Evaluation of an Oxygen Diffusion Dressing for Accelerating Healing of Donor Site Wounds

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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 siginificant 3-day decrease in the time to healing with the OxyBand versus the Xeroform dressing.

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

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- 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:

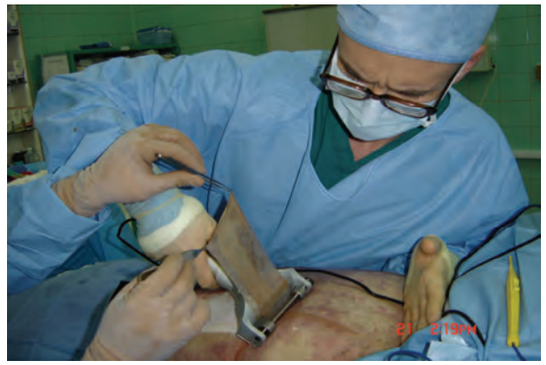
- OxyBand dressings supplied by the manufacturer
- Secured to intact skin around the donor site by the adhesive edge of the dressing
- Replaced if non-adherent or leaky
- Removed and site photographed on days 4, 8, and every 2 days till healed

Control dressing:

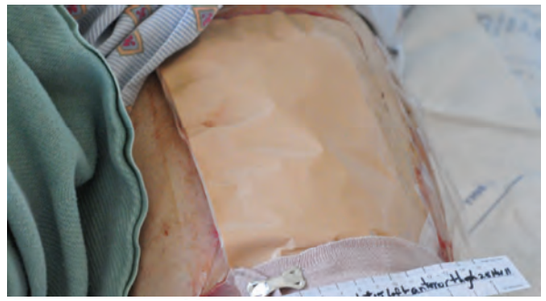
- Xeroform gauze (3% bismuth tribromophenate and petrolatum) on fine mesh gauze
- Trimmed as healing occurred underneath
- Bacitracin applied to assist with separation, beginning on post-operative day 14

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

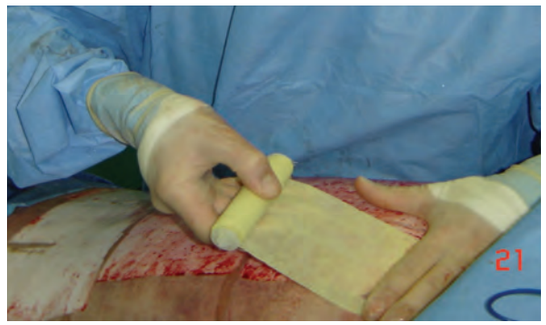
Statistics: A power analysis concluded that 17 patients, providing 34 matched donor sites, would be required to demonstrate a difference in healing time with a confidence level of 95%. Data were analyzed using SAS. Continuous and score variables were compared by Wilcoxon Test. All tests for significance 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: Donor site as a model of wound healing

- 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±1.7 days (range 6-12); for Xeroform = 12.4±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 statistically significant .

References

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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 #I.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. Greggory Housler 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 ISR Statistician Mr. John Jones.

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