OxyBand™ Hydrocolloid Delivery System vs. Xeroform™: Accelerated Healing and Less Pain

OxyBand™
the Healing Power of Oxygen

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Pre Clinical Trial, The Efficacy of OxyBand™ Hydrocolloid Device compared to Xeroform™ on Laser Induced Donor Sites In Healthy Volunteers

The OxyBand™ FDA 510(K) device has been shown to speed wound healing by delivering high concentrations of oxygen directly to the wound bed. In addition to significantly speeding healing, human clinical trials have demonstrated significant decrease in pain and exudate. Preliminary to instituting a USAISR clinical trial on donor site wounds, with the hypothesis that treating with the OxyBand™ device will result in faster healing than the standard of care dressing, Xeroform™. OxyBand specification is a hydrocolloid interface. This preliminary trial was conducted to evaluate the OxyBand Hydrocolloid compared to the standard of care, Xeroform™.

Methods

13 healthy human volunteers, after obtaining appropriate informed consent, received identical burns on opposite extremities. Each subject served as his or her own control. Wounds were produced with an erbium laser set to an ablation depth of 250 microns. This depth was selected as approximately equal to a 10/10000-inch thickness donor site wound. Wounds were treated with either OxyBand™, Hydrocolloid device, or Xeroform™ randomly assigned and covered with a sterile 4x4 gauze dressing.

The study cohort was divided into 2 groups, dressing change every 4 days and dressing change every 5 days with follow up wound evaluation, to confirm the optimal wear time. OxyBand™ is a multilayer wound dressing that keeps out water, dirt and germs, and supplies oxygen to the wound. OxyBand™ is designed to be applied directly over clean skin or wounds and received its FDA 510 (k) clearance for wear time 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. The FDA approves providing oxygen for 5 days of continuous use. Group 1 (subjects 1-6) wounds were evaluated on Days 4 and 8, and in Group 2 (subjects 7-13) the wounds were evaluated on Day 5, when the OxyBand™ dressing was removed. After Day 5, wounds were evaluated daily without additional treatment and compared to Xeroform™. The poster presents the results from comparison of the pain scores during dressing changes and evaluation of wounds on Days 4 and 8 for six subjects in Group 2, Protocol 1, and Day 5 for 7 subjects in Group 2, Protocol 2. The data below was collected however the graphs show a significant difference in pain between the two groups.

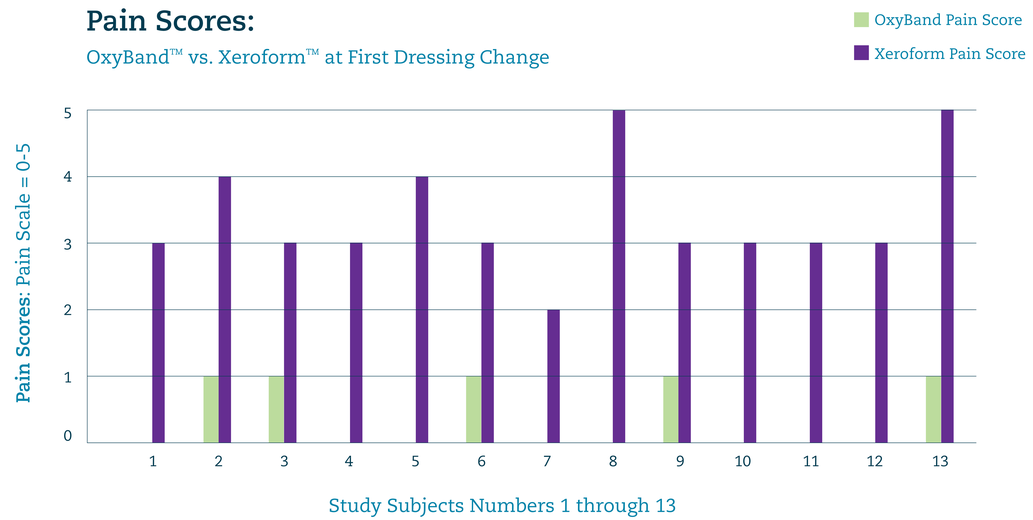
Days of Healing • Pain • Redness • Exudate • Cosmetic Appearance

CONCLUSIONS

- The pre clinical trial of OxyBand™, a new hydrocolloid oxygen dressing for donor sites, showed that wounds healed more quickly than with the traditional method, Xeroform™.
- Patients experienced 10 times less pain than with the traditional method, Xeroform™ and also experienced enhanced patient satisfaction.

Pain Scores:

OxyBand™ vs. Xeroform™ at First Dressing Change



Group 1 (N=6) Perceived Pain Day 8 Dressing Change;
OxyBand™ Vs. Xeroform™ (24 data Points)

- Results show, subjects felt 10 times less pain for wounds treated with OxyBand™ than the same subject with wounds treated with Xeroform™ on the first dressing change POD 4, 4 days after surgical wounds.
- Results show on Day 8, there was 6 times less pain for OxyBand™ wounds compared to Xeroform™ wounds on POD 8, 8 days after surgical wounds.

Group Two (N =7) Perceived Pain Day 5 Dressing Change OxyBand™ vs. Xeroform™

- Results show for each subject, wounds treated with OxyBand™ felt 10 times less pain than the same subject for wounds treated with Xeroform™ on POD 5 for First Dressing Change 5 Days after Surgical Wounds.

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A Clinical Study Evaluating OxyBand Hydrocolloid Delivery System vs. Xeroform™

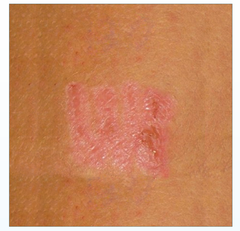
OXYBAND HYDROCOLLOID CLINICAL STUDY

The OxyBand™ FDA 510(k) has been shown to speed wound healing by delivering high concentrations of oxygen directly to the wound bed. The USAISR is scheduled to onduct a clinical trial on donor site wounds, with the hypothesis that treating with OxyBand will result in faster healing than the standard of care dressing, Xeroform™. OxyBand specification is a hydrocolloid interface. A pilot study was conducted prior to the USAISR clinical trial to evaluate the OxyBand Hydrocolloid compared to the standard of care, Xeroform™.

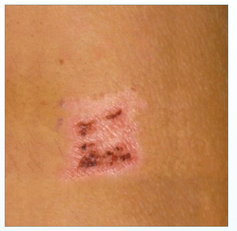
Methods

13 healthy human volunteers received identical burns on opposite extremities. The wounds were induced with an erbium laser set to an ablation depth of 250 microns. This depth was selected as approximately equal to a 10/10000 inch thickness donor site wound. One wound was treated with the OxyBand Hydrocolloid and the other with Xeroform™ and covered with a 4x4 gauze. The study cohort was divided into 2 groups, 4 day, and 5 day, follow up, to confirm optimal wear time. OxyBand is cleared by the FDA for up to 5 days. Group 1, Subjects 1-6 wounds were evaluated on day 4 and day 8, and Group 2, Subjects 7-13 wounds were evaluated on day 5, when the OxyBand dressing was removed. After day 5, wounds were evaluated daily without additional treatment and compared to Xeroform for, Day of Healing, Pain, Redness and Exudate. In addition, acute scaring, "tattooing", and other cosmetic differences were also evaluated.

CLINICAL STUDY RESULTS: OXYBAND HYDROCOLLOID VS. XEROFORM PHOTOGRAPHS



OxyBand™ 5 Day Post Op



Xeroform™ 5 Day Post Op

Clinical Study Results:

OxyBand™ Hydrocolloid On Healing Time vs. Xeroform™ on Standardized 250 Micron Laser Burn Wounds