

**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.

**METHODOLOGY:** 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) bum 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 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 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 Asso 2012)
- Many of these patients require excision and skin grafting
- In patients with major burns (>20%), wound healing is the key to survival (Nitschke et al., Am Burn Asso 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 designed 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:**
- **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 (i.e.: ongoing mechanical ventilation, vasoactive medications, diabetes, peripheral vascular disease, corticosteroids, coagulopathy)

**Study design:**
- Prospective, single-center, randomized, controlled, open-label study
- 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 backing
- Trimmed as healing occurred underneath
- 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 1

**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 with Wilcoxon Test. All tests for significance were two-tailed with α = 0.05.

**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 = 36 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±7.5 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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