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CVderm German Center for Health Services Research in Dermatology

IVDP Institute for Health Services Research in Dermatology and Nursing

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 cm² at visit 1 to 2.7 cm² 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 cm²

		Day 0	After 4 Weeks	After 8 Weeks	After 12 Weeks
Number of patients	Valid	11	11	9	7
	Missing	0	0	2	4
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 (cm²)

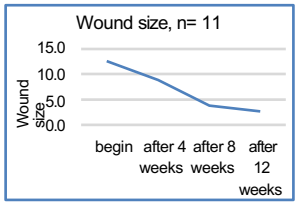
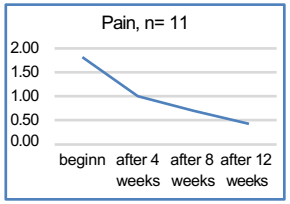


Figure 2. Pain score (VAS 0-10)



Painscore

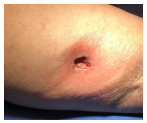
The pain score decreased from 1.8 (SD 2.1) at visit 1 to 0.4 (SD 1.1) at the last visit (Figure 2). Four of 11 patients had painless wounds.

Drop outs

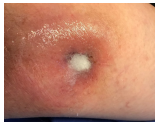
During the treatment period 3 dropouts were observed. Patient 2 discontinued treatment because lack of time for consultations. Patients 10 and 11 discontinued treatment because of the progression of the wounds in week 8.

Clinical presentation

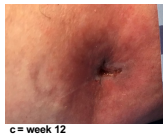
Figure 3. Patient 1 - Postoperative wound healing disorder



a = week 0



b = visit 1 after application of powder dressing

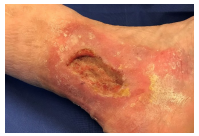


c = week 12

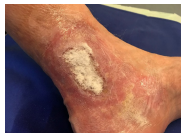
RESULTS

Clinical presentation

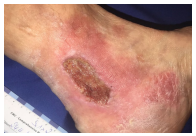
Figure 4. Patient 6 – Urticaria vasculitis



a = week 0

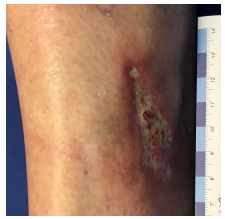


b = visit 1 after application of powder dressing

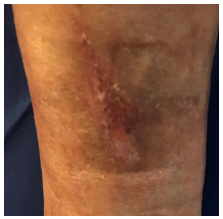


c = week 12

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

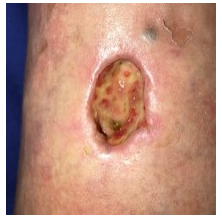


a = week 0



c = week 12

Figure 6. Patient 7 – Calcinosis cutis



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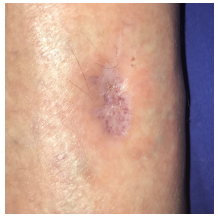

c = week 12

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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OPTIMIZING CARE OF PERI-STOMAL SKIN COMPLICATIONS WITH A NOVEL TRANSFORMING POWDER

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Symposium on Advanced Wound Care (SAWC) Spring Meeting, April 2022

BACKGROUND | RATIONALE

Patients with Crohn's Disease and stomas frequently develop peri-stomal skin complications such as wounds and Pyoderma Gangrenosum (PG) that are challenging to manage. These patients often experience excruciating pain in the wounds. Enterostomal leakages also exacerbate existing skin damage making it difficult to secure stomal appliances.

The resulting increase in the frequency of appliance and wound dressing changes aggravates pain and frustration, decreases quality of life, and increases overall costs of care. Traditional dressings used to manage such wounds often require daily dressing changes multiplying the time, materials and labor needed to provide adequate care.

The purpose of this poster is to introduce ostomy and wound care clinicians to a new technique for managing peristomal skin and wound complications using Altrazeal® Transforming Powder Dressing (TPD).

A methacrylate-based novel wound modality, TPD is available in the form of sterile white granules. Upon hydration, TPD granules aggregate over the wound bed to form a moist, oxygen permeable barrier that conforms to and seals the wound surface while allowing fluid and gaseous exchange and preventing bacterial penetration. TPD may be left on the wound for up to 4 weeks.

OBJECTIVE

The objective was to test the feasibility of TPD in simplifying care of complicated peri-stomal wounds.

METHOD

TPD's performance was tested in a challenging case involving a patient with significant systemic and peri-stomal wound complications including:

- **Crohn's disease**
- **Pyoderma Gangrenosum (PG)**
- **Moisture associated dermatitis (MAD)**
- **Chemical (irritant) dermatitis**

THE CHALLENGE: A CASE STUDY[1]

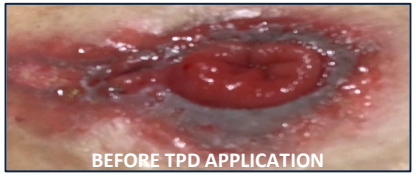
Female, 60 years old with:

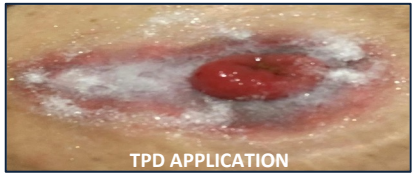
- **Crohn's Disease for 26 years with 27 hospitalizations**
- **Ileum resection, colostomy, loop colostomy revision secondary to hernia complication**
- Diagnosed with **peri-stomal PG 3** years ago
- **18%+ unintentional recent weight loss**
- **Excruciating pain (10/10 based on VAS score)** secondary to PG and irritant dermatitis requiring
  - Narcotics
  - Hospital admissions for pain management
  - Frequent appliance changes due to severe burning pain around the stoma
- **Poorly fitting ostomy appliance and irritant dermatitis** from leaking stool

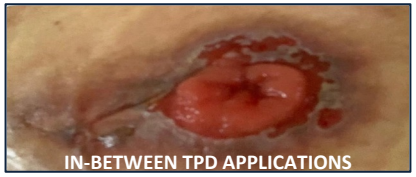
Failed Treatments: Tested **several devices and dressings.** In addition, injectable and topical steroids were tried without improvement. **Opioids** were taken every six hours to control pain.
Onerous Care Regime: Daily or **twice daily appliance changes** performed by the patient with **homecare nurse visits every other day** for ostomy evaluation and wound care.

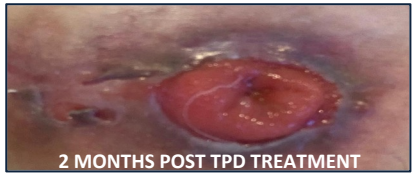
TREATMENT WITH TPD

TPD was used as a **"last resort"** after consultation with the patient's gastroenterologist to manage moisture and exudate of peristomal wounds, protect the skin with MAD and irritant dermatitis, and cover PG wounds. TPD was applied after wound cleansing and covered with the appliance. The appliance remained in place over TPD without further leakage of stool.









REFERENCES | ACKNOWLEDGEMENTS

1. Real life case study, self-reported, photographed, and provided to authors with patient permission and encouragement to share her success story with other patients with similar issues.
2. Manufactured in USA by ULURU Inc. Please see Altrazeal Instructions for Use for a complete listing of indications for use, warnings and precautions.
3. This work was supported by ULURU Inc.

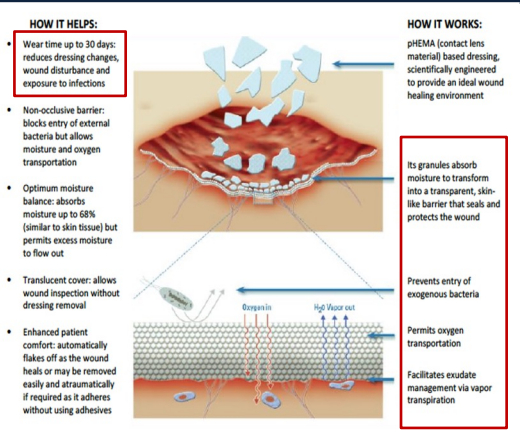
OUTCOMES | CONCLUSION

All peri-stomal skin complications, pain, and wounds were resolved while using TPD. Within 1 week, pain reduced from severe to minimal and wound quality improved markedly. Skin complications were resolved within days and the appliance was worn comfortably for 4 days continuously, without pain or leakage. All oral pain medications were discontinued.

- **Pain scores dropped from 10/10 to 0/10** within minutes of TPD application
- All **wounds healed within two months**
- Significantly **improved patient's quality of life**
- TPD application also resulted in several **cost savings:**
  - **Reduced home nursing visits**
  - **Eliminated pain medications**
  - **Reduced appliance changes, supplies and labor costs**
  - **Avoided readmission for permanent ileostomy**

Conclusion: Challenging ostomy complications can be successfully managed and resolved. Involving specialists and adoption of new technologies like TPD are key to delivering successful interventions and outcomes.

ABOUT TPD[2]



Novel Treatment of Necrotizing Fasciitis with Transforming Powder Dressing

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WOCNext 2022 Meeting, Fort Worth, TX | June 5-8, 2022

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.1 Associated mortality is 12-46% as infection can spread quickly causing severe systemic toxicity and sepsis.2 Proper management requires aggressive surgical debridement and appropriate adjuvant therapies. Early amputation of impacted tissues and maximum intensive care treatment are often required.3 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

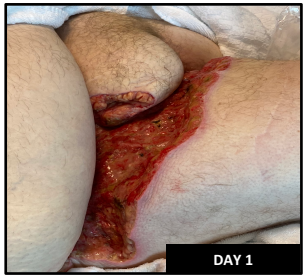
Three case studies incorporating treatment using a novel Transforming Powder Dressing (TPD) in patients with NF and other comorbidities were reviewed. In all cases, patients had extensive wounds with high pain scores, using Visual Analogue Scale (VAS), making NPWT or conventional dressing changes intolerable. 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.

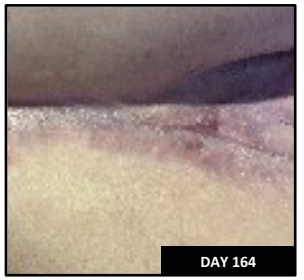
TPD is comprised primarily of biocompatible polymers (used in contact lenses). Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration. Once applied, TPD may 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:

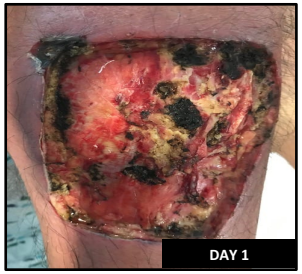
- VAS pain score reduced from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced home health visits (3x to 1x weekly)
- Reduced dressing encounters (<20 versus > 66 estimated with SOC)
- Avoided grafting, amputation & readmission

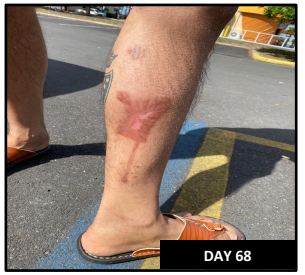




PATIENT 2: 51 y/o male with HIV
Wound Dimension: 72cm^2
Challenge: Painful daily gauze dressing changes
Treatment: Conversion to TPD
Outcomes Post-TPD Treatment:

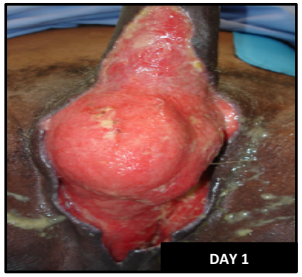
- VAS pain score reduction from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced dressing changes
- (11 vs. 60 estimated with SOC)
- and required visits from 3x to 1x weekly
- Avoided readmission for grafting

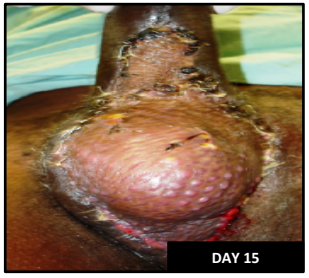




PATIENT 3: 71 y/o male with diabetes, Fournier's gangrene, penile implant malfunction4
Challenge: Painful, challenging location to conduct frequent dressing changes
Treatment: Wound was surgically debrided. Two meshed split-thickness skin grafts were applied, anchored using peripheral sutures covered 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

(1) Chen, L. L., Fasolka, B., & Treacy, C. (2020). Necrotizing fasciitis: A comprehensive review. Nursing, 50(9), 34–40. https://doi.org/10.1097/01.NURSE.0000694752.85118.62
(2) Goh, T., Goh, L. G., Ang, C. H., & Wong, C. H. (2014). Early diagnosis of necrotizing fasciitis. The British journal of surgery, 101(1), e119–e125. https://doi.org/10.1002/bjs.9371 (3) Leiblein, M., Marzi, I., Sander, A. L., Barker, J. H., Ebert, F., & Frank, J. (2018). Necrotizing fasciitis: treatment concepts and clinical results. European journal of trauma and emergency surgery: official publication of the European Trauma Society, 44(2), 279–290. https://doi.org/10.1007/s00068-017-0792-8 (4) Gleaves, J; Eldridge, K; Treatment of severe Fournier's necrotizing fasciitis involving the scrotum and volar penile skin associated with a malfunctioning penile prothesis; 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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(1) Northwell Health System, Comprehensive Wound Care Healing and Hyperbaric Center, Lake Success, NY; (2) Alexandria University, Alexandria, Egypt; (3) SPS MD, Wellesley, MA; (4) Alleghany Health Network, Pittsburg, PA; (5) ULURU Inc., Addison, TX

American Professional Wound Care Association (APWCA) Wound Week 2022

BACKGROUND

Atypical wounds, or wounds of unknown or uncommon etiologies, comprise approximately 10-20% of all chronic wounds.[1,2] 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.[4] 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.[3,4] 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)

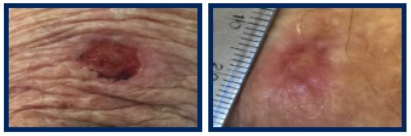
Transforming Powder Dressing (TPD) is a powder dressing comprised primarily of biocompatible polymers (same as those used in contact lenses). Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable barrier that protects the wound from contamination while helping to manage 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

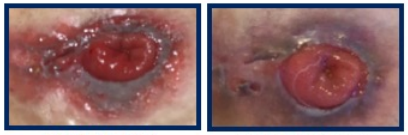


Day 0: Before Altrazeal Application | Day 17: Re-epithilialised + Smaller

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 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

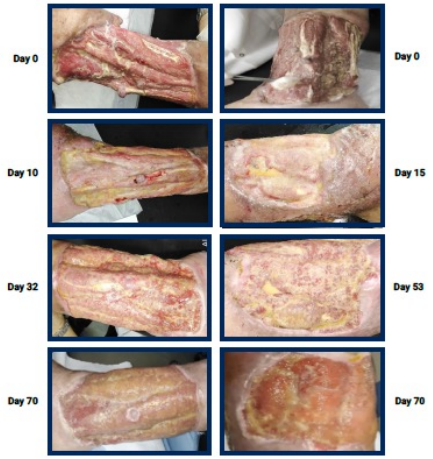


Before TPD Application | 2-months Post TPD Treatment

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.

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Acknowledgement: This poster was developed and presented in collaboration with ULURU Inc.

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Transforming Powder Wound Dressing Relieves Pain and Manages Moisture Restoring Quality of Life

Purpose:

Painful wounds limit a patient's activities and interfere with quality of life. Transforming Powder Wound Dressing relieves pain while managing wound moisture, restoring quality of life for patients. This presentation demonstrates pain reduction in two patients who had wounds that limited their activity. Transforming Powder Dressing has a unique property in that it reduces or eliminates pain when applied to the wound.

Objectives:

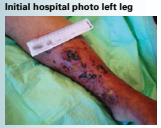
At the conclusion of this presentation the participant will be able to:
1. Realize that pain from wounds impacts on quality of life for patients with wounds.
2. Identify that nociceptive pain can be Procedural; related to dressings and their changes, Incident; related to movement with activity, and Background; related to factors related to wound etiology and local wound factors.
3. Identify a new novel Transforming Powder Dressing that has the ability to significantly impact on Procedural, Incident and Background pain and improve quality of life for wound patients.

Abstract:

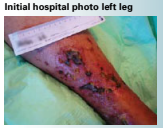
Pain has been categorized as Operative (debridement or surgically related), Procedural (related to dressing removal and application), Incident (related to movement, dressing slippage, etc.) and Background (persistent and underlying pain due to wound etiology). While Operative pain is managed by anesthetic agents and Procedural pain may be managed by both anesthetic agents and oral analgesics, Incident pain and Background pain are typically managed by oral analgesics either opioid or non-opioid. Co-analgesic medications are often added to manage Incident and Background pain. Patients tend to focus more on their Incident and Background pain as they experience this type of pain after they leave the clinic. Patients often understand that they will experience pain with surgical debridement and dressing change. Pain experienced in the clinic with debridement and dressing change can be addressed with topical anesthetics or other agents and techniques. When left on their own, Incident pain and Background pain are dealt with directly by the patient taking an oral medication. A new dressing material is available that has an exceptional unique property to reduce the pain commonly experienced by patients with wounds. Application of Transforming Powder Dressing not only reduces pain, but has a long wear time. Pain experienced with dressing change is less as the dressing lifts off easily. Oral opiates were not required in two patients with commonly painful wounds to manage pain with dressing change, during dressing wear or as Background pain treatment.

CASE 1

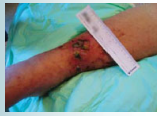
Initial hospital photo left leg



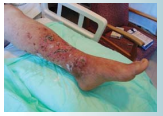
Initial hospital photo left leg



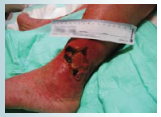
Initial hospital photo right leg



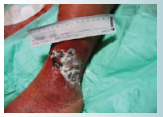
Transforming Powder Dressing applied



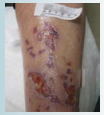
Left leg wound



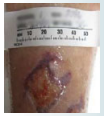
Left leg wound with powder



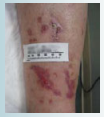
Outpatient wounds



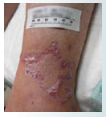
Outpatient wounds



Outpatient healed

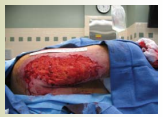


Outpatient healed



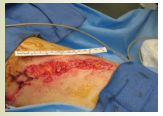
CASE 2

Arm wound

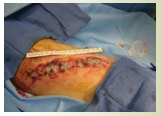


Arm wound

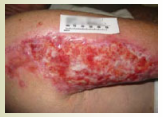
Thigh wound



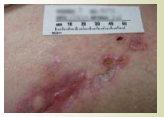
Thigh wound



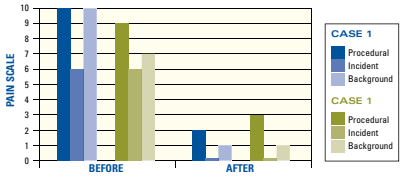
Arm wound healing



Thigh wound healed



Pain Reduction with Transforming Powder Dressing



Methods:

A new Transforming Powder Dressing became available for use in our wound clinic and hospital. Transforming Powder Dressing was applied to the wounds and pain evaluated by the patients response to standard pain scoring measures. Patients were asked to rate their pain on a scale of 1-10. They compared their pain experienced before the use of Transforming Powder Dressing and during treatment with Transforming Powder Dressing. Assessment of Procedural pain (relative to application and removal of dressing), Incident pain (related to dressing slippage) and Background pain (underlying pain) was performed during patient interviews.

Case Studies:

Case 1: A 54 year old female undergoing chemotherapy for metastatic ovarian cancer had suffered with bilateral lower extremity edema from obstructed lymphatics. She had suffered significant edema for 5 months; initially developed blistering was hospitalized and had multiple deep marginated ulcerations of both lower extremities. The patient suffered pain from daily dressing changes, pain from movement of the dressings and Background Pain from her wounds. With a pain level rating of 10, she couldn't stand for the initial evaluation. Transforming Powder dressing was applied and the patient noted a marked decrease in background pain. She also reported a significant decrease in pain with dressing changes and did not experience pain from dressing movement. Prior to discharge to outpatient care, the patient was engaged in physical therapy and active.

Case 2: A 57 year old male undergoing chemotherapy and radiation therapy for metastatic intracranial melanoma fell against a steam radiator and suffered 3rd degree burn wounds to his right arm and right thigh. He had been treated as an outpatient with daily Silvadene dressing changes. Concern for failure of skin grafting during chemotherapy, the patient underwent tangential excision of dead burn eschar and was treated with Transforming Powder Dressing. He was followed weekly in the wound clinic and had his dressing reapplied at each visit.

Results:

When applied to the wounds both patients experienced a decrease in Procedural pain, Incident pain, and Background pain as reported to nursing staff on pain assessment scoring (Figure 1). As an inpatient, Patient 1 required IV narcotics to control her pain. With application of Transforming Powder Dressing, she was weaned to oral narcotics and subsequently required no pain medicine on discharge to outpatient care. She had a family member reapply the powder as needed and continued her care as an outpatient in the wound clinic. Patient 2 was using oral narcotics every 6 hours as allowed, after surgery but transitioned to non-narcotic analgesics when his wounds were covered with Transforming Powder Dressing. He reported some pain with dressing changes but did not require narcotic pain management for dressing changes. His Incident pain was nonexistent as the Transformed Powder stayed in place and he noted little Background pain throughout the week.

Conclusion:

Both patients experienced a reduction in their pain level when the powder dressing was applied to their wounds. The intimate contact with the wound surface and the ability to manage moisture may be an important aspect of this effect. The moisture content of the dressing material is very close to that of normal skin. Optimizing the wound environment and sealing the wound may also contribute to this observed effect. The wounds of patient 1 healed while she was managed as an outpatient. Her activity level was not limited by her wounds. She has become productive and active. Patient 2 succumbed to his disease but benefited from his dressing in that he did not suffer from the pain of daily dressing changes or the side effects of narcotic medications. His dressings were changed weekly or biweekly rather than daily which greatly reduced the episodes of pain may have experienced.

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

2010 SAWC Meeting
Orlando, FL

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Darlene Saucier APRN, MSN, BC-FNP, CWCN

Connecticut Clinical Nursing Associates, LC
Bristol Hospital Wound, Ostomy, Lymphedema Center
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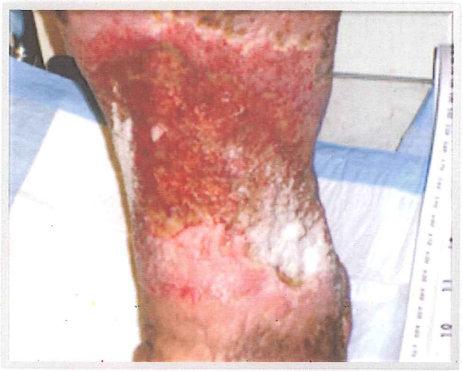
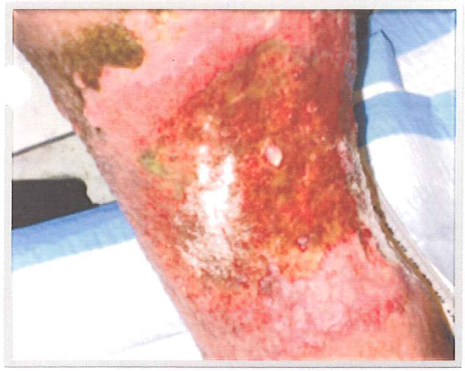
Clinical Problem: Wound pain is a significant issue for many patients with chronic wounds. 80% of patients with venous leg ulcers (VLUs) experience pain.[1] Its sequelae include fatigue, alterations in interpersonal relationships, sleep disturbances, and depression[2, 3].

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.



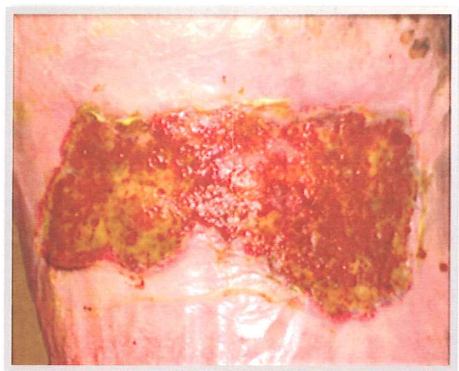
Initial Application of Transforming Powder Dressing



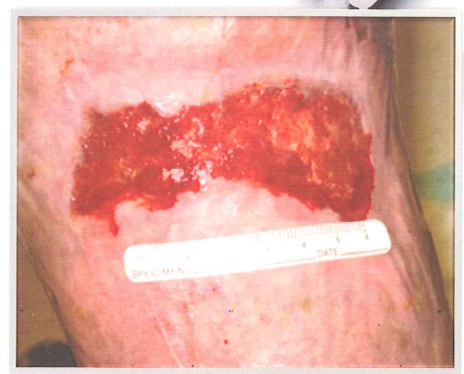
Initial Application of Transforming Powder Dressing

Presented Case: 62 year old male developed a right lower leg ulceration after post-phlebitic 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.



5 Months on Treatment Regimen of TPD with Compression



15 Months on Treatment Regimen

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 I 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.

IR-042

A Randomized Clinical Study Comparing a Novel Transforming Powder Dressing to a Carboxymethylcellulose-Silver Dressing in Skin Graft Donor Sites

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Agnes Burris, RN, Research Coordinator, Department of Surgery, University of Texas Southwestern Medical School

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Christiane M. Baud, PhD, Director Clinical Research, ULURU, Inc.

Introduction

Donor site wounds are a necessary and painful byproduct of graft procedures used to regenerate large sections of damaged skin. The split thickness skin graft (STSG) is typically harvested from large sections of a patient's own skin using a microtome and has a thickness of 1-2 mm depending on the blade and surgical technique. The resulting donor site is usually painful and irritating to the patient but will typically heal in 10-30 days with moist wound healing techniques. The acute nature of the donor site makes it a good choice of wound for a pilot study to evaluate a dressing and compare pain and discomfort associated with a wound and treatment.

We report on the results of a single center, randomized, prospective clinical study comparing a novel Powder Wound Dressing (PWD)* to a carboxymethylcellulose dressing containing silver (CMC-Ag) when applied to patients having two split thickness skin graft donor sites. Results include an analysis of time to healing, pain, and patient comfort.

Objectives

- To evaluate the time-to-wound healing in skin graft donor sites with a new treatment PWD compared to standard of care treatment CMC-Ag
- To evaluate pain level, incidence of infection, and patient's satisfaction comparing the PWD to CMC-Ag.
- To compare tolerance of the two dressings.

Methodology

This study was designed as a single-center, prospective, randomized study in which each patient served as his/her own control. Each patient was to have at least two split-thickness donor sites identified prospectively as A or B. One skin donor site was dressed with PWD, the other with CMC-Ag in a randomized fashion. This study was performed in compliance with Good Clinical Practices including the archiving of essential documents. Prior to study initiation, the protocol was reviewed and approved by the Institutional Review Board (IRB) of UTSW Medical Center and the IRB of Parkland Health and Hospital System, Dallas, Texas.

Number of subjects (planned and analyzed)

40 patients were planned to be enrolled at one clinical trial site in the U.S. Enrollment into the study was closed after 20 patients were enrolled and 19 were treated with the study devices.

Major criteria for inclusion

1. Male or female patient between the ages of 3 and 85 (In order to maintain a broad representation of ages, no more than 50% of the patients enrolled in the study were to be between the ages of 3 and 16, inclusive.)
2. Patient in general good health
3. Patient with two independent skin donor sites of approximately the same dimensions.

Major Criteria for Exclusion

1. Male or female patient less than 3 years of age or more than 85 years of age
2. Acutely infected wounds
3. Wounds with surrounding cellulitis

Efficacy Assessments

Efficacy Analyses

Time to Healing

Mean days to healing were estimated using survival analysis methods. Matched-pairs t-test was used.

Pain Scores

Pain scores were averaged for each patient and each donor site side as follows: Day 2 to Day 5, Day 6 to Day 10, Day 11 to Day 15. Average pain scores at each of these 3 time points were compared between side using a mixed model repeated measures ANOVA analysis that accounted for the treatments being observed on the same patient.

Safety Assessments

Adverse Events

Throughout the course of the study, all adverse events were monitored and reported on an Adverse Event Case Report Form. When adverse events occurred, the main concern was the safety of the study subjects.

Procedure:

The NPD is a powder dressing that transforms from a powder into a moist wound dressing. This PWD is designed to provide high moisture vapor transpiration and does not typically require a secondary dressing. The CMC-Ag is a woven material containing 1.2% ionic silver. This dressing was applied to the surface of the wounds and anchored into place using staples.

The Investigator first identified the skin donor sites (A and B) for each patient and took baseline digital images and measurements immediately following surgery (Day 1). The investigator then applied the dressings provided by the Sponsor and labeled as A or B by the Sponsor in a random fashion. Typical meticulous wound care and adequate analgesic medical coverage were provided for the duration of the study. Patients were monitored daily as part of standard procedure while they were in the in-patient setting. If and when patients moved to the out-patient setting, they were to be monitored every-other-day at the study center. At each visit, the investigator determined whether each skin graft donor site had healed per standard care guidelines (i.e. >95% re-epithelization). Subjects were questioned about pain level, and adverse events were monitored. The last study visit was on Day 24 or on the day when both wounds had been assessed as "healed", whichever came first. If one or both of the graft donor sites were not healed on Day 24, a Follow-Up Visit (25-30 days post-surgery) was to be scheduled at the investigator's discretion. The medical staff recorded all dressing changes during the course of the study.

Results

Efficacy evaluation

Data Sets Analyzed

All 19 Subjects enrolled were included in the efficacy analysis.

Demographic and Other Baseline Characteristics

Demographic Characteristics

Table 01 summarizes Subject demographic information. Age ranged from 5 to 76 years and averaged 36.6. Only 4 subjects were female (21%) and 15 were male (79%).

Table 01 – Summary of Demographic Characteristics

Number of Subjects:	19 (100%)
Age (years)	
Mean (SD)	36.6 (16.7)
Median (Min–Max)	36.0 (5, 76)
Gender	
Male	15 (78.9%)
Female	4 (21.1%)

Source: Section 16.2.1

Donor Site Characteristics

Table 02 summarizes the donor sites characteristics. The mean (SD) size was 264 cm² (281.9) for PWD site and 229 (157.3) for CMC-Ag sites.

Table 02 – Summary of Donor Site Characteristics

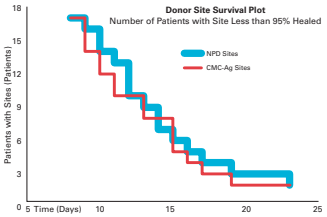
	PWD	CMC-Ag
Number of Subjects	19	19
Size (cm²)		
Mean (SD)	264 (281.9)	229 (157.3)
Median (Min-Max)	154 (36, 1008)	197 (64, 759)

Source: Section 16.2.3

Efficacy Results

Twenty Patients (15 male, 4 female) were enrolled into the study and 19 received study devices. Twelve subjects (63%) completed the study as planned, while 7 subjects (37%) prematurely discontinued due to adverse event (1 subject), subject's request (1 subject), protocol violation/non compliance (1 subject), lost to follow-up (3 subjects) and other reason (1 subject who became confused).

Time to Healing



Time to Healing

There was no significant difference in time-to-healing between the two treatment sides.

Table 03 – Mean Time to Healing (based on patients with healing day < 24 days)

	PWD	CMC-Ag	Difference (PWD minus CMC-Ag)	p-value a
N	17	17	17	
Means Estimate	14.2	13.16	1.1	0.16
(Standard Error)	(0.81)	(0.74)	(0.77)	
Minimum	10	9	-1	
Maximum	23	20	3	
95% Confidence Interval	12.5, 15.9	11.5, 14.6	-0.5, 2.8	

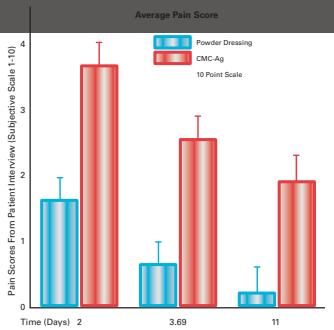
a p-value from matched-pair t-test.

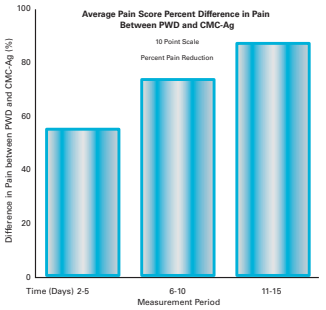
Pain Scores

Pain Scores

Pain scores showed significant differences at all time periods between the two dressings, with PWD eliciting lower pain scores than CMC-Ag. Between day 2 and day 5, the average pain score recorded was 3.69 on the CMC-Ag side versus 1.64 on the PWD side (p<0.0001). Similarly on days 6 to 10, the average pain score was 2.57 on the CMC-Ag side compared with 0.67 on the PWD side (p<0.0001).

Average Pain Score





Subject's Satisfaction Survey

Table 08 summarizes responses to the 3 subject satisfaction survey questions at the final visit. Questions were based on a 10-point scale with 1 being the worst score and 10 being the best score (except for pain).

When asked about comfort of the dressing at the edges, study subjects found PWD to be more comfortable than CMC-Ag (average score of 8.6 versus 5.9; p<0.001). Likewise, study subjects reported experiencing less pain when the dressing came in contact with clothes or bedding at the PWD side compared with the CMC-Ag side (average pain score of 2.1 versus 5.1; p<0.001).

There was no significant difference between the two dressings regarding how well the dressing remain in place after application as both dressings performed well on that measure (average score of 9.5 for PWD versus 8.6 for CMC-Ag).

Table 04 – Summary of Subject Satisfaction Survey Results

FINAL VISIT		PWD	CMC-Ag	p-value a
Number of Subjects with Responses:		17	17	
Q1 – On a scale of 0 to 10, with 0 being not at all and 10 being very secure, did the dressing remain in place after application?	Mean (SD)	9.5 (0.94)	8.6 (1.91)	0.06
	Median	10	10	
	(Min-Max)	7 to 10	5 to 10	
Q2 – On a scale of 0 to 10, with 0 being very uncomfortable and 10 being very comfortable, did you find the edges of the dressing to be comfortable?	Mean (SD)	8.6 (2.27)	5.9 (1.87)	<0.001
	Median	10	6	
	(Min-Max)	2 to 10	2 to 8	
Q3 – On a scale of 0 to 10, with 0 being no pain and 10 being the worse pain you have ever experienced, did you notice significant pain when the dressing came in contact with your clothing or bedding?	Mean (SD)	2.1 (2.5)	5.1 (2.22)	<0.001
	Median	1	5	
	(Min-Max)	0 to 10	2 to 9	

a p-value from matched-pair t-test

Discussion

Protocol Deviations

Timely Follow-up After Release of Subjects from In-patient Hospital Setting

[One main deviation from the protocol was that timely follow-up proved to be difficult after subjects were released from the hospital and asked to return for regular clinical check-up. A number of patients did not have twice-weekly follow-up. This impacted the precision with which the time to healing could be determined in this study. Both donor sites were impacted in the same manner by these protocol deviations.]

Randomization Deviation

It was noted that for 2 subjects (Subjects 01 and 08), the A versus B randomization sequence of the 2 donor sites was reversed. Per the randomization list, in both cases, PWD should have been applied to donor site B, but was applied to donor site A instead.

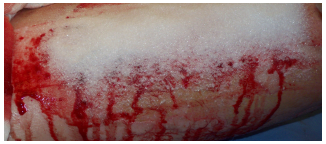
The clinical study personnel instituted a "second check" procedure to confirm site A and site B and which packet was to be applied to each. This deviation was not expected to impact either the safety of the subjects, or the validity of the data collected from these 2 subjects.

Donor Sites as Wound Healing Model

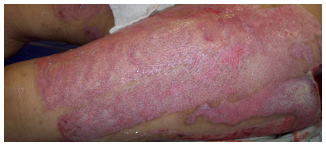
The use of donor sites as wounds in a healing model provides for a reproducible wound but also makes wound healing endpoint comparisons difficult for comparative treatments since the wound is partial thickness and acute. Thus the result of equivalent healing timepoints was not unexpected.

One major complaint among patients with donor sites is pain and comfort management, therefore, a dressing which reduces pain and increases patient comfort is an important finding for any donor site wound healing study.

An important extension of this study would be to determine if similar pain and comfort findings extend to wounds of a more chronic nature.



Initial Powder Dressing Application



Donor Site at Healing

Conclusions

In this clinical study it was demonstrated that for acute donor sites, a comparison of time to healing provides no statistically significant difference in the rate or percentage of donor sites closed between day 0 and day 23 (p=0.16) when covered by the NPD or the CMC-Ag.

For the mean pain scores of donor sites covered with the two dressings, the NPD showed a statistically significant difference of less pain at three different time periods (p<0.0001 at 2-5 days, p,0.001 at 6-10 days, and p=0.004 at 11-15 days).

For patient comfort, there was a statistically significant difference in comfort with the NPD having greater comfort (scale of 1-10 with 10 being more comfortable) (p<0.001).

Patients with donor sites can benefit in the areas of pain management and comfort if the NPD is used to treat the graft site over the CMC-Ag dressing.

References

1) Wiechula R, 2001 Post Harvest Management of Split Thickness Skin Graft Donor Sites. A Systematic Review No. 13, The Joanna Briggs Institute, Adelaide.
2) Fitzgerald RH, Bharara M, Mills JL, Armstrong DG. Use of a Nanoflex powder dressing for wound management following debridement for necrotising fasciitis in the diabetic foot. Int Wound J. 2009;6(2):133-139.

Acknowledgements

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*Altrazeal™ Transforming Powder Dressing