

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

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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 peristomal wound complications including:

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

THE CHALLENGE: A CASE STUDY¹

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
 - o 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

- 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.
- 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.

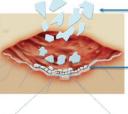
- Pain scores dropped from 10/10 to 0/10 within minutes of TPD application
- All wounds healed within two months
- Significantly improved patient's quality of life
- TPD application also resulted in several cost savings:
 - Reduced home nursing visits
 - Eliminated pain medications
 - Reduced appliance 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 TPD²

HOW IT HELPS:

- Wear time up to 30 days: reduces dressing changes, wound disturbance and exposure to infections
- Non-occlusive barrier: blocks entry of externa bacteria but allows moisture and oxygen transportation
- Optimum moisture balance: absorbs moisture up to 68% (similar to skin tissue) but permits excess moisture to flow out
- Translucent cover: allows wound inspection withou dressing removal
 Enhanced patient
- comfort: automatically flakes off as the wound heals or may be removed easily and atraumatically if required as it adheres without using adhesives





Prevents entry of exogenous bacteria

HOW IT WORKS

pHEMA (contact lens material) based dressin

scientifically engineere

Its granules absorb

protects the wound

into a transparent, skin

like barrier that seals and

to provide an ideal woun

Permits oxygen transportation

Facilitates exudate management via vapor transpiration



Colorectal Abdominal Wounds: Challenges and Innovative Solutions Using Transforming Powder Dressing

WOCNext 2023 Meeting | June 3 – 7 Las Vegas, NV Tammy Lichtman, RN, BSN, CWON; Ron Sotomayor, BA, RN, BSN, CWOCN;
Theresa Pineda, RN, BSN, CWOCN; Rosalyn Barnabee, RN, BSN, WOCN; Daniel Galante, DO, FACS, FASCRS
AdventHealth System; Orlando, FL

CLINICAL PROBLEM

Acute abdominal wounds with enteroatmospheric fistulas (EAF) have burdened healthcare systems with costly and difficult to manage complications associated with colorectal surgeries. Challenges with standard of care (SOC) treatments include pain, bleeding, psychosocial consequences, and time intensive nursing care. Proper management is critical to improving patient recovery and healing.¹

METHODS AND MATERIALS

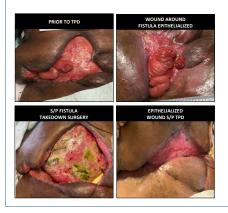
We evaluated three cases where patients developed complications while being treated with SOC therapies including skin barriers, dressings, NPWT and/or large pouching systems,² consuming considerable time and resources (usually 3x/week).

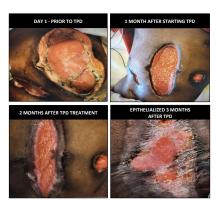
A novel extended wear transforming powder dressing (TPD*), comprised of polymers similar to those used in contact lenses, was sprinkled over the damaged skin areas, transformed with sterile saline. TPD was evaluated to reduce wound management resources and protect wounds from exposure to contamination.

RESULTS

38 y/o female s/p motor vehicle accident c/b high output EAF surrounded by large open abdominal wound.

- Initial Application: Large wound manager applied 2x/week was unable to isolate the fistula, leaving the wound untreated.
- TPD Treatment: After transitioning to TPD, the patient experienced reduced pain, expedited healing, a manageable pouching system, and returned to ADLs.
- **20 y/o female** with ulcerative colitis/Crohn's, ileostomy takedown/stoma re-sited, c/b dehisced abdominal wall.
- Initial Application: Abdominal wound vacuum assisted closure was c/b EAF and associated pain/anxiety, delaying hospital discharge.
- TPD Application: NPWT was replaced with TPD and patient was discharged to home with reduced dressing changes (weekly) and less pain/anxiety.
- **58 y/o female** with perforated diverticulitis, s/p sigmoid colectomy required open abdominal wound vacuum assisted closure, c/b pain followed by rectal stump blowout.
- Initial Application: Severe pain with NPWT.
- TPD Application: Pain significantly reduced after transitioning to TPD; dressing changes decreased to 1x/week. VAS scores went from 10/10 to 0/10 post TPD application.









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CONCLUSION

Treatment with TPD facilitated wound healing, fistula isolation, pain reduction, and overall decrease in nursing time and supply costs. Based on the outcomes, we conclude that TPD provides a viable alternative for the treatment of colo-rectal abdominal wounds.

*Altrazeal" Transforming Powder Dressing



Using Transforming Powder Dressing to Heal Chronic Pilonidal Cyst Wounds



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BACKGROUND

A pilonidal cyst is an inflammatory process in the skin and subcutaneous tissue in the sacrococcygeal region containing hair and debris.¹ These wounds are known to be very painful and may become infected. Treatment is typically surgical and involves excising the cyst and draining the pocket of fluid and debris.² Due to the location of the wounds, healing can be challenging and dressing changes can be time-consuming and painful. Healing of these types of wounds can take from months to years and necessitate multiple trips to clinicians for dressing changes or surgical interventions.³

PAST MANAGEMENT

In addition to surgical incision and drainage, standard of care (SOC) treatment of these wounds includes decreasing strenuous activities, increasing protein in the diet and packing the wound bed multiple times a week or utilizing negative pressure wound therapy (NPWT). Prior treatment methods utilized in the cases presented included NPWT and packing with packing strips, hydrofibers, antimicrobial gauze, or hydrogels.

CURRENT CLINICAL APPROACH

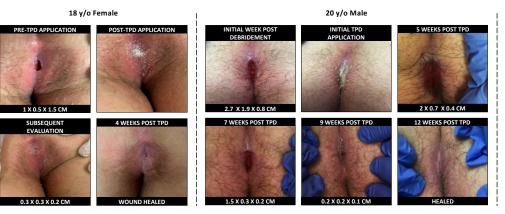
Three young adults (18 y/o female, 17 y/o female, and 20 y/o male) had received multiple SOC treatments (over 3.5 months to 2 years) with minimal improvement. Transforming powder dressing (TPD*) was initiated and applied weekly to the wounds with a non-adherent cover dressing.

MATERIAL

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

PATIENT OUTCOMES

All wounds healed upon conversion to TPD without any adverse events. In two of the patients, the wounds had been present for two years despite SOC treatment. The 18 y/o female healed after four weeks (2 TPD applications), 17 y/o female healed after one week (1 TPD application) and the 20 y/o male healed after twelve weeks.



17 y/o Female

- Nonhealing pilonidal cyst for 15 weeks refractory to SOC wound care with daily packing
- Originally, wound volume measured 1 x 1 x 2.5 cm.
 After 15 weeks, when converted from SOC to TPD, wound measured 0.5 x 0.5 x 1.5 cm
- Wound was closed in one week with a single TPD application
- No re-opening on follow up and no complications reported

CONCLUSION

TPD offers a unique alternative to current SOC for treatment of pilonidal cysts. For the three patients presented, TPD filled and protected cavities in challenging locations, creating an environment conducive to healing, and accelerated wound closure while reducing the frequency of required dressing changes and enhancing patient comfort.

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Acknowledgements: This poster was created in collaboration with Altrazeal Life Sciences Inc. For application instructions and risks of this device please refer to Altrazeal® Instructions for Use. | EDU-0069, REV 01



Quality Improvement Project: Management of Complex Painful Postoperative Wounds

Jeffrey Chiu, MD; Ron Sotomayor, RN, BA, CWOCN; Reagan Taylor, PA-C; Tammy Jensen Lichtman, RN, BSN, CWON; Rosalyn Barnabee, BSN, RN, WOC; Tracy Decker, DNP, RN; Daniel Farinas Lugo, MD; Marcus Darrabie, MD, FACS; AdventHealth System, Orlando, FL SAWC Fall 2022, Las Vegas, NV | October 13-16, 2022

INTRODUCTION

Management of painful postoperative wounds is difficult and expensive 1:

- Medicare estimated costs for treatment of acute and chronic wounds range from \$28 to \$97 billion annually with surgical wounds contributing the largest amount²
- Over 82% of surgical patients report severe wound related pain
- Pain affects length of stay (LOS) and patient satisfaction scores^{3,4}
- Pain can persist for weeks after discharge from the hospital, lowering a patient's quality of life⁵ (QOL)
- Opioids, often prescribed for pain management, are associated with negative side effects and caused over 100,000 deaths in 2021^{6,7}
- Standard of care wound therapies, including NPWT and conventional dressings, require frequent dressing changes that can be painful and increase the need for opioids and risk of dependency

There is a critical need for a multidisciplinary collaboration and quality initiatives to identify alternate modalities for management of painful acute and chronic postoperative wounds.⁶

QIP OVERVIEW & METHODOLOGY

A quality improvement project (QIP) was initiated to test the potential of a novel wound treatment technology, a transforming powder dressing (TPD*), to improve the current standard of care (SOC) practices for the management of painful postoperative wounds. TPD is comprised primarily of biocompatible polymers. Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping manage excess exudate through vapor transpiration. Once applied, TPD may be left on for up to 30 days. More powder may be added as needed without requiring primary dressing changes. Simple secondary dressings may be used in areas of high exudation or friction. TPD dries and flakes off as the wound heals.

Hypothesis: Utilization of TPD, an extended-wear dressing, will reduce change frequency, pain scores, narcotics, and nursing time.

Method: Prospective evaluation. Pain was measured using Visual Analog Scale (VAS) within 15 minutes before and after TPD application. Prescribed medication records were reviewed at each assessment.

Sample: 12 adults with surgical wounds and pain scores > 5 (VAS 0-10)

RESULTS

Sample Population (n=12):

- Gender: Male: n= 6; Female: n= 6
- Age: 21 95 years (mean: 49.1)
- · Wound Etiologies: Diverse debrided or excised wounds necrotizing fasciitis, hidradenitis suppurativa, burn, pilonidal cyst, peri-stomal, pressur injury, abscess, hematoma
- Wound Size: 7.5 1,350 cm² (mean= 272 cm²)
- Pain Scores: Average patient reported pain scores prior to TPD application: 8/10 (range: 6-10)
- · SOC Dressings: NPWT or conventional moist dressings
- · Frequency of SOC dressing changes: 3 or more times per week

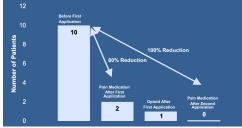
QIP SAMPLE POPULATION

| Subject | Wound Type / Surgical Procedure | Sex | Age | Complication and Comorbidities | Starting Wound Area (cm²) | Starting Pain Score | Pain Score Post Initial Application | % Pain Reduction |
|---------|--|------------|------|--|---------------------------------|------------------------|---|---------------------|
| 1 | Pilonidal cyst (recurrent) excision (3rd) | М | 21 | Obese, non-healing wound, poor hygiene and compliance | 15 | 8 | 4 | 50% |
| 2 | Hidradenitis suppurativa excision (axilla) | F | 25 | Hidradenitis suppurativa, history of non-healing wounds | 72 | 10 | 3 | 70% |
| 3 | Necrotizing infection excision (arm) | F | 43 | Infection, necrotizing fasciitis | 16 | 7 | 0 | 100% |
| 4 | Necrotizing fasciitis I&D/debridement | М | 51 | HIV, progressive necrotizing fasciitis | 72 | 10 | 0 | 100% |
| 5 | Excision/debridement RLE through muscle | М | 40 | DVT, lymphedema, failed treatment with STSG and NPWT | 1350 | 9 | 3 | 67% |
| 6 | Burn debridement (thigh) | М | 72 | CABG x 3, MI, cancer, DM | 765 | 9 | 2 | 78% |
| 7 | Surgical biopsy (ear, atypical wound) | F | 52 | History of slow/non-healing wounds, stroke/paralysis | 7.5 | 6 | 0 | 100% |
| 8 | Stage 3 pressure injury debridement | F | | DM, dementia, kidney dx, history of slow/non-healing wounds, waldenstrom macroglobulinemia | 21 | 8 | 2 | 75% |
| 9 | Necrotizing fasciitis excision (right thigh) | М | | Infection, HTN, obesity, significant pain with NPWT taking morphine | 900 | 7 | 3 | 57% |
| 10 | Peristomal irritation post ileostomy | F | 30 | Hirschsprung, ileostomy, renal failure | 12 | 8 | 0 | 100% |
| 11 | Abscess excision (right buttock) | М | 45 | DM, obesity, HTN, multiple abscesses | 9 | 8 | 0 | 100% |
| 12 | Hematoma post debridement (LLE) | F | | Impaired mobility, HTN, AF, bipolar, CKD, long COVID, OSA, Hepatic stenosis | 25 | 8 | 0 | 100% |
| | AVERAGE OR TOTAL COUNT | 6 M 6 F | 49.1 | | 272.0 | 8 | 1 | 83% |

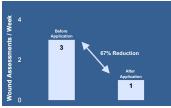
PAIN SCORES



PAIN MEDICATION



WOUND ASSESSMENTS



POST TREATMENT WITH TPD:

- Reduction of Average VAS Pain Score: 83% (range 50% 100%)
 - o All patients reported pain reduction within few minutes of first application
 - o 6/12 patients reported 100% pain reduction after TPD treatment
- Reduction of Pain Medication: 80% after first TPD application
 - o All pain medications were discontinued by the second TPD dressing application
- Frequency of Wound Care Assessments or Dressing Changes: Reduced from 3 or more / week to 1 / week
- · Complications: All wounds healed without any complications. No adverse events were reported

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CONCLUSION

Pain can adversely impact healthcare costs, clinical outcomes and LOS as well as patient satisfaction/HCAHPS scores and QOL^{1,3,4,5}. The QIP data suggests that TPD presents a safe and effective solution for management of painful postoperative wounds. The following observations were recorded for all patients:

- Reduction in patient-reported pain scores and prescribed pain medications
- Decrease in wound assessments and nursing time for dressing changes
- · Achievement of full wound closure with no wound related complications

*Altrazea® Transforming Powder Dressing (USA)

Mary Gloeckner: RN, MS, CWON, Ostomy/Wound CNS Gregory Bohn, MD FACS Medical Director Trinity Medical Center Bettendorf, Iowa

Peristomal Skin complications treated with **Transforming Powder Dressing: A new Technology** improves standard approaches to management



The purpose of this poster is to introduce WOCN's and other providers to the value of a new technique to manage peristomal skin and periwound complications using a new Transforming Powder dressing.

- Objectives:

 At the conclusion of this presentation the participant will be able to:

 1. Identify Peristomal skin complications and the need for new
 management bechiques.

 2. Introduce the concept of peristomal skin management with
 Transforming Powder dressing.

 3. Revisit novel approaches to stoma management with new
 innovative wound materials.

Abstract:

ADSTRACT:
Surgical patients with stomas and abdominal fistulae are some of the most challenging patients to manage when the peristomal and periwound skin is damaged. The weeping moisture from the damaged skin affects the ability to keep an appliance in place to control enteral skin affects the ability to keep an appliance in place to control enteral discharge. Enterstormal soliage will exceeptate the skin condition making management even more difficult. The end result is a painful storal or fistual sist that patients find nearly impossible to manage on their own and require frequent re-application of the appliance increasing their cost of supplies. A new Transforming Powder Dressing material has become available that can help protect and heal damaged existence to discuss the supplies of the protect peristomal and wound skin while managing moisture successfully.

Moisture management becomes critical to success with problematic appliance placement, Creativity with pouching and a new Transforming Powder Dressing has helped natients with peristomal skin wounding Fowder Dressing has neiped patients with perstomal skin wounding and mucocutaneous separation. Transforming powder dressing not only allowed them to heal, but helps extend wear time of the applianc Two illustrative cases are presented to demonstrate this innovative approach to stomal care.

Methods and Materials:

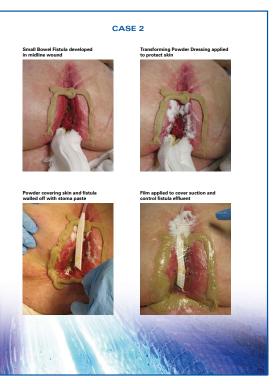
Transforming Powder dressing was applied to a patients stoma complicated by mucocutaneous separation and peristomal skin wounding. The appliance was applied over the powder dressing and

Transforming powder dressing was used to protect the skin damaged by enteric content. With skin protected by Transforming Powder Dressing, the fistula was controlled with suction and film.

Used under a stomal appliance, the mucosal separation healed as did Used under a stomal appliance, the mucosal separation healed as did the skin wounding. The stoma appliance was placed over the powder dressing and worked well to protect the skin from further damage from leakage. The mucosal skin separation was filled with Transforming Powder dressing and sealed with the stomal appliance to avoid leakage. Appliance wear time was extended which contributed to healing the peristomal skin.

Transforming powder protected the skin in a case of difficult to control high output fistule and allowed the patent to be successfully managed. Without the powder dressing, the patient had pain and irritation from the skin exposure from enteric contents. The Transforming Powder Dressing worked well to protect the skin and conformed to the shape of the wound. These results are illustrated in the Case Studies.

CASE 1 Fransforming Powder Dressing applied Peristomal Skin and mucocutaneous



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SAWC Fall 2022 Meeting | Las Vegas, NV | October 13-16, 2022 **BACKGROUND**

Despite advances in surgical care, enteroatmospheric fistulas (EAFs) present a highly challenging and devastating problem in wound care therapy.1 Proper management of EAFs is critical to improving recovery and fistula healing and requires rapid intervention to prevent sepsis.2 EAF standard of care (SOC) is variable and may include dressings, pouches, floating stoma, and negative pressure wound therapy (NPWT).3

Proper wound care management is vital to ensure wound healing and prevent sepsis. Therefore, alternative treatments to address the following criteria must he considered:

- Promote wound healing
- Isolate the fistula to permit proper treatment
- Improve patient quality of life (QoL)
- · Reduce overall healthcare costs

CASE OVERVIEW

A 37 y/o female presented with extensive trauma to the chest and abdomen following a motor vehicle accident (Day 1). Treatment included wound vac placement on the patient's abdomen. Computed tomography revealed a colocutaneous fistula extending from the right colon into the right pelvic wall. Postoperative procedures involved the right colon, left lower quadrant colostomy and an ileal loop extending into the right pelvic wall, likely representing ileostomy. Hospital course was complicated by a high output EAF extending from the right colon into the right pelvic wall, a left sided abdominal wound measuring 13cm x 11cm x 3.5cm, and three stomatized abdominal fistulae on the right. As the wound was refractory to SOC treatment. NPWT treatment was discontinued (Day 11). Treatment was switched to an expensive specialty pouch (\$900-\$1,200/each). Due to high output effluent, the pouch required two drainage bags, suction set up and 2 replacements per week with 2 staff members dedicating two-hours per replacement. The patient was discharged home with instructions to return to the Ostomy Clinic for appliance replacement 1-2x per week. She was subsequently readmitted to the hospital with a fever and indications of sepsis.

METHODOLOGY & MATERIALS

Upon readmission, and because the wound was refractory to SOC treatment, wound treatment was converted to a Transforming Powder Dressing (TPD*), a novel dressing with which our team had successful experiences in complex wounds.

TPD is comprised primarily of biocompatible polymers. 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 were used in areas of high exudation or friction. The TPD remained adhered in the wound bed promoting proliferation and flaked off as the wound healed.

The patient was discharged home and returned to the clinic three weeks later. The wound had decreased in size (9cm x 8cm x 1.2cm), and the stomatized fistulae were able to be isolated with a smaller, less costly patient management appliance. Within 10-days of initial TPD treatment, the patient was able to resume daily living activities.

Novel Treatment of an Enteroatmospheric Fistula with Transforming Powder Dressing

Ron Sotomayor, RN, BA, CWOCN; AdventHealth Medical Group; Orlando, FL

RESULTS

SOC Treatment Course for First 11 Weeks (Prior to TPD Application):

- Wound measurement on admission: 13cm x 11cm x 3.5cm
- NPWT: Utilized post-admission to day 11
- Specialty Pouches: Due to high output effluent, 2 drainage bags, suction set up, replacement twice/week, and 2 staff members for 2 hours were required for each change
- · Wound was refractory to SOC treatment









Treatment Course Post TPD Application:

- Wound significantly decreased in size after 3 weeks of TPD treatment; 9cm x 8cm x 1.2cm
- · Fistulae were isolated with less costly appliance
- · Frequency of dressing changes reduced compared to SOC
- Total labor resource allocation requirements reduced compared to SOC
- · Patient resumed activities of daily living within 10 days of initial TPD treatment









CONCLUSION

In this case study, conversion of wound treatment from SOC to TPD resulted in:

- · Facilitation of wound healing
- · Isolation of the fistula
- Formation of a barrier protecting the exceriated skin from fluids and thus promoting proliferation
- Improved QoL
- · Reduction of labor resources and supply costs

Based on the clinical observations and outcomes of this case study, the use of TPD provided a safe and effective modality for the treatment of this challenging wound and EAF.

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*Altrazeal® Transforming Powder Dressing (USA). EDU-0045, REV 01



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

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Introduction

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

Transforming powder dressing (TPD) forms a 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 wound treatment modality

Materials and Methods

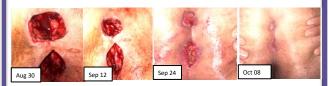
We used a novel methacrylate-based transforming powder dressing, which transforms in-situ to a shape-retentive wound matrix once in contact with moisture. (Altrazeal® TPD, ULURU Inc.).

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

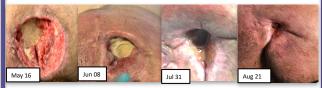
Results



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



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



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

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

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

Conclusion

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

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