



# The Utility of Transforming Powder Dressings in the Management of Stage 4 Chronic Venous Leg Ulcers



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## Introduction

Venous leg ulcers (VLUs) remain a public health issue with significant economic and psychosocial impacts. Due to chronicity and high recurrence rate, VLU care is costly for the individual and the healthcare system. Yearly care costs average between \$13,653 - 18,986 per patient. Standard treatment options tend to utilize compression therapy or direct wound care. There is no consensus as to which dressings promote wound healing significantly better than others do.

Transforming powder dressing (TPD) forms a non-occlusive 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 treatment modality.

## Materials and Methods

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

Patients had chronic, Stage 4 VLUs that failed to heal after standard of care therapies. Days to healing, number of dressing changes, days between dressing changes, and pain scores were recorded.

## Results



62-year-old male with a non-healing VLU. Wound prior to TPD is shown on the left. The wound at Day 14, Day 28, and the completion of wound healing at Day 45 are also shown.



48-year-old male with a non-healing VLU for seven months. Wound prior to application of TPD is shown in the top left image. The wound at Days 15, 30, 48, and 65 are shown sequentially. A significant reduction in wound size is visible after the second dressing change and complete wound closure was observed within 60 days.



54-year-old female with a painful, non-healing VLU for two years. Wound prior to TPD application is shown followed by Days 14, 30, 50, and 70. Patient expressed significantly less pain after second TPD change. Wound reduction was visible by the 3rd change with complete wound closure by Day 70.

## Conclusion

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

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**2010 SAWC Meeting  
Orlando, FL**

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**Clinical Problem:** Wound pain is a significant issue for many patients with chronic wounds. 80% of patients with venous leg ulcers (VLUs) experience pain.<sup>1</sup> Its sequelae include fatigue, alterations in interpersonal relationships, sleep disturbances, and depression<sup>2,3</sup>.

**Methods:** Seven patients with VLUs were treated with a transforming powder dressing (TPD) during an initial evaluation of this dressing's utility in wound management. All patients had failed previous attempts using various advanced dressings, bioengineered skin, or split thickness skin grafts. All had varying levels of non-adherence to the systemic plan of care – including inconsistency with compression garments/dressings, management of glucose, and routine, consistent dressing changes. Age of wounds varied from 3 to 27 years. All patients reported pain as an inhibiting factor with adherence with recommended regimen and wound sizes and had not decreased in several months.

**Initial Application of Transforming Powder Dressing**



## Serendipity: Use of a Novel Transforming Powder Dressing to Treat Chronic Wounds Reduces Lower Extremity Wound Pain in Patients with Venous Wounds



**Initial Application of Transforming Powder Dressing**

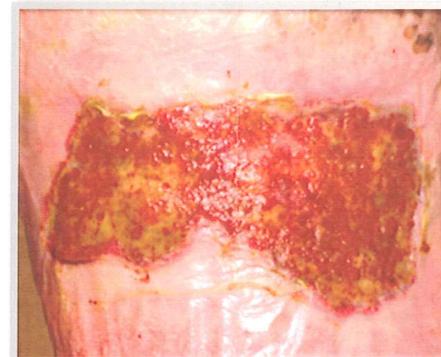
**Presented Case:** 62 year old male developed a right lower leg ulceration after post-phlebotic syndrome as a sequelae to a work accident. Co-morbidities include obesity, +MRSA, COPD, HTN, hyperlipidemia and Type 2 diabetes. Patient lives alone and refused home health services after receiving care from 5 different agencies. Patient has received a number of previous treatments for the last 27 years including STSGs, compression, NPWT, bioengineered skin, lymphedema, IV and oral antibiotics, pain management referral, and a variety of topical antimicrobial and non-antimicrobial dressings. Adherence to the treatment plan would vary but always would eventually fail. Pain associated with the wound itself, coupled with treatment pain often hindered compliance. The patient refused further surgical interventions to achieve wound closure. Pain levels were reported by the patient as 9-10 continuously.

At the time of application of the TPD followed by a nonadherent dressing to absorb drainage, the patient reported immediate reduction of wound pain to a level of 2. Within 2 weeks of continuous pain reduction, he agreed to light compression. He has steadily increased his compliance to the recommended treatment regimen and is now on full therapeutic compression levels but continues to refuse other modalities of care.



**15 Months on Treatment Regimen**

**5 Months on Treatment Regimen of TPD with Compression**



**Results:** All patients reported serendipitous and unexpected improvements in pain levels within 15 minutes of TPD application. As a result, this group of chronic wound patients increased compliance to the recommended treatment plan – including compression, the mainstay of VLU treatment. All patients reduced oral pain medications and had slow, steady decreases in wound size and drainage.

**Conclusion:** The mechanism of sudden reduction of wound pain after dressing application may have several explanations including bacterial toxin binding, high moisture vapor transmission rate, or Substance P blockade. Regardless of the physiological mechanism, the reduction of pain in this group, this serendipitous finding and its subsequent impact of patient adherence and quality of life measures warrants further study.

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\* Altrazeal™ Transforming Dressing-ULURU, Inc.  
Financial Disclosure: Costs associated with poster presentation were provided by ULURU, Inc.

# Application of a Novel New Wound Conforming Dressing

**Purpose:**  
The purpose of this presentation is to demonstrate the versatility of a new powder dressing.

**Background:**  
The ideal wound dressing would maintain a moist wound environment, allow gaseous exchange so that oxygen, carbon dioxide and water vapor can pass in and out of the dressing, be thermally insulating, be impermeable to bacteria to protect from contamination, be non-traumatic and not adhere to the wound, be user friendly and easy to apply, remain in place, be cost effective and have minimal need for secondary dressing (2,3,4). Dehydrated particles that contain a methacrylate backbone and a terminal hydroxyl group have been developed such that when placed in a wound and exposed to physiological fluid aggregate into a structural gel that intimately covers the wound (1). Poly-2-hydroxyethylmethacrylate (pHEMA) and Poly-2-hydroxypropylmethacrylate (pHPMA) particles are synthesized as a powder that can be applied into a wound and hydrated with saline by drip method or misting that aggregate into a wound contour conforming dressing (1). When hydrated, this dressing aggregates to a final content of approximately 65% moisture by weight (1). This presentation illustrates uses of this novel new technology with three clinical case studies.

**Methods:**  
A new powder dressing became available. To evaluate this dressing in our clinic, we applied the dressing to a variety of wounds. Applied alone, under compression wraps and under contact casts; this powder dressing was observed for ease of use, staying in place, and for effectiveness in healing wounds by weekly wound measurements (5).

**Case 1:** A 47 yo Insulin dependent Diabetic white male presented with a neuropathic Wagner Grade 2 ulcer on the lateral aspect of his right foot. He had been treated with an offloading DH Walker and daily dressing with a currently available collagen silver dressing. Wound healing progress had stalled and powder dressing was used under a contact cast to better offload and treat his neuropathic ulcer. A breathable wound veil was placed over the aggregated dressing along with a foam under the cast. The wound healed on a sharp trajectory based on calculated wound volume measurements (Figure 1).

**Case 2:** A 59 yo white male with chronic venous stasis had been on palliative care with his ulcers for 30 months. He had in the past been treated with bioengineered skin grafts, operative skin grafts, and multiple different wound products. He currently was returning to the clinic for twice weekly Multi-layer compression wrapping. Powder dressing was applied weekly after selective debridement while his compression wraps were changed twice weekly. The powder dressing was applied and covered with veil and absorbent foam under the compression wraps. Patient went on to heal his wounds.

**Case 3:** A 57 yo white male undergoing active chemotherapy and radiation for intra-cranial metastatic melanoma lost his balance and fell against a steam heat radiator and suffered 3rd degree burn wounds to his right thigh. Concerned that the patient's disability while undergoing active chemotherapy would not support a graft or heal a donor site, dressing therapy was to be used. After debridement of dead eschar, powder dressing was used without a secondary dressing. It stayed in place over the course of the week and reduced the patients pain. His wound healed without grafting.

## CASE 1

### Diabetic Wagner Grade 2 Neuropathic Ulcer



### Application of Powder Dressing



### Powder Dressing Covered with Wound Veil



### Diabetic Ulcer with Foam Before Contact Cast



### Application of Contact Cast



## CASE 2

### Right Leg Venous Ulcer



### Powder Application



### Powder Dressing Left Leg Venous Ulcer



### Left Leg Venous Ulcer



### Powder Dressing Right Leg Venous Ulcer



### Compression Wraps Applied After Powder Dressing



## CASE 3

### 3rd Degree Burn Wound to Right Thigh



### Application of Powder Dressing



### Dressing on Right Leg Burn Wound Aggregating with Saline



### Powder Dressing in Place



### Third Degree Burn Wound Healed



## Powder Dressing and Diabetic Ulcer

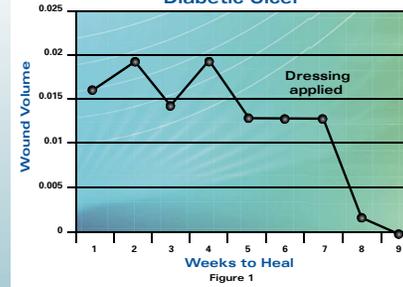
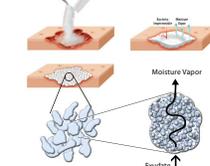
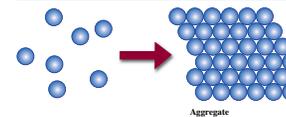


Figure 1



The dressing components consist of polymer particles. The polymer particles are composed of 85% poly-2-hydroxyethylmethacrylate (pHEMA) and 15% poly-2-hydroxypropyl methacrylate (pHPMA). The polymers pHEMA and pHPMA are both non-resorbable, non-degradable, hydrophilic crosslinked polymers that are in the ratio of 85:15 by weight and maintain a fluid content of approximately 65% by weight of the matrix. The powder aggregates (coalesces) immediately and irreversibly from polymer particles into an intact dressing. There is no chemical reaction during dressing formation. The dressing binds together physically and not chemically and remains bound together with the wound exudate through hydrophilic/hydrophobic interactions, hydrogen bonding and VanDerWaals forces. An illustration of the dressing displaying the mechanism of action is shown.



**Conclusions:**  
Powder dressing is a versatile new wound dressing material that can be applied in a variety of wound conditions. The ability to leave the dressing in place for up to 30 days is a characteristic that is desirable in applications where dressings aren't typically changed daily. Treating wounds under contact casting is one such application. Dressing worked well under contact casting in the treatment of diabetic neuropathic ulcers. A similar observation was made in use in conjunction with compression wrapping of venous stasis wounds. Although the compression wraps were changed twice weekly according to our protocol, the dressing was left in place for the week and changed at the patients weekly physician visit after debridement. In treatment of burn wounds, this dressing reduces pain and does not require frequent changes which also reduces painful dressing change episodes. It stays in place and does not require a secondary dressing. This treatment brought about healing of a third degree burn wound in a difficult patient who was undergoing active chemotherapy. Dressing worked well in these 3 applications and all three wounds healed.

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Exceptional Results

# Altrazeal™ Transforming Powder Wound Dressing: The Clinical Experience

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## Introduction

The optimal moist dressing should maintain intimate contact at a wound surface yet allow high rates of moisture vapor transfer, prevent external contamination, while extending the dressing change interval. We demonstrate a new product that meets these criteria. Altrazeal™, a Transforming Powder Wound Dressing is designed to interact, protect and seal the wound bed, ultimately resulting in optimized wound healing. When applied to a wound, the nanoflex particles hydrate upon interaction with wound exudate. Hydration causes the particles to rapidly aggregate forming a strong uniform gel material with intimate contact to irregular surfaces of the wound bed.



## Technology Description



Altrazeal™ Transforming Powder Wound Dressing is applied to wounds by pouring or sprinkling the product onto the open wound. Immediate and irreversible aggregation occurs upon contact with wound exudate. Normal saline or hypochlorous solutions may be added to provide additional moisture in wounds without heavy drainage. The hydrogel aggregate seals the wound and provides a strong but flexible dressing that has been maintained in some patients for up to 18 days. The dressing remains in intimate contact with the wound surface without a secondary dressing while allowing high moisture transpiration. The aggregate can be easily removed without harming underlying granulating tissue and then reapplied as necessary.

## Conclusion

A series of patients with a variety of wound types have been successfully managed with Altrazeal™ Transforming Powder Wound Dressing. The early clinical experience demonstrates excellent patient toleration, with superb clinical results with improved wound healing trajectories. Additional benefits include a single application with extended wear times with or without a secondary dressing.



1. Control of Vascular Proliferation and Healing in Acute Wounds with Controlled Release of VEGF from Hydrogel Nanoparticle Dressings 2008 World Biomaterials Meeting, Oral Presentation, **Strategies for Vascular Regeneration Symposium**, Amsterdam, J. St. John (presenter), B. Ponder, D. Hatef, J. Huang, S. A. Brown.
2. Hydrogel Nanoparticle Aggregates at the Wound-Dressing Interface 2007 Fall Materials Research Society Meeting. Oral Presentation, **Solids at the Biological Interface Symposium**. Boston J. St. John (presenter), L. Waller, D. Moro, D. Hatef, S. A. Brown

## Application Technique



Sprinkle Altrazeal™ on Clean Wound Base



Hydrate Altrazeal™ with Saline



Cover Aggregated Altrazeal™ with Nonadherent Dressing

## Case Study 1



7-29-2008  
Ulcer present for 6 months.



8-5-2008  
Altrazeal™ applied.



8-8-2008



8-12-2008  
Wound Healed.

## Case Study 2



7-7-2008  
Ulcer present for 6 months.



8-18-2008  
Altrazeal™ initiated.



9-15-2008



10-21-2008  
Wound Healed.