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A Retrospective Evaluation of Transforming Powder Dressings in the Treatment of Chronic Stage II-IV Pressure Injuries

Chitang Joshi¹, Shin Young Yu¹, Joshua Weissman¹, Peter Ullrich¹, Reagan Taylor², Safwat El Hoseney³, Robert Galiano¹

(1) Northwestern Feinberg School of Medicine, USA, Division of Plastic and Reconstructive Surgery (2) AdventHealth Medical Group, USA, General Surgery (3) Al Qassimi Hospital, UAE, Plastic Surgery

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Introduction

Pressure Injuries (PrIs) are difficult to heal wounds that afflict millions worldwide. On average, less than 50% of Stage III and IV pressure injuries heal by the sixth month. The resulting physical, mental, social, and financial impairments cause significant suffering, negatively impacting patient quality of life. PrI wound treatment is highly variable depending on a patient's comorbidities, demographics, and wound features and there is no established standard of care.

Transforming powder dressing (TPD) forms a nonocclusive barrier on the wound bed that helps optimize wound moisture to promote healing. Extended wear time reduces dressing changes, infection risk and complications, presenting a promising new wound treatment modality

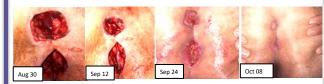
Materials and Methods

We used a novel methacrylate-based transforming powder dressing, which transforms in-situ to a shaperetentive wound matrix once in contact with moisture. (Altrazeal® TPD, ULURU Inc.).

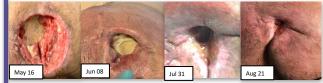
A retrospective case series was conducted for 20 patients with 21 non-healing, Stage II-IV PrIs following standard of care treatment. Dressing change frequency and time wound closure were evaluated.



74-year-old male with a non-healing, sacrococcygeal, Stage IV PrI for two months. After three dressing changes his pain score decreased from 9/10 to 1/10. Nine dressing changes were made over 18 weeks (every 15 days on average).



56-year-old female with two Stage III sacrococcygeal PrIs for five months. Pain reduced from 9/10 to 1/10 by the second dressing change. Three dressing changes were required to close the wound in 39 days, with an average time of 13 days between changes over the five-week period.



24-year-old male with paraplegia and Stage IV PrI for five months. Seven dressing changes were made over 14 weeks (every 15 days on average).

Stage of Ulcer	Cases Analyzed	Average Days to Healing	Average Dressing Changes	Average Days Between Dressing Changes	
All	21	52.2	4.1	13.9	
Stage 4	7	87.4	6.3	17.7	
Stage 3	11	40.6	3.5	12.3	
Stage 2	3	12.7	1.3	10.8	

Summary: All patients experienced successful and expedited wound closure. On average, Stage IV PrIs closed on in 87 days with six dressing changes, Stage III PrIs closed in 41 days with four dressing changes, and Stage II PrIs closed in 13 days with one dressing change. Patients with painful wounds experienced significant pain reduction. Pain scores decreased from from 8/10 or 9/10 to 1/10 or 2/10.

Conclusion

TPD presented a safe and effective modality for treatment of non-healing PrIs; significantly reducing the duration of healing, patient pain and number of dressing changes.

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Contact: chitang.joshi@northwestern.edu

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Acknowledgement: This poster was developed and presented in collaboration with ULURU Inc. For application instructions and risks of this device refer to Altrazeal Instructions for Use | EDU – 0007, Rev 02



DECREASING NURSING WORKLOAD: SIMPLIFYING WOUND MANAGEMENT WITH AN INNOVATIVE TRANSFORMING POWDER DRESSING



Ron Sotomayor, BA, RN, CWOCN, Department of Wound Management, AdventHealth System, Orlando, FL Jonathan Saxe, MD, MAR, MBA, FACS, Department of Surgery, Ascension St. Vincent's Hospital, Indianapolis, IN

SOC TREATMENT MIX

INTRODUCTION

The current nursing shortage is expected to intensify, especially as an aging population burdens our healthcare systems¹. Limited staffing can:

- Cause safety and care issues for patients
- Negatively impact wound healing, and
- Increase hospital length of stay.^{2,3}

We investigated if using an extended-wear transforming powder dressing (TPD) would simplify wound management and decrease nursing workload by reducing requisite dressing changes and time associated with wound care, without compromising outcomes.

METHODOLOGY AND MATERIALS

Global data from 76 patients in six patient cohorts treated with TPD was aggregated. Dressing change frequency and nursing time spent on wound care using TPD was compared to standard of care (SOC) dressings. SOC dressing, dressing change time and number of weekly treatments were recorded where available or estimated based on the most conservative of three expert opinions.

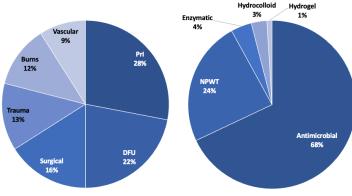
TPD is a commercially available dressing comprised primarily of hydrogel polymers like those used in contact lenses. When hydrated with saline, TPD aggregates to form a moist, oxygen-permeable barrier that covers and protects the wound while releasing excess exudate through vapor transpiration. TPD may be left in on the wound for up to 30 days and topped off as needed without requiring primary dressing changes. Simple secondary dressings may be used in areas of high exudation or friction. TPD flakes off as the wound heals.

DEMOGRAPHICS

> N: 76 | Age: 4 – 95 years

Gender: 33% female / 67% male | Wounds: 41% acute / 59% chronic

WOUND ETIOLOGIES DISTRIBUTION



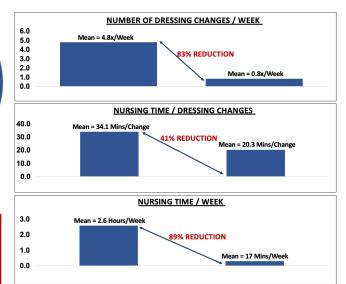
NURSING EFFICIENCIES ACHIEVED ACROSS ETIOLOGIES

WOUND TYPE	WEEKLY DRESSING CHANGE FREQUENCY		TIME / CHANGE (MINS)			TIME / WEEK (MINS)			
	SOC	TPD	% CHANGE	SOC	TPD	% CHANGE	SOC	TPD	% CHANGE
Surgical	5.6x	1.1x	-81%	34	20	-53%	154	17	-90%
Trauma	4.1x	1.1x	-73%	49	23	-53%	174	25	-86%
Burns	7.0x	0.7x	-90%	29	19.4	-33%	202	13	-94%
Prl	5.4x	0.7x	-88%	23	16	-30%	122	11	-91%
DFU	3.6x	0.8x	-77%	33	23	-31%	111	19	-83%
Vascular	2.9x	0.9x	-70%	20	14	-29%	52	13	-75%
All	4.8x	0.8x	-83%	34	20	-41%	154	17	-89%
Acute	5.5x	1.0x	-83%	46	23	-49%	223	22	-90%
Chronic	4.3x	0.8x	-83%	26	18	-30%	107	14	-87%

RESULTS

- SOC: mean dressing change frequency of 4.8x /week (3x/day to 1x/week) requiring 34 mins / change (10 -120 mins)
- TPD: mean dressing change frequency of 0.8x / week (0.2x to 2.0x/week) requiring 20 mins / change (10 -60 mins)

MEAN TIME / WEEK FOR WOUND CARE = 2.6 HOURS / WEEK WITH SOC VERSUS 17 MINS / WEEK WITH TPD



CONCLUSION

Mean dressing change frequency and required nursing time was significantly lower with TPD versus SOC for all wound etiologies. All wounds healed without complications. Pain and pain medications reduced in cases with patient reported pain. Wound management may be simplified with TPD without compromising healing outcomes by reducing dressing changes and overall costs by decreasing utilization of nursing time and material resources.

REFERENCES & ACKNOWLEDGEMENTS

(1) AACN Fact Sheet-Nursing Shortage aacnnursing.org/news-information/fact-sheets/nursing-short/ Accessed online 29OCT2022 | (2) Nursing Shortages: Implications on Wound Care and The Way Forward. April 5, 2022. Healiant Training & Education. https://healiant.com/nursing-shortages-implications-on-wound-care-and-the-way-forward | (3) Nurse staffing models, nursing hours, and patient safety outcomes. nlm.nih.gov. age. Accessed online 28OCT2022.

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

Dawn J. Geisler Wang, MD, MPH | Medical Director, UPMC Passavant Wound Healing Center

Symposium on Advanced Wound Care | April 26 - 30 | National Harbor, MD



Week 4

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.

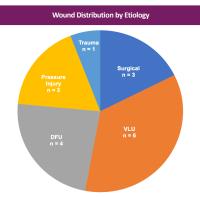
Sample Population: Patients with chronic wounds not responding to SOC therapy with the following wound criteria: <75% necrotic/slough present in the wound bed, mild to moderate drainage, non-malignant, no active infection, and no active autoimmune disorder.

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 methacrylatebased TPD, sprinkled into the wound, and hydrated with saline until it aggregated to form a moist, flexible, oxygenpermeable 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

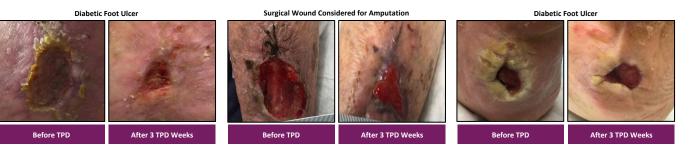
TPD is a novel powder dressing comprised primarily of biocompatible polymers (similar to those used in contact lenses). Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through 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.



		WEEK U	WEEKI	WEEK Z	WEEK J	WEEK 4	Overall
Patient	Туре	Wound Size (cm^3)	% 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%

Week 1 Week 2 Week 3

CASE STUDIES



Week 0

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 cm³ to 0.6 cm³ 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.

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