of care, Tegaderm™ that showed OxyBand™ treated wounds healed significantly faster than standard of care Tegaderm™ treated wounds, day 3, OxyBand™ wounds were 65% epithelialized compared to Tegaderm™ treated wounds which were 25% epithelialized, by day 7, OxyBand™ treated wounds were 91% epithelialized compared to Tegaderm™ treated wounds which were only 72% epithelialized.

Table 1: Mean Epithelialization, Exudate, Redness and Pain for OxyBand™ vs. Placebo

	Day 3		Day 5		Day 6		Day 7		Day 8		Day 9		Day 10	
Treatment	Oxy-Band	Placebo	Oxy-Band	Placebo	Oxy-Band	Placebo	Oxy-Band	Placebo	Oxy-Band	Placebo	Oxy-Band	Placebo	Oxy-Band	Placebo
(N) Number of Wounds	19	19	19	19	19	19	19	19	19	19	19	19	19	19
Mean Epithelialization	13%	0%	31%	14%	92%	63%	100%	67%	100%	87%	100%	94%	100%	100%
Mean Exudate Score	1.21	2.42	0.50	1.50	0.32	1.21	0.00	0.05	0.00	0.00	0.00	0.00	0.00	0.00
Mean Redness Score	1.89	3.05	1.67	2.83	0.84	2.37	0.23	0.95	0.11	0.53	0.00	0.43	0.00	0.75
Mean Pain Score	0.84	2.32	0.50	1.33	0.32	0.83	0.00	0.07	0.00	0.05	0.00	0.00	0.00	0.00

Table 2: Cumulative Subjects Fully Epithelialized

Oxy/P	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
OxyBand	0	0	5	10	19	19	19	19
Placebo	0	0	0	0	0	7	16	19

Conclusions

The poster presents the results from an RCDB study evaluating the efficacy of OxyBand™ (O_2) dressing to accelerate healing of standardized partial thickness wounds compared to an identical placebo (air filled) dressing. The results show that OxyBand™ significantly accelerated wound healing as measured by 100% epithelialization compared to placebo, with a correlative decrease in pain, redness and exudate. The efficacy of OxyBand™ was tested previously against a standard of care dressing, Tegaderm™ on standardized partial thickness burn wounds and showed the rate of wound healing, as measured by the reduction in size of the burn wound, was significantly greater in wounds treated with OxyBand™ compared to wounds treated with Tegaderm™. Together these results strongly suggest that OxyBand™ significantly accelerates wound healing of partial thickness wounds compared to both standard of care and placebo. The potential benefits to combat casualty care for treating burns and other wounds is significant. Further studies are warranted.

* References upon request.