altrazeal®
transforming powder dressing
up to 30-day wear time

A PILOT SAFETY AND EFFICACY PORCINE STUDY FOR MULTIFACETED TRANSFORMING POWDER DRESSING: NO TOXICITY OR INCREASE OF INFLAMMATION

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INTRODUCTION

Excessive or prolonged inflammatory response has been associated with heightened tissue injury, impaired wound healing, and increased scarring. The objective of this study was to evaluate the potential toxicity and clinical inflammation observed when transforming powder dressing (TPD*) is used for wound care. TPD, a novel, commercially available powder wound care dressing with an extended wear time (up to 30 days), is composed of biocompatible methacrylate-based polymers similar to those used in contact lenses.

METHODS

- IACUC-approved protocol
- Yorkshire pigs (150- 250 lbs.)
- 24 surgical wounds were created using a 6mm skin punch biopsy tool
- Partial thickness wounds were generated using phenol in hill chambers
- Wounds were treated with one of various TPD formulations
  - Control wound was covered with sterile cotton gauze
- Microdialysis probes were inserted near one wound from each of the test articles, and dialysates were collected over a two-hour period

Microdialysis Technique:

Commercially available microdialysis probes (100,000-Da cutoff membrane) with a 10 mm length (CMA/20 Microdialysis Probe, CMA Microdialysis, North Chelmsford, Mass.) were used to collect interstitial tissue fluids. Probes were sterilized and an 18-gauge angiocatheter was passed in and out of the subcutaneous tissue, leaving a narrow opening for passage of the probe. Individual probes were introduced in the individual wound beds. Once in situ, the probe shaft was secured to the dermis with 4-0 nylon sutures. Sterile lactated Ringer's solution was pumped through the microdialysis probe at a constant flow rate of 2 liter/minute and specimens (200 to 400 uL) were collected from each site every 4 hours using 1-ml sterile Eppendorf tubes. Samples were immediately frozen at 80°C for later analysis. TNF-α levels were measured using an ELISA kit and urea levels were assessed using a standard urea/ammonia kit. TNF-α levels were expressed as a ratio relative to urea concentration. Full punch biopsies were performed on day 7.

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RESULTS

- Upon hydration, TPD aggregated to form a moist matrix, filling the biopsy wound and exhibiting **clot-like behavior, contracting, moving upwards within the wound bed**
  - **TPD was not absorbed into the wound**
- Cross sections of biopsies evaluated histologically showed the dressing material was in direct contact with the wound bed
- The wound formed an undifferentiated granulation bed as **evidence of vascular reorganization**
- Biopsies showed **robust fibroblast growth** (day 2 and 7) and **keratinocyte migration** (day 14). Dialysate samples indicated that **TNF-α levels remained within normal pro-inflammatory ranges**
- **No dressing changes were required** over the 14-day period
- **No instances of TPD rejection** were observed
- Analysis of TNF-α levels in the control wounds revealed **no evidence of inflammation when compared to a control** wound without dressing.
- There were **no indications of increased inflammation**

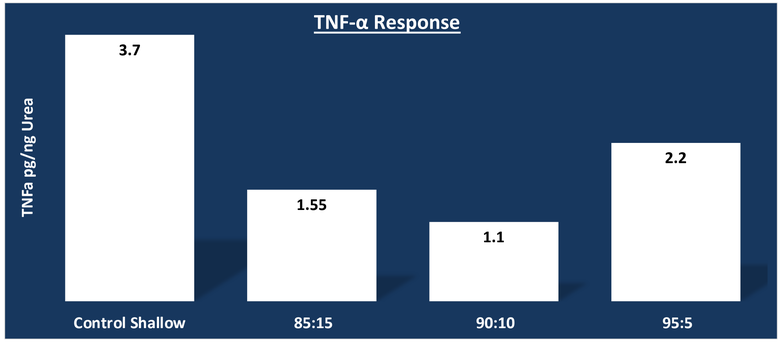

Figure 2. The average of duplicate microdialysis probes TNF alpha levels on Day 7. TNF alpha levels are expressed as picograms of TNF alpha /nanogram of serum urea. Three different TPD polymer combinations (w/w) demonstrated the trend of decreased TNF alpha levels in the presence of all three TPD polymers. | **Disclaimer:** This study has been conducted in compliance with the Animal Welfare Act, the implementing Animal Welfare Regulations, and the principles of the Guide for the Care and Use of Laboratory Animals.

Please refer to Altrazeal Instructions for Use for information about its uses and benefits.

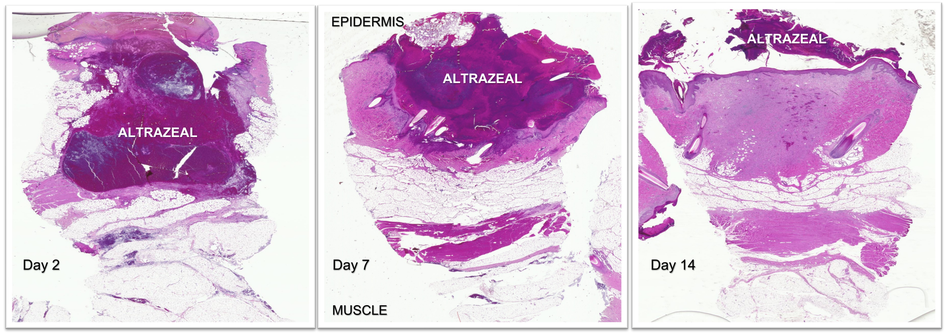

Figure 1: Cross sections of whole wound biopsies evaluated histologically showed the TPD dressing in direct contact with the wound bed and over time the wound formed an undifferentiated granulation bed which showed evidence of vascular reorganization. The biopsies showed robust fibroblast growth (day 2 and 7) and keratinocyte migration (day 14). Notably, dressing changes were not required. No instances of TPD material rejection were observed in the wounds.

DISCUSSION

- TPD was an easy-to-use dressing that did not demonstrate tissue toxicity or increased inflammation over 14 days in a porcine soft tissue wound
- With TPD, normal wound healing cellular responses were observed and the trend of decreased TNF alpha levels were observed
- TPD acted as clinical clot and was gradually pushed from the wound bed over 14 days. No residual TPD was observed in wound beds after 14 days

ABOUT TPD

TPD is comprised primarily of two biocompatible polymers, Poly(2-hydroxyethyl methacrylate and Poly(2-hydroxypropyl methacrylate, similar to those used in contact lenses). Upon hydration, TPD granules aggregate to form a moist, oxygen permeable barrier that protects the wound from contamination while helping to manage excess exudate through vapor transportation. Simple secondary dressings may be used in areas of high friction or exudation. Once applied, TPD may be left on the wound for up to 30 days. If necessary, the dressing may be removed atraumatically by lifting off with a pair of forceps. As the wound heals, Altrazeal dries and flakes off.