A Clinical Study Evaluating OxyBand Hydrocolloid Healing Time, Pain, Swelling, Drainage & Redness Vs. Xeroform On Standardized Wounds

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The Healing Power Of Oxygen

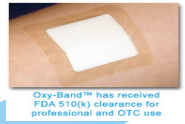
Benefits
Accelerates Healing
Reduced pain
Easy to apply
Easy to remove

OxyBand FDA 510(K) Clearance

Features
Controlled Oxygen Delivery
Conformal
Scalable Delivery Platform
Variable Adhesion Options

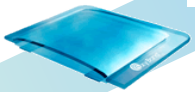
Oxy-Band™ Anti-Microbial

OxyBand™ Optimize Delivery System - Hydrocolloid System

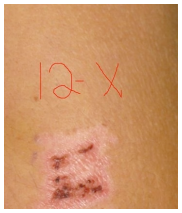


OxyBand™ Receives FDA Clearance Gen-1

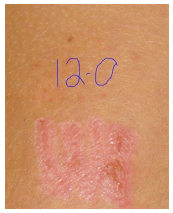
OxyBand™ Demonstrates Faster Healing



Concept Development Over 36 Patents



Xeroform 5 days



Oxyband 5 days

Oxygenated Hydrocolloid Dressing Pilot Study

The OxyBand oxygen diffusion dressing has been shown to speed wound healing by delivering high concentrations of oxygen directly to the wound bed. This dressing has FDA 510(k) clearance. A clinical evaluation will be conducted at the USAISR using this product on human burn patient donor site wounds, with the hypothesis that treating with OxyBand will result in faster healing than the standard of care dressing, Xeroform. The OxyBand for this specification is a hydrocolloid interface with polyurethane areas for diffusion of oxygen into the wound bed. All of the OxyBand materials are deemed safe by the FDA. An initial clinical 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 FDA 510(k) for up to 5 days. Group 1, Subjects 1-6 wounds were evaluated on day 4 and day 8, and Subjects 7-13 wounds were evaluated on day 5 when the OxyBand dressing was removed and after removal, wounds were evaluated daily without treatment. Wounds were evaluated and compared for, **Day of Healing, Pain, Redness and Exudate**. In addition, acute scaring, "tattooing", and other cosmetic differences were evaluated. Result showed no tattooing after treatment and at follow up with OxyBand treatment.