Clinical Evaluation to Test the Impact of a Powder Dressing on Chronic Wounds Refractory to Healing

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BACKGROUND

The prevalence of chronic wounds continues to increase to epidemic proportions in the world and currently affects 6.7 million people in the United States.[1] Chronic wounds are challenging for many complicated reasons, and often do not respond to standard of care (SOC) treatments.[2]

OBJECTIVE

The aim of this product evaluation was to evaluate a novel, biocompatible, nonocclusive transforming powder dressing (TPD*) to determine its impact on chronic wounds that were refractory to healing using SOC therapies.

METHODOLOGY

Setting: Four outpatient wound healing centers at University of Pittsburgh Medical Center, a large integrated academic health system with over 20 wound care centers.

Sample Population: Patients with chronic wounds not responding to SOC therapy with the following wound criteria: <75% necrotic/slough present in the wound bed, mild to moderate drainage, non-malignant, no active infection, and no active autoimmune disorder.

Procedure:

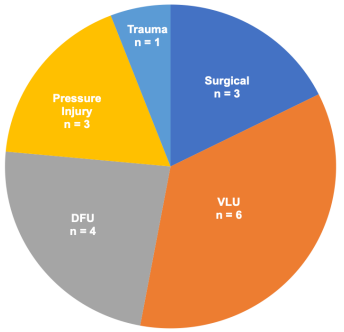
- The product evaluation was first reviewed by and approved by the Value Analysis Team (VAT).
- Each site was able to choose up to 6 patients and provide up to 3 treatments per patient.
- All preselected patients were informed of the product evaluation and consented to participation.
- All wounds were prospectively treated with methacrylate-based TPD, sprinkled into the wound, and hydrated with saline until it aggregated to form a moist, flexible, oxygen-permeable film that contoured and adhered to the wound.
- TPD was covered with a contact layer and secured with rolled gauze. Some patients also received compression wraps or offloading devices as prescribed.
- TPD was topped off or reapplied weekly for 3 weeks and patients were followed for a total of 4 weeks.
- Post TPD application, change in percent volume reduction (PVR) was measured on a weekly basis.

MATERIALS

TPD is a novel powder dressing comprised primarily of biocompatible polymers (similar to those used in contact lenses). Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration. Once applied, TPD may be left in place for up to 30 days and topped off as needed without requiring primary dressing changes. Simple secondary dressings are used in areas of friction or exudation and changed when wet or clinically necessary. TPD flakes off as the wound heals.

**Altrazeal® Transforming Powder Dressing*

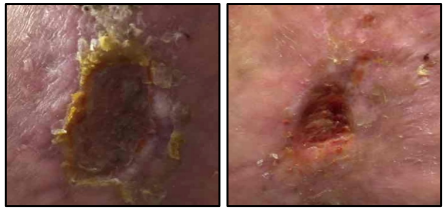
Wound Distribution by Etiology



		Week 0	Week 1	Week 2	Week 3	Week 4	Overall
Patient	Type	Wound Size (cm^3)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)
1	DFU	97.9	-57%	-86%	0%	-45%	-97%
2	DFU	0.5	-15%	153%	-59%	26%	26%
3	DFU	0.2	-56%	0%	400%	-18%	100%
4	DFU	1.5	33%	7%	-3%	-75%	-87%
5	PRESSURE	0.4	36%	-50%	43%	-44%	-46%
6	PRESSURE	1.6	61%	-31%	-58%	-71%	-86%
7	PRESSURE	0.2	-59%	0%	0%	87%	300%
8	SURGICAL	8.3	-32%	-32%	-9%	-25%	-68%
9	SURGICAL	19.2	-88%	50%	50%	0%	-97%
10	SURGICAL	3.5	-66%	-83%	-50%	0%	-97%
11	TRAUMATIC	1.51	0%	-56%	0%	9%	-52%
12	VLU	1.1	-60%	-57%	0%	-42%	-91%
13	VLU	0.6	-35%	0%	0%	-89%	-83%
14	VLU	1.5	-47%	-25%	0%	-17%	-67%
15	VLU	0.3	40%	-20%	0%	0%	33%
16	VLU	0.6	-17%	20%	17%	-14%	0%
17	VLU	3.9	-0.179	-0.5	-0.375	-10%	-77%
						Mean	-29%
						Median	-68%

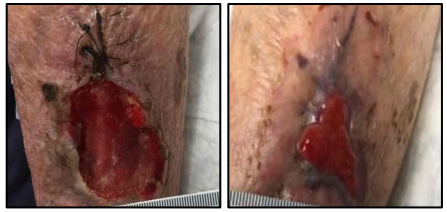
CASE STUDIES

Diabetic Foot Ulcer



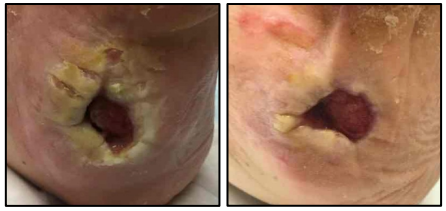
Before TPD | After 3 TPD Weeks

Surgical Wound Considered for Amputation



Before TPD | After 3 TPD Weeks

Diabetic Foot Ulcer



Before TPD | After 3 TPD Weeks

RESULTS AT WEEK 4 (3 TREATMENT WEEKS)

- 19 patients consented to participation; 17 completed the study
  - **Median wound volume reduction (WVR) = 68% in three treatment weeks**
  - WVR reduction observed in 12 patients (71%) / 50% or more patients in each etiology
  - Seven patients (41%) with > 80% WVR
  - 11 (65%) patients with > 50% WVR
- **One 90-year-old patient was deemed "limb salvage:"**
  - Wound volume reduced from 19.2 cm^3 to 0.6 cm^3 in four weeks
  - Wound healed after the study
- **No adverse effects related to the product were reported.** Five patients (29%) had wounds that increased in size for reasons unrelated to TPD

DISCUSSION

The results support that TPD may be a useful therapy for chronic wounds that have failed SOC. A longer evaluation would have been helpful to determine the full impact of TPD on overall healing outcomes.

REFERENCES AND ACKNOWLEDGEMENTS

(1) Wound Care Awareness Week Highlights of the Chronic Wound Epidemic in U.S. Businesswire.com/news/home/20160607006326/en/Wound-Care-Awareness-Week-Highlights-Chronic-Wound. Accessed 11/5/2020. (2) Han G, Celery R. Chronic Wound Healing: A review of current management and treatments. Adv. There 2017; 34 (3): 599-610. Ncbi.nim.nih.gov/pmd/articles/PMC5350204/Accessed online 11/5/2020.

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