

## Novel Treatment of Necrotizing Fasciitis with Transforming Powder Dressing

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### Background

Necrotizing Fasciitis (NF) is a rare but life-threatening soft tissue infection caused by bacteria that target the skin, subcutaneous tissue, and fascia, resulting in progressive necrosis.<sup>1</sup> Associated mortality is 12-46% as infection can spread quickly causing severe systemic toxicity and sepsis.<sup>2</sup> Proper management requires aggressive surgical debridement and appropriate adjuvant therapies. Early amputation of impacted tissues and maximum intensive care treatment are often required.<sup>3</sup> Routine wound care includes utilizing conventional antimicrobial dressings or negative pressure wound therapy (NPWT) to facilitate adequate wound granulation prior to grafting. Repeated dressing changes drain medical resources, increase patient pain and exposure to infection, presenting a significant clinical challenge.

### Material

Three case studies incorporating treatment using a novel Transforming Powder Dressing (TPD) in patients with NF and other comorbidities were reviewed. In all cases, patients had extensive wounds with high pain scores, using Visual Analogue Scale (VAS), making NPWT or conventional dressing changes intolerable. In two of three cases, TPD was applied directly to the wound with secondary dressings. In one case, TPD was applied over a meshed split thickness skin graft (STSG) in the penile and scrotal area.

TPD is comprised primarily of biocompatible polymers (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 more powder may be added as needed without requiring full dressing changes. Simple secondary dressings may be used in areas of high exudation or friction. TPD dries and flakes off as the wound heals.

### Results

**PATIENT 1:** 44 y/o male with DM, obesity, HTN, HCL

**Wound Dimension:** 50cm x 18cm x 22cm

**Challenge:** Extreme pain during NPWT

**Treatment:** Conversion to TPD

**Outcomes Post-TPD Treatment:**

- VAS pain score reduced from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced home health visits (3x to 1x weekly)
- Reduced dressing encounters (<20 versus > 66 estimated with SOC)
- Avoided grafting, amputation & readmission



**PATIENT 2:** 51 y/o male with HIV

**Wound Dimension:** 72cm<sup>2</sup>

**Challenge:** Painful daily gauze dressing changes

**Treatment:** Conversion to TPD

**Outcomes Post-TPD Treatment:**

- VAS pain score reduction from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced dressing changes (11 vs. 60 estimated with SOC)
- and required visits from 3x to 1x weekly
- Avoided readmission for grafting



**PATIENT 3:** 71 y/o male with diabetes,

Fournier's gangrene, penile implant malfunction<sup>4</sup>

**Challenge:** Painful, challenging location to conduct frequent dressing changes

**Treatment:** Wound was surgically debrided. Two meshed split-thickness skin grafts were applied, anchored using peripheral sutures covered with TPD and net underwear

**Outcomes Post-TPD Treatment:**

- Graft took by day 15 as TPD flaked off
- Reduced pain from use of fewer stitches



### Conclusion

TPD presents a safe and effective modality for treatment of NF wounds with the potential to reduce healing times, pain and frequency of dressing changes.

### References

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- (4) Gleaves, J., Eldridge, K. Treatment of severe Fournier's necrotizing fasciitis involving the scrotum and volar penile skin associated with a malfunctioning penile prosthesis; Presented at the 2009 CSAWC, San Antonio, TX | **Acknowledgements:** This poster was developed and presented in collaboration with ULURU Inc.

# A TRANSFORMING POWDER DRESSING FOR MANAGEMENT OF COMPLEX ATYPICAL WOUNDS

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## BACKGROUND

Atypical wounds, or wounds of unknown or uncommon etiologies, comprise approximately 10-20% of all chronic wounds.<sup>1,2</sup> Treatment presents an ongoing challenge to wound care specialists. Inflammatory diseases, infections, chronic illnesses, malignancies, or genetic disorders may predispose a patient to atypical wounds.<sup>4</sup> Atypical wounds can be painful with prolonged healing times, resulting in a reduction in patient quality of life and increased mortality. With an aging population and the presence of a progressively diverse array of identified etiologies, atypical wounds are being identified with a higher frequency.

Current treatment for patients with atypical wounds is a challenge as these wounds are typically nonresponsive to conventional therapy.<sup>3,4</sup> Alternative treatment strategies for atypical wounds are under investigation and should be considered to address the current gap in knowledge and clinical management of these patients.

## MATERIAL AND METHOD

We present a case series which evaluates the clinical outcomes of 3 patients with diverse atypical wounds which were refractory to prior treatment, including diagnoses with bullous pemphigoid (BP), pyoderma gangrenosum (PG), and vasculitis. Prior treatment in all cases was converted to a novel Transforming Powder Dressing (Altrazeal®, ULURU Inc., USA)

Transforming Powder Dressing (TPD) is a powder dressing comprised primarily of biocompatible polymers (same as those used in contact lenses). Upon hydration with saline, 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. Once applied, TPD may be left in place for up to 30 days. Additional powder may be added ("topped off") as needed without requiring primary dressing changes. TPD dries and flakes off as the wound heals.

For application instructions and risks of this device refer to Altrazeal Instructions for Use | EDU - 0014

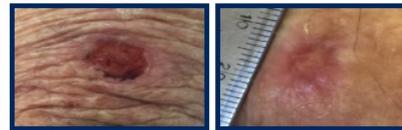
## RESULTS

### BULLOUS PEMPHIGOID

**History:** 89 y/o male with 1.0 x 1.2 cm erosion on left elbow | **Wound Duration:** 3-4 months

**TPD Treatment:** Weekly dressing changes with TPD

**Outcomes:** Fully healed in three weeks



### PYODERMA GANGRENOSUM

**History:** 60 y/o female with 26 years of Crohn's disease, peristomal PG for three years, 27 hospitalizations

**Challenge:** Excruciating pain requiring use of narcotics every six hours. Developed irritant dermatitis from leaking stoma appliance. Required daily or twice a day changes of stomal appliance.

**TPD Treatment:** TPD applied and topped off every 4 days

**Outcomes:**

- Healed PG wound
- Reduced reapplication of stomal appliance from once or twice per day to every four days
- Pain score reduced from 10/10 to 0/10
- Reduced home health visits
- Discontinued all pain medications



### VASCULITIS

**History:** 42 y/o male with uncontrolled cutaneous vasculitis and history of p. aeruginosa. Developed circumferential venous ulcer on lower extremity with exposed bone and excruciating pain score (9/10).

**Wound Duration:** 4 months

**TPD Treatment:** TPD was changed twice a week for the first week and then on a weekly basis. Amikacin was used for infection control.

**Outcomes:**

- Accelerated granulation facilitated coverage of exposed bone
- Wound bed was ready for grafting in 70 days
- Patient reported reduction in pain immediately after the first application of TPD
- Prevented amputation



## CONCLUSIONS

The implementation of the novel powder treatment showed improvement from a healing perspective in all three cases. The stagnating BP wound was fully healed in three weeks. In the second case, all peristomal skin complications were resolved after using TPD under the stomal appliance and the patient was able to wear the appliance for extended periods without pain or leakage. In the patient with vasculitis, a marked reduction in pain was observed within a few minutes of application of TPD. TPD stimulated granulation to cover the exposed bone and the extensive wound was ready for grafting within ten weeks. The powder form allowed for easy application to wounds of irregular shapes and causes. The reported cases demonstrate the effectiveness of TPD in the treatment of patients with painful or refractory atypical wounds.

### References:

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# P2323 | Case Series: Chronic Wounds Treated With a Novel Transforming Powder Dressing

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## BACKGROUND

Chronic wounds are associated with differing burdens for patients, health care professionals and health care systems. There is a high impact on quality of life for patients. Pain, exudation, malodor, and the resulting restrictions of leisure activities are typical. Transforming Powder Dressing (TPD) represents a novel transforming methacrylate-based dressing in powder form. Hydration of the powder granules leads to an irreversible aggregation. The resulting dressing conforms exactly to the wound surface and provides a moist wound environment. We present the results of a case series of patients with chronic stagnating wounds treated with TPD.

## OBJECTIVES

The objective was to evaluate the impact of treatment with TPD on the reduction of wound size and pain score over an observational period of 12 weeks.

## METHODS

We treated 11 patients with chronic wounds of different etiologies (Table 1) with Transforming Powder Dressing. All patients had received the best practice treatment and had experienced stagnation of wound healing for at least three months prior to the treatment with TPD. The observational period lasted 12 weeks. Wounds were inspected for a dressing change (or addition / top-off of more powder) every seven to fourteen days by a wound specialist. For every visit wound size and pain score (on the visual analogue scale - VAS) were obtained. Descriptive measures were computed. Quantitative variables were described as qualitative data as n in %, as mean with standard deviation (SD) for continuous variables. All analyses were performed using IBM SPSS, Windows® software version 23.0.

## RESULTS

### Study population

We included and analysed data of 11 chronic wounds from 11 patients, of which seven patients (64%) were female. The mean age was 63 years. The wounds were of different etiologies. Table 1 shows basic characteristics of the study population.

Tab. 1 Study population

Patient Number	Age in years	Gender	Duration before treatment in months	Etiology of the wound
1	74	Female	24	Post-thrombotic syndrome
2	61	Female	11	Pyoderma gangrenosum
3	24	Female	12	AV-Malformation
4	76	Female	12	Postoperative wound healing disorder
5	70	Female	12	CVI and mixed connective tissue disease
6	52	Female	156	Urticaria vasculitis
7	79	Female	7	Calcinosis cutis
8	64	Male	28	Peripheral arterial occlusive disease
9	72	Male	10	Diabetic foot and peripheral arterial occlusive disease
10	71	Male	8	Peripheral arterial occlusive disease
11	47	Male	30	CVI and mixed connective tissue disease

## RESULTS

### Wound size

The mean wound size decreased from 12.6 cm<sup>2</sup> at visit 1 to 2.7 cm<sup>2</sup> at last visit in week 12 (Table 2, Figure 1). The mean relative difference of wound size between visit 1 and the last visit was reduced by 40.9 % (SD 86.6 %). Four of 11 wounds full closure.

Tab. 2 Wound size in cm<sup>2</sup>

	Day 0	After 4 Weeks	After 8 Weeks	After 12 Weeks
Number of patients	Valid	11	11	9
	Missing	0	0	2
Mean	12.60	8.85	3.78	2.65
Median	8.75	7.50	1.33	1.08
Standard deviation	13.69	12.82	5.28	3.05
Minimum	1.80	.30	0.00	0.00
Maximum	49.00	45.50	14.00	6.96

Figure 1. Wound size (cm<sup>2</sup>)

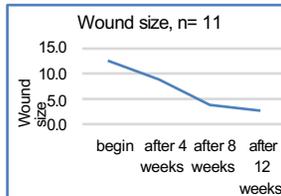
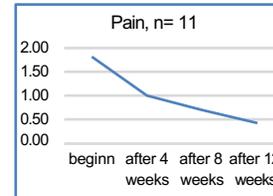


Figure 2. Pain score (VAS 0-10)



### Pain score

The pain score decreased from 1.8 (SD 2.1) at visit 1 to 0.4 (SD 1.1) at the last visit (Figure 2). Four of 11 patients had painless wounds.

### Drop outs

During the treatment period 3 dropouts were observed. Patient 2 discontinued treatment because lack of time for consultations. Patients 10 and 11 discontinued treatment because of the progression of the wounds in week 8.

### Clinical presentation

Figure 3. Patient 1 - Postoperative wound healing disorder



## RESULTS

### Clinical presentation

Figure 4. Patient 6 – Urticaria vasculitis



Figure 5. Patient 5 - CVI and mixed connective tissue disease

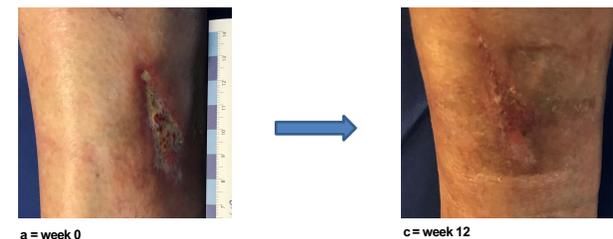


Figure 6. Patient 7 – Calcinosis cutis



## CONCLUSION

TPD offers a promising approach to treat chronic wounds. Reduction of wound size and pain contribute to a better quality of life and can reduce costs for the health care system. A highly beneficial characteristic of TPD observed during this study was the marked reduction in the frequency of dressing changes. In clinical routine, the mean period between dressing changes was about 2 weeks, suggesting the product offers a promising alternative to conventional dressings.

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# Clinical Observations on the Use of a Novel Powder Wound Dressing in the Treatment of Atypical Wounds

## Introduction:

Atypical wounds are notoriously difficult to treat. Challenges involved in treating these wounds typically involve managing pain, an inability to debride due to Koebner's phenomenon or pathergy, and decreasing inflammation both peri-wound and in the wound. We describe the application of a novel powder dressing with unique properties to atypical wounds with positive results.

## Methodology:

The clinical evidence of a novel powder wound dressing has been demonstrated previously for wounds such as venous ulcers or diabetic foot ulcers. In this case study, atypical wounds such as ruptured lymphangiomas in a patient with chronic lymphedema, pyoderma gangrenosum, and a sickle cell ulcer developing after hallux valgus surgery are studied with different treatment options. All of these wounds were treated with a novel powder wound dressing once weekly for four to eight weeks.

For each wound, the powder was applied according to manufacturers instructions where it transformed from a white powder into a translucent, flexible film on the wound bed. The dressing did not overlap onto tissue surrounding the wound. For the patient with lymphangiomas, the powder was allowed to transform and a compression boot was applied over the dressing with no complications between dressing changes.

## Results:

The ruptured lymphangiomas healed uneventfully with application of the powder dressing. The sickle cell ulcer decreased in size and pain substantially in order for a skin substitute to be utilized. The pyoderma gangrenosum showed a decrease in pain and increase in granular tissue formation and continues to show improvement to date.



Lymphangioma Day 0



Lymphangioma Day 11



Lymphangioma Day 31



Sickle Cell Hematoma Day 0



Sickle Cell Hematoma Day 7



Sickle Cell Hematoma Day 21  
Healed with Dermal Substitute



Pyoderma Day 0



Pyoderma Day 7



Pyoderma Day 21



## Conclusion

The implementation of a novel powder dressing in treatment showed improvement from a healing perspective in all three challenges. The primary benefit seemed to be decreased pain for each wound as all of these clinical conditions have marked pain associated with the wounds. In addition, the wounds showed a decrease in depth accompanied by an increase in granulation tissue at each dressing change. The properties of this novel powder wound dressing allow for application to atypical wounds of irregular shapes and causes. The dressing demonstrates the capability to remain in contact with the wound bed for periods of up to seven days between dressing changes. More importantly, it provided a painless, efficient, and protective wound treatment that not only assisted in wound closure, but also in wound preparation for further interventions.

## Learning Objectives:

The objective of this presentation is to show the physical and chemical characteristics of a unique powder wound dressing and demonstrate the use of this dressing in the treatment of atypical wounds.

## References:

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## Transforming Powder Dressing Used Under Contact Cast for Complicated Charcot Arthropathy with Ulcer

Gregory A Bohn, MD; Matthew R Wilber, DPM



### Introduction

When wounds complicate treatment of Acute Charcot Arthropathy, challenges with the requirements for optimal care of the wound may affect the choice of structural support and immobilization. A dressing that will be effective for the length of cast placement is a desirable.

### Case Presentation

A diabetic male with a wound to his right foot, pathologic first metatarsal fracture and acute osteomyelitis underwent first ray amputation despite aggressive IV antibiotic therapy, Hyperbaric Oxygen Therapy and wound care. After having healed, he returned in 7 weeks with acute warmth and swelling. X-rays demonstrate changes of Acute Charcot Arthropathy. A wound developed and was treated with Transforming Powder dressing.

### Methods

Transforming Powder dressing was used with cadexomer iodine and becaplermin to control bioburden and impact healing while in contact cast.

### Results

Transforming Powder dressing works well under a total contact cast and stays in place. This dressing is effective in providing covering to bring about wound healing.



Arthropathy stabilized with Contact Casting



Patient developed warm swollen foot and Arthropathy 7 weeks after he healed



Heel wound developed while in Contact Casting



Transforming Powder used over an active; i.e., becaplermin.



Transforming Powder applied over active



Wound healed with active management under contact cast.

### Conclusions

Transforming Powder dressing has unique properties and applications that make it a preferred choice for a wide variety of applications. Difficulty in addressing Charcot Arthropathy when complicated with a wound requiring treatment poses a structural support problem as well as a wound problem. This new and unique dressing works well under a total contact cast to treat complicated wounds.

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