AdventHealth
SAWC Fall 2022, Las Vegas, NV
October 13-16, 2022

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

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 amount[2]
- 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 life[5] (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 (SOC) wound therapies, including NPWT and conventional dressings, require frequent dressing changes that can be painful and increase the need for opioids and the potential 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.[8]

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 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, pressure injury, abscess, hematoma
- **Wound Size:** 7.5 - 1,350 cm^2 (mean= 272 cm^2)
- **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

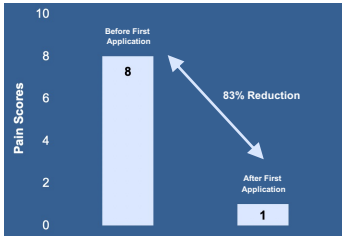
QIP SAMPLE POPULATION

Subject	Wound Type / Surgical Procedure	Sex	Age	Complication and Comorbidities	Starting Wound Area (cm^2)	Starting Pain Score	Pain Score Post Initial Application	% Pain Reduction
1	Pilonidal cyst (recurrent) excision (3rd)	M	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	M	51	HIV, progressive necrotizing fasciitis	72	10	0	100%
5	Excision/debridement RLE through muscle	M	40	DVT, lymphedema, failed treatment with STSG and NPWT	1350	9	3	67%
6	Burn debridement (thigh)	M	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	95	DM, dementia, kidney dx, history of slow/non-healing wounds, waldenstrom macroglobulinemia	21	8	2	75%
9	Necrotizing fasciitis excision (right thigh)	M	44	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)	M	45	DM, obesity, HTN, multiple abscesses	9	8	0	100%
12	Hematoma post debridement (LLE)	F	71	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%

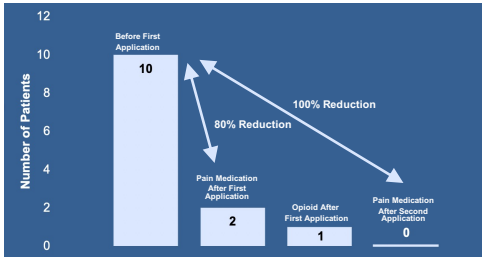
POST TREATMENT WITH TPD

- **Reduction of Average VAS Pain Score: 83% (range 50% - 100%)**
  - All patients reported pain reduction within few minutes of first application
  - 6/12 patients reported 100% pain reduction after TPD treatment
- **Reduction of Pain Medication: 80%** after first TPD application
  - 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

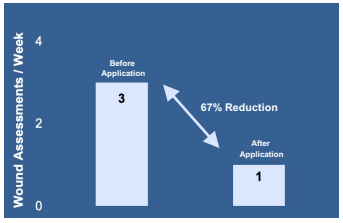
PAIN SCORES



PAIN MEDICATION



WOUND ASSESSMENTS



REFERENCES

(1) Chetter IC, Oswald AV, et al. Patients with surgical wounds healing by secondary intention: A prospective, cohort study. International journal of nursing studies. 2019. 89, 62–71. (2) Sen CK. Human Wounds and Its Burden: An Updated Compendium of Estimates. Advances in wound care. 2019. 8(2), 39–48. (3) Diane Glowacki, Effective Pain Management and Improvements in Patient's Outcomes and Satisfaction. CriticalCareNurse Vol 35, No.3, June 2015. (4) Quianyu Hu et al. Effects of Surgical Wound Types, Pain Levels and Length of Stay on the CAHPS Hospital Survey. (5) Shahriari M, Golshan A, et al. Effects of pain management program on the length of stay of patients with decreased level of consciousness: A clinical trial. Iranian journal of nursing and midwifery research. 2015. 20(4), 502–507. (6) Garimella V, Cellini C. Postoperative pain control. Clinics in colon and rectal surgery. 2013. 26(3), 191–196. (7) Lopez G. New York Times; Good morning. Overdoses are increasing at a troubling rate. 2022FEB13. (8) Becker's Hospital Review. "Wound care by the numbers: Medicare cost and utilization of patients with chronic wounds" Healogics. White paper - 090717. | **Acknowledgements:** This poster was created in collaboration with ULURU Inc. All protocols and clinical assessments were conducted independently by AdventHealth without any compensation.

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

Altrazeal® Transforming Powder Dressing (USA). For application instructions and risks of this device refer to Altrazeal Instructions for Use.

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

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

INTRODUCTION

The current nursing shortage is expected to intensify, especially as an aging population burdens our healthcare systems[1]. Limited staffing can:

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

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

METHODOLOGY AND MATERIALS

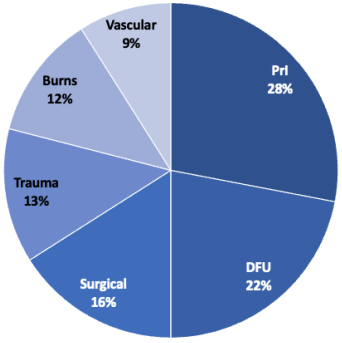
Global data from 76 patients in six patient cohorts treated with TPD was aggregated. Dressing change frequency and nursing time spent on wound care using TPD was compared to standard of care (SOC) dressings. SOC dressing, dressing change time and number of weekly treatments were recorded where available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

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

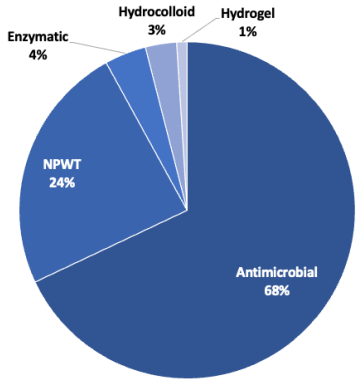
DEMOGRAPHICS

- **N:** 76 | **Age:** 4 – 95 years
- **Gender:** 33% female / 67% male | **Wounds:** 41% acute / 59% chronic

WOUND ETIOLOGIES DISTRIBUTION



SOC TREATMENT MIX

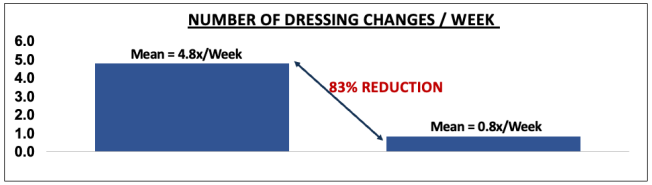


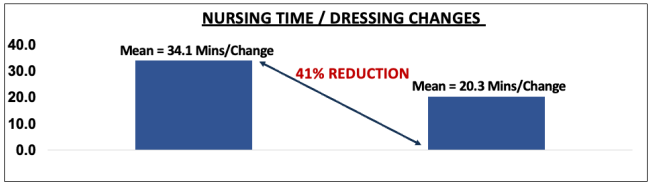
NURSING EFFICIENCIES ACHIEVED ACROSS ETIOLOGIES

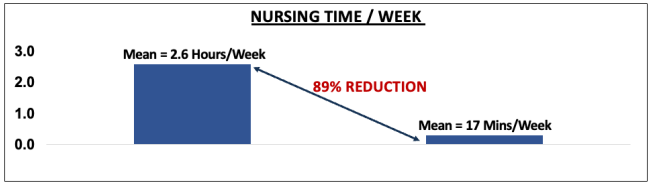
WOUND TYPE	WEEKLY DRESSING CHANGE FREQUENCY			TIME / CHANGE (MINS)			TIME / WEEK (MINS)		
	SOC	TPD	% CHANGE	SOC	TPD	% CHANGE	SOC	TPD	% CHANGE
Surgical	5.6x	1.1x	-81%	34	20	-53%	154	17	-90%
Trauma	4.1x	1.1x	-73%	49	23	-53%	174	25	-86%
Burns	7.0x	0.7x	-90%	29	19.4	-33%	202	13	-94%
Prl	5.4x	0.7x	-88%	23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

RESULTS

- SOC: mean dressing change frequency of 4.8x /week (3x/day to 1x/week) requiring 34 mins / change (10 -120 mins)
- TPD: mean dressing change frequency of 0.8x / week (0.2x to 2.0x/week) requiring 20 mins / change (10 -60 mins)
- **MEAN TIME / WEEK FOR WOUND CARE = 2.6 HOURS / WEEK WITH SOC VERSUS 17 MINS / WEEK WITH TPD**







CONCLUSION

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

REFERENCES & ACKNOWLEDGEMENTS

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

Acknowledgements: This poster was created in collaboration with Altrazeal Life Sciences Inc. (ALSI). Mr. Ron Sototmayor and Dr. Johnathan Saxe serve as clincial consultants to ALSI. Dr. Saxe also served as ALSI's Medical Director. | EDU-0076, Rev 01

NOVEL EXTENDED-WEAR POWDER DRESSING USED IN PATIENT WITH LARGE SURGICAL WOUND S/P SPINAL EPIDURAL ABSCESS EVACUATION AND POTENTIAL RISK OF AUTONOMIC DYSREFLEXIA

Amay Parikh, MD; Michael Philip Bellew, MD; Ron Sotomayor, RN, BA, CWOCN | AdventHealth System; Orlando, FL

Symposium on Advanced Wound Care (SAWC) Spring 2023 Meeting | April 26 – 30 | National Harbor, MD

INTRODUCTION

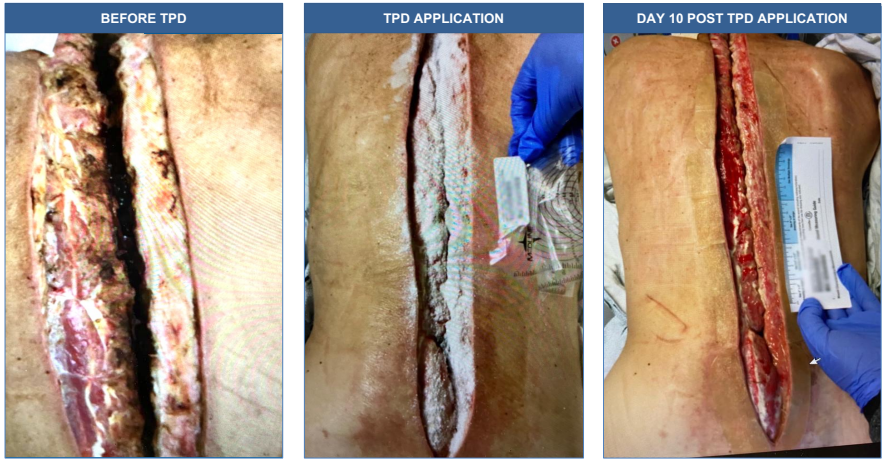
The incidence of spinal epidural abscess has increased in the United States over the last 40 years, largely due to an aging population, increased number of spinal procedures, intravenous (IV) drug abuse, increased number of compromised immune system conditions (e.g., diabetes mellitus, AIDS, cancer, etc.).[1] Surgical decompression remains the mainstay treatment[1]. Postoperatively, these surgical wounds can be extremely difficult to manage due to risk of infection with frequent dressing changes and potential risk for autonomic dysreflexia (AD)[2].

METHODS AND MATERIALS

This case study involves a 56-year-old male with hepatitis C, severe malnutrition, and IV drug abuse that contracted MSSA bacteremia and epidural abscesses from C4-C5, T12-L1, L1-S2-S3. He underwent C3 to C7 and T1 to T9 hemilaminectomies with abscess evacuation. The resulting surgical wound was 55 x 5 x 4 cm extending from posterior cervical to lumbosacral spine with exposed dura and tendon. Since the patient was not a candidate for surgical closure post-operatively, the initial goal for wound treatment was to achieve granulation tissue over the dura. He was initially treated with moist sterile gauze packing 2x daily (for one week) with a ketamine drip and opioids for pain control. NPWT was contraindicated due to exposed dura and concerns for autonomic dysreflexia. Due to the lack of progress with daily packing, the patient was converted to a novel extended-wear transforming powder dressing (TPD*). TPD was applied and topped off once in 10 days.

TPD is an extended-wear powder dressing (up to 30 days) comprised primarily of biocompatible polymers similar to those used in contact lenses. Upon hydration with saline, TPD forms a moist oxygen-permeable matrix that covers, seals and protects the entire wound surface. TPD can be left in place for up to four weeks and topped off as needed.

RESULTS



After conversion to TPD, pain was significantly reduced and the ketamine drip and opioids were discontinued. The patient rapidly developed granulation tissue over the exposed bone and was discharged within two weeks of initiating TPD treatment.

DISCUSSION

For this patient, TPD was a viable alternative until the dura was covered by granulation tissue. TPD facilitated wound healing, reduced wound and dressing change related pain, and decreased the frequency of requisite dressing changes and associated nursing times. No adverse events were reported.

REFERENCES & ACKNOWLEDGEMENTS

(1)Chao D, Nanda A. Am Fam Physician. 2002;65(7):1341-1347; (2) MSKTC.org/sci/factsheets/autonomic-dysreflexia

Acknowledgements: This poster was presented in collaboration with Altrazeal Life Sciences Inc. All protocols and clinical assessments were conducted independently by AdventHealth without any compensation. For application instructions and risks of this device please refer to Altrazeal Instructions for Use.

**Altrazeal® Transforming Powder Dressing*

Treatment Of Complicated Post-Operative Vascular Wounds: Utilizing A Novel Transforming Powder Dressing In Lieu Of Conventional Wound Dressings

Johnathan A. Allen, PA-C; Maggie Gallagher, MD; Praise Njoku Austin, MD; Nicholas Quartararo; Rajiv K. Chander, MD

Division of Vascular Surgery, James J. Peters Veterans Affairs Medical Center, Bronx, New York 10468

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

INTRODUCTION

Management of surgical site wounds and complications is an important consideration for any vascular surgery team. Patients desire a dressing which is pain-free, easy to apply and requires minimal changes and manipulation. This case series evaluates the use of a novel transforming powder dressing (TPD*) with extended wear time (up to 30 days) as a wound dressing option in managing amputation sites and incisional surgical wounds complicated by dehiscence. TPD is a powder dressing that transforms upon hydration to form an oxygen permeable matrix that covers and protects the wound.

METHODOLOGY

We performed observational case reviews of post-surgical wounds in two patients with severe vascular pathology and significant co-morbidities. TPD was used as an alternative to conventional wound dressings. Patient demographics, past medical and surgical history, and anatomical pathology were described. Evaluation of wound closure progress was followed with the participation of multi-specialty teams.

DISCUSSION

Both patients experienced remarkable wound healing results and reduced pain using TPD. TPD provided the benefit of promoting wound healing, while being a less expensive alternative to other modalities that require more frequent dressing changes. It also allowed for ease of use in both clinic and home settings, significantly reducing the need of office visits for dressing changes.

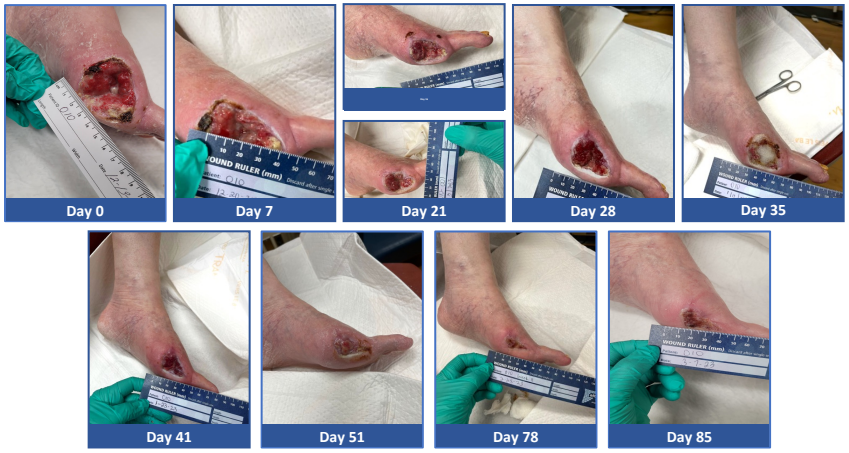
Based on these results, we concluded that TPD is an appropriate treatment for use in the post-surgical setting that may be easily and competently managed by a patient at home.

RESULTS

#1 AMPUTATION SITE WOUND

71 y/o male with h/o HLD, DM, CAD (s/p CABG 1993), severe AS (s/p TAVR 2021), COPD, PAD s/p LLE angiogram with L SFA atherectomy and angioplasty on 10/2022

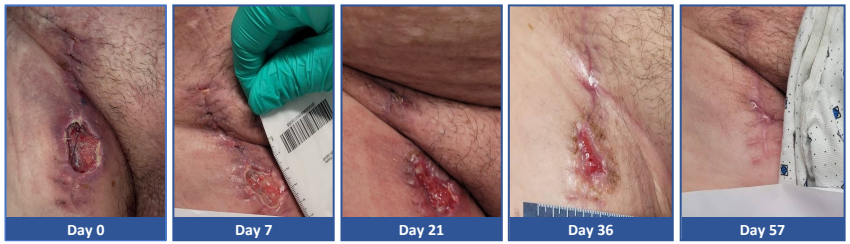
- Open surgical wound of the foot s/p partial 1st ray resection and wound debridement performed 11/2022 for OM
- Location: Left foot
- Baseline Measurements: 4.5 x 4.0 x 1.3 cm
- Dressing: TPD, contact layer, rolled gauze wrap
- Dressing Frequency: Weekly
- Time to Healing / Total Applications:
  - 85 days
  - 12 total applications



#2 SURGICAL WOUND C/B DEHISCENCE

72 y/o male with h/o HTN, AAA, depression, CKD3, HLD, A-fib, MI, diverticulitis, colovesicular fistula, PAD s/p R iliac stenting with femoral endarterectomy (08/2022) with postop course c/b by R groin infection and wound dehiscence

- Location: Right groin
- Baseline Measurements: 3.0 x 2.0 x 0.5 cm
- Dressing: TPD, contact layer, rolled gauze wrap
- Dressing Frequency: Weekly changes at home
- Time to Healing: 57 days with four clinic visits



Altrazeal® Transforming Powder Dressing, USA. For application instructions and risks of this device please refer to Altrazeal Instructions for Use.

Acknowledgements: This poster was developed in collaboration with Altrazeal Life Sciences Inc. All clinical cases and analyses were performed independently by the authors and no compensation was paid.

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

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

WOCNext 2023 Meeting | June 3 – 7
Las Vegas, NV

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

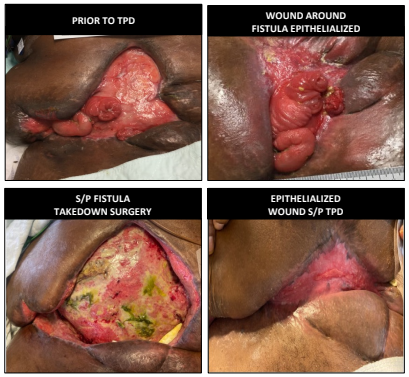
We evaluated three cases where patients developed complications while being treated with SOC therapies including skin barriers, dressings, NPWT and/or large pouching systems,[2] consuming considerable time and resources (usually 3x/week).

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

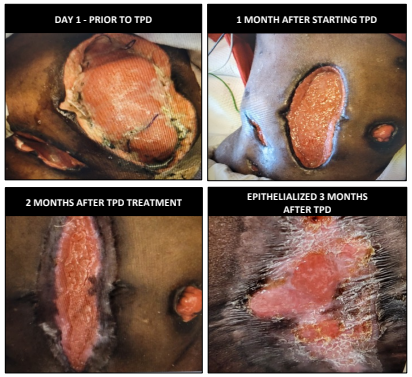
38 y/o female s/p motor vehicle accident c/b high output EAF surrounded by large open abdominal wound.

- **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.



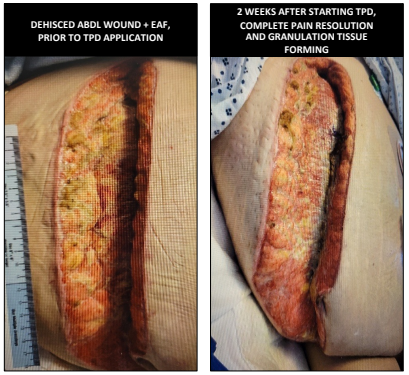
20 y/o female with ulcerative colitis/Crohn's, ileostomy takedown/stoma re-sited, c/b dehisced abdominal wall.

- **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.



REFERENCES & ACKNOWLEDGEMENTS

(1) Meshikhes AW, Al-Hariri A, Al-Zahir AA, Al-Nahawi M. A rare approach to entero- atmospheric fistula. Am J Case Rep. 2013;14:476-480. Published 2013 Nov 13. doi:10.12659/AJCR.889638 | (2) Ludlow E. What is an Entero-cutaneous Fistula and Entero-atmospheric Fistula? https://www.insidescompany.com/blog/what-is-an-enterocutaneous-fistula-and- enteroatmospheric-fistula; Published online 2020 Nov 9 | (3) Terzi C, Egeli T, Canda AE, Arslan NC. Management of enteroatmospheric fistulae. Int Wound J. 2014;11 Suppl 1(Suppl 1):17-21. doi:10.1111/iwj.12288 | **Acknowledgements:** This poster was presented in collaboration with Altrazeal Life Sciences, Inc. All protocols and clinical assessments were conducted independently by AdventHealth. For application instructions and risks of this device please refer to Altrazeal® Instructions for Use.

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*

A Novel Pre-Grafting Wound Management Technique to Promote Granulation in Complex Painful Wounds

Jonathan M. Saxe, MDMAR, MBA, FACS; Ascension St. Vincent Hospital, Indianapolis, IN, USA; Mounir Mabrouk, MD; Alexandria University, Egypt | WOCNext 2022 Meeting, Fort Worth, TX, June 5-8, 2022

BACKGROUND

Skin grafting (SG) is used to provide coverage in both acute and chronic wound settings. Preparation of the wound bed with development of granulation tissue is vital for graft success.[1] Traditional standard of care (SOC) wound management principles involve debriding the wound followed by negative pressure wound therapy (NPWT), bolstering or conventional dressing applications to accelerate wound healing prior to grafting.[2] Current SOC is limited in complex painful wounds. NPWT deployment and application is often difficult and painful.[3] Pain is also a significant issue often associated with repeated wound dressing changes.

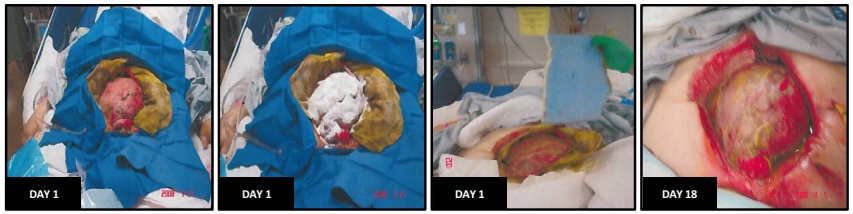
METHODOLOGY & MATERIAL

Three case studies incorporating treatment with Transforming Powder Dressing (TPD) to promote granulation in patients with complex wounds are reviewed. In each case, patients had extensive wounds with high levels of reported pain. Prior treatment in all cases failed to progress wounds to the stage to permit grafting. Cases reviewed include a large abdominal wound resultant of an automobile accident, complex wounds associated with uncontrolled chronic vasculitis, and an improvised explosive device (IED) accident. TPD was introduced to facilitate and promote granulation and allow grafting.

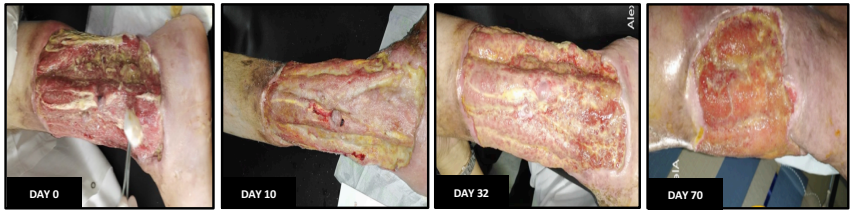
TPD is comprised primarily of biocompatible polymers. Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration. Once applied, TPD may be left in place for up to 30 days and additional powder may be added ("topped off") 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.

RESULTS

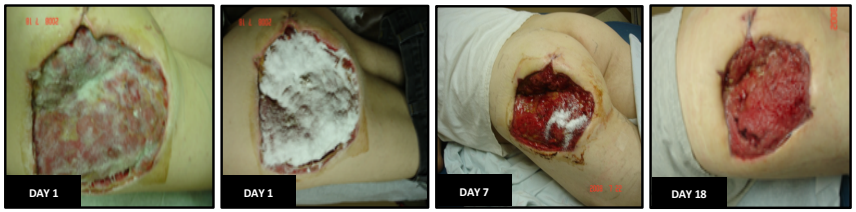
PATIENT 1: 40 y/o female with large complex abdominal wound resultant of car accident
Challenge: NPWT could not be placed due to risk of fistula
TPD Treatment: TPD applied to wound with foam for excess exudate absorption
Outcomes Post-TPD Treatment:
- Wound was ready for grafting by Day 18



PATIENT 2: 42 y/o male with non-healing progressive venous ulcer, uncontrolled vasculitis, infection history, necrosis, exposed bone
Challenge: High pain score (9/10), failed SOC treatment
Treatment: TPD 2x/week in the first week and 1x/week after
Outcomes Post-TPD Treatment:
- Significant reduction in pain
- Granulation tissue covered bone and patient was grafted
- Avoided amputation



PATIENT 3: 40-year-old male with a 25cm x 25cm x 5cm IED blast wound due to consumer firework accident (M-80)
Challenge: NPWT was discontinued due to patient pain, porcine matrix failed to stimulate granulation
Treatment: TPD applied weekly
Outcomes Post-TPD Treatment:
- Wound depth reduced from 5cm to 2cm by day 7
- Wound was ready for grafting by day 18



CONCLUSION

A marked acceleration in granulation was observed in all three cases. Patients reported reduced pain and the frequency of dressing changes were also reduced relative to SOC. No adverse events were reported. Based on the clinical observations and outcomes, we conclude that TPD presents a safe and effective modality for preparing complex painful wounds for successful grafting.

REFERENCES

1. Kirsner, R. S., Bernstein, B., Bhatia, A., Lantis, J., Le, L., Lincoln, K., Liu, P., Rodgers, L., Shaw, M., & Young, D. (2015). Clinical Experience and Best Practices Using Epidermal Skin Grafts on Wounds. Wounds : a compendium of clinical research and practice, 27(11), 282–292.
2. Harries, R. L., Bosanquet, D. C., & Harding, K. G. (2016). Wound bed preparation: TIME for an update. International wound journal, 13 Suppl 3(Suppl 3), 8–14.
3. Upton, D., & Andrews, A. (2015). Pain and trauma in negative pressure wound therapy: a review. International wound journal, 12(1), 100–105.

Acknowledgements: This poster was developed and presented in collaboration with ULURU Inc.; Jonathan M. Saxe, MDMAR, MBA, FACS currently serves as Medical Director for ULURU Inc.

Novel Treatment of Necrotizing Fasciitis with Transforming Powder Dressing

Ron Sotomayor, RN, CWOCN; Reagan Taylor, PA; Jeffrey Chiu, MD; Allan Allicock, MSN, RN, CWON | AdventHealth System; Orlando, FL

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

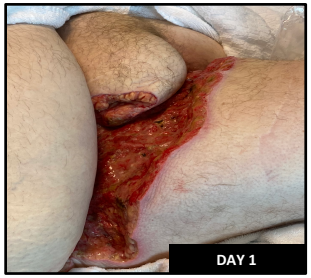
Three case studies incorporating treatment using a novel Transforming Powder Dressing (TPD) in patients with NF and other comorbidities were reviewed. In all cases, patients had extensive wounds with high pain scores, using Visual Analogue Scale (VAS), making NPWT or conventional dressing changes intolerable.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

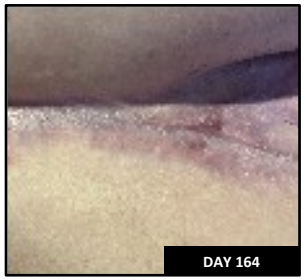
TPD is comprised primarily of biocompatible polymers (used in contact lenses). Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration. Once applied, TPD may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

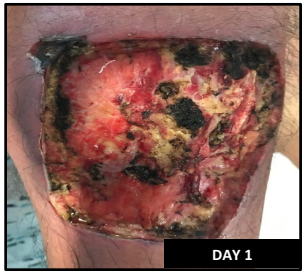
- VAS pain score reduced from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced home health visits (3x to 1x weekly)
- Reduced dressing encounters (<20 versus > 66 estimated with SOC)
- Avoided grafting, amputation & readmission

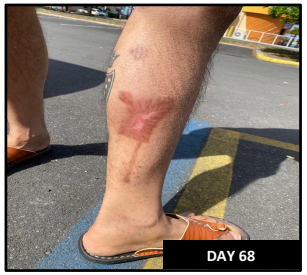




PATIENT 2: 51 y/o male with HIV
Wound Dimension: 72cm^2
Challenge: Painful daily gauze dressing changes
Treatment: Conversion to TPD
Outcomes Post-TPD Treatment:

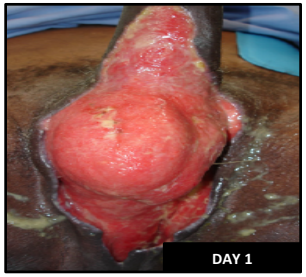
- VAS pain score reduction from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced dressing changes
- (11 vs. 60 estimated with SOC)
- and required visits from 3x to 1x weekly
- Avoided readmission for grafting

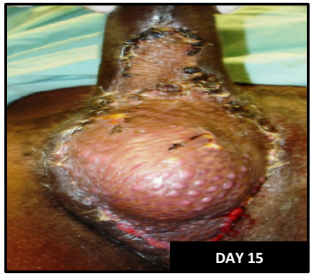




PATIENT 3: 71 y/o male with diabetes, Fournier's gangrene, penile implant malfunction4
Challenge: Painful, challenging location to conduct frequent dressing changes
Treatment: Wound was surgically debrided. Two meshed split-thickness skin grafts were applied, anchored using peripheral sutures covered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

Using Transforming Powder Dressing to Heal Chronic Pilonidal Cyst Wounds

Ann Marie Nie, PhD, MSN, APRN, FNP-BC, CWOCN[1]; Erica Eberhard, MSN, APRN, FNP-BC, CWOCN[2]; Dawn Jennifer Wang, MD, FACS[3]
1. Dayton Children's Hospital; 2. Children's Minnesota; 3. UPMC St. Margaret Hospital

UPMC LIFE CHANGING MEDICINE
WOCNext 2023 | Las Vegas, NV

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

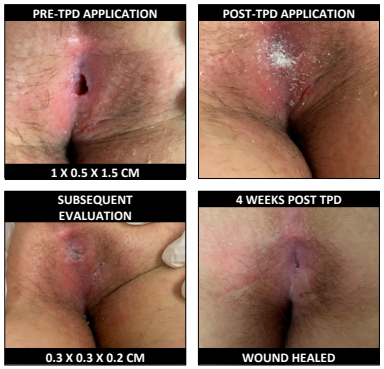
TPD* is a novel powder dressing comprised primarily of biocompatible polymers (similar to those used in contact lenses). Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through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

*Altrazeal® Transforming Powder Dressing

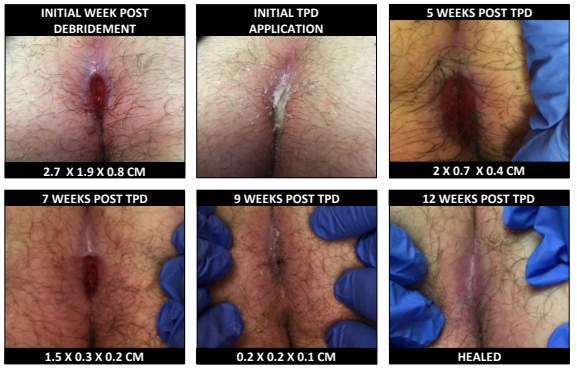
PATIENT OUTCOMES

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.

18 y/o Female



20 y/o Male



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.

REFERENCES AND ACKNOWLEDGEMENTS

1. Hap W, Frejlich E, Rudno-Rudzinska J, et al. (2017) Pilonidal sinus: finding the righttrack for treatment. 2017-02-28. Review article. Polish Journal of Surgery, 2017:89(1), 71-78. Accessed online 31OCT2022. Warby, R., & Maani, C. V. (2021). Burn Classification. In StatPearls. StatPearls Publishing.
2. Harris C, Sibbald RG, Mufti A, Fomayaji R. (2016) Pilonidal Sinus Disease: 10 Steps to Optimize Care. Adv Skin Wound Care. Oct;29(10):469-78.
3. Herrod PJ, Doleman B, Hardy EJ, et al. (2019) Dressings and topical agents for the management of open wounds after surgical treatment for sacrococcygeal pilonidal sinus. Cochrane Database Syst Rev. 2019 Sep 27;2019(9):CD013439.

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

Treatment of Large Painful Lower Extremity Ulcer with Edema and Deep Vein Thrombosis (DVT) Using Transforming Powder Dressing (TPD)

Reagan Taylor, PA-C; Joshua Goldberg, MD; AdventHealth Medical Group; Orlando, FL | Symposium on Advanced Wound Care (SAWC): April 2022

Background

The management of lower extremity (LE) wounds in patients with chronic edema is challenging. Edema may be present for many reasons, including deep venous thrombosis (DVT), which can result in morbidity and mortality if not properly treated.[1,2] Skin damage, prolonged healing times, infection, malodor, and diminished quality of life (QoL) all may develop from excessive wound exudate.[3]

Pain, another common issue in LE wounds like venous ulcers, as well as in cases of LE chronic edema, can negatively impact patient compliance with seeking wound care, further reducing time to healing and overall QoL.

Case Overview: Methodology

A 39-year-old male presented with DVT, chronic RLE edema, and a large leg ulcer. He sought treatment only after he was unable to walk.

Treatment Course:

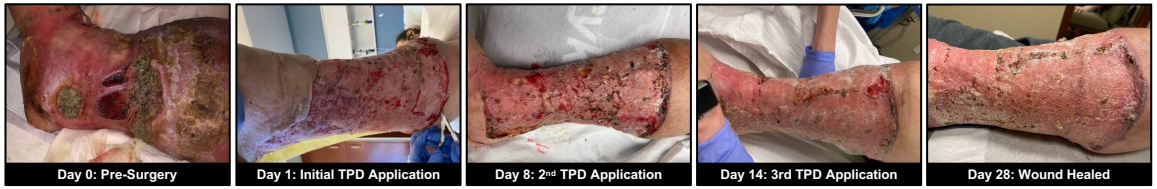
- Circumferential excisional debridement through muscular fascia was performed resulting in a wound area of 1,350 cm^2
- Negative pressure wound therapy (NPWT) was applied post debridement
- A second debridement was performed four days later and NPWT treatment was continued
- A Split thickness skin graft (STSG) procedure was conducted two days later, and the graft was covered with a NPWT device
- Patient reported high levels of pain, requiring management with hydromorphone, oxycodone, and hydrocodone
- After 2 weeks NPWT therapy was discontinued, and the patient was transitioned to Transforming Powdered Dressing (TPD*) and discharged from the hospital
- Pain scores, wound dimensions and number of dressing changes were tracked

**Altrazeal® Transforming Powder Dressing (USA)*

Results

The following effects were noted post-TPD treatment:

- Wound was fully healed within 28 days with three applications of TPD
- Pain score (based on the validated Visual Analog Score) reduced from 9/10 to 3/10 after the first application of TPD
- TPD was reapplied 1 week later, and pain score was reported as 0-1/10
- Additional TPD was applied 6 days later, and pain score was reported as 0
- The wound was observed to be fully healed two weeks later without any further applications of TPD



Day 0: Pre-Surgery | Day 1: Initial TPD Application | Day 8: 2nd TPD Application | Day 14: 3rd TPD Application | Day 28: Wound Healed

Materials

TPD is a novel 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 matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration, and some negative pressure effects on the wound. Once applied, TPD may be left in place for up to 30 days and additional powder may be added ("topped off") 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.

Conclusion

Based on the outcome of this challenging case, which included significant initial comorbidities and high pain levels, treatment of patients with LE wounds associated with edema and DVT which are refractory to SOC and advanced wound care therapies should be considered for treatment with TPD.

References

1. Trayes, Kathryn P, et al.; Edema: Diagnosis and Management. American Family Physician, vol. 88, no. 2, 2013, pp. 102-10.
2. Kesieme, E, Kesieme, C, Jebbin, N, Irekpita, E, Dongo, A. (2011). Deep vein thrombosis: a clinical review. Journal of blood medicine, 2, 59–69. https://doi.org/10.2147/JBM.S19009
3. Aviles Jr, F; Managing the "Weepy Leg" of Chronic Wound Edema. Wound Care Learning Network; September 2019; https://www.hmpgloballearningnetwork.com/site/twc/articles/managing-weepy-leg-chronic-wound-edema

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

Case Series: Treatment of Complex Post-Operative Vascular Wounds with a Novel Transforming Powder Dressing (TPD)

Johnathan A. Allen, PA-C; Xiomara Benavide-Lopez, MD; Bessie M. Roca Loor, MD; Dian G. Nesbeth, NP; Rebecca K. Barksdale, RN; Nicholas Quartararo; Rajiv K. Chander, MD

Division of Vascular Surgery, James J. Peters Veterans Affairs Medical Center, Bronx, New York 10468

INTRODUCTION

Vascular ulcers occur in an estimated 1 to 3 percent of adults worldwide and remain a public health issue with significant economic and psychosocial impacts.

Wound management of vascular ulcers requires frequent dressing changes and drain valuable material and labor resources.

This case series aimed to evaluate the safety and efficacy of utilizing a novel transforming powder dressing (TPD*) with extended wear time as an alternative treatment modality in three patients with complex vascular wounds of varying etiologies.

METHODOLOGY

We performed an observational case series assessment on complex wounds of differing etiologies resultant of sequela related to severe vascular pathology. Each patient was observed to have significant co-morbidities complications with history of poor wound healing and one or more wounds refractory to standard of care (SOC) treatment and required consideration for alternate treatment to facilitate wound healing. Three patients were treated with TPD. Patient demographics, past medical and surgical history, and anatomical pathology were described. Evaluation of wound closure progress was followed with the participation of multi-specialty teams.

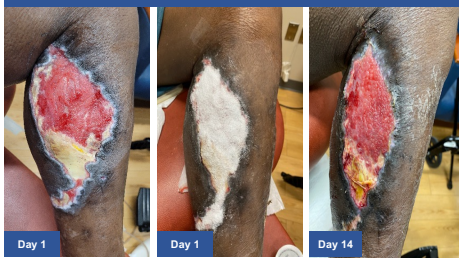
RESULTS

#1. ARTERIAL INFECTED / NECROTIC ULCER

- 71 y/o male, PVD with claudication, CLI
- Left fem-pop bypass in-situ c/b infection. Subsequent native artery revascularization, bypass coil embolization/ligation, refractory ulcer post distal infective / necrotic tissue evacuation

Outcome: TPD used at home with good healing. Dressing changes reduced from once every 2 days (NPWT) to once a week (TPD).

Arterial Medial Ulcer: 2-Weeks Post TPD



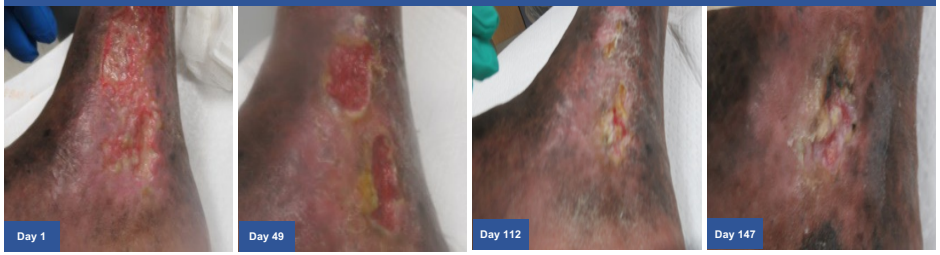
Arterial Lateral Ulcer: 2-Weeks Post TPD

#2. REFRACTORY VENOUS ULCER

- 73 y/o male, refractory VLU
- Bilateral GSV ablations

Outcome: LLE ulcer healed and RLE ulcer was significantly reduced with TPD. Dressing changes reduced from once every other day (various antimicrobial dressings) to once a week (TPD).

Venous RLE Ulcer: 5-Months Post TPD

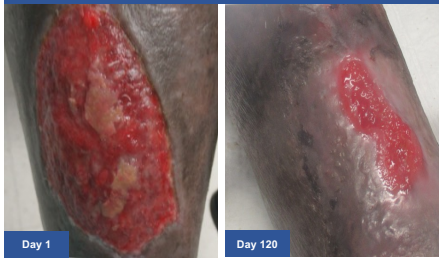


#3. REFRACTORY GRANULOMATOUS ULCER

- 74 y/o male, PVD progressed to rest pain, CLI
- Right fem-AT bypass with PTFE. Disease progression at distal anastomosis with jump bypass from PTFE to distal AT using basilic vein

Outcome: Significant wound area reduction of chronic granulomatous wound with TPD. Dressing changes reduced from thrice (various antimicrobial dressings) to once per week (TPD).

Granulatomous RLE Ulcer: 4-Months Post TPD



CONCLUSION

All patients experienced accelerated healing and wound area reduction with TPD despite significant co-morbidities, vascular complications, and poor history of wound healing. Based on these results, we conclude that TPD is appropriate for use in complex vascular wounds with varying etiologies: active infection, venous stasis, and chronic granuloma wounds. TPD has the benefit of promoting wound healing while being a less expensive alternative to other modalities that require more frequent dressing changes and is easy to use in both clinic and home settings.

***Altrazeal® Transforming Powder Dressing, USA.** For application instructions and risks of this device please refer to Altrazeal Instructions for Use.

Acknowledgements: This poster was created in collaboration with ULURU Inc. All clinical cases and analyses were performed independently by the authors and no compensation was paid.

A Unique Technique for Management of Challenging Surgical Wounds: Treatment of a Thoracic Wound Complication with a Transforming Powder Dressing (TPD)

Rosalyn Barnabee, BSN, RN, WOC; Tammy Jensen Lichtman, RN, BSN, CWON; AdventHealth Medical Group; Orlando, FL

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

BACKGROUND

Traditional standard of care (SOC) management of surgical wounds involves conventional dressing applications or negative pressure wound therapy (NPWT) to accelerate wound healing.[1] Current SOC, however, is limited in treating complex surgical wounds. NPWT can be painful and difficult to apply in certain anatomical locations.[2] Conventional dressings require frequent applications and drain medical resources while increasing patient discomfort and exposure to wound contamination.

Alternative treatment modalities must be considered to provide optimal patient care. We present a case study incorporating treatment with Transforming Powder Dressing (TPD*) in a patient with a complicated thoracotomy related wound with a chest tube.

CASE OVERVIEW AND METHODOLOGY

A 34-year-old male with no significant prior medical history was admitted for COVID-19. Hospital course was complicated by pulmonary hemorrhage s/p right thoracotomy, and a subcutaneous hematoma evacuation requiring incision and drainage resulting in a nonhealing right thoracotomy wound. NPWT was utilized unsuccessfully (hard to get a proper seal) due to the presence of a nearby chest tube.

Patient reported pain (VAS 5/10) at the wound site, worsening with dressing changes. The clinical goal was to expedite wound healing so that he could be evaluated for a lung transplant, and to reduce overall pain and number of dressing changes.

NPWT was discontinued and treatment with a novel wound technology, TPD, was initiated in conjunction with anti-microbial therapy to manage the wound.

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 may be used in areas of high exudation or friction. TPD dries and flakes off as the wound heals.

CHALLENGES AND TPD TREATMENT

Challenges and Prior Treatment:

- NPWT: Unsuccessful due to location of chest tube in right lung and central line to right jugular; patient was also receiving ECMO
- Lack of mobility
- Necrosis to tips of fingers and toes
- Unable to lay in bed
- Required assistance to elevate arm for dressing changes

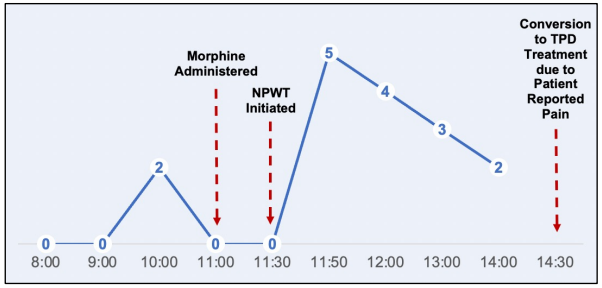
Patient- Reported Pain:

- Pain levels of increased intensity after NPWT treatment despite pre-administration of IV morphine
- High-level of patient reported pain (VAS 5/10) immediately after NPWT activation
- Moderate to mild patient reported pain (VAS 2/10 to 4/10) continued post NPWT treatment
- Patient reported pain compounded by inability to maintain seal with NPWT

TPD Treatment:

- **NPWT discontinued due to disturbance to chest tube system and patient reported pain**
- TPD mixed with solution of hypochlorous acid to create a gel-like mixture that was used to fill in the wound and stimulate wound base to promote tissue growth**. A silver hydro fiber rope was used to cover the fenestration as an additional barrier

Patient Reported Pain Levels (VAS 0-10): NPWT Treatment

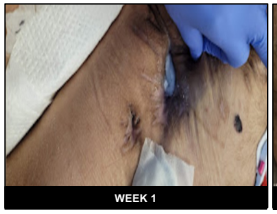


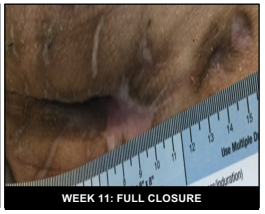
**Altrazeal's intended use is as a hydrogel wound covering without drugs or biologics. Combinations with active agents is considered off-label.

RESULTS

- VAS pain levels reduced to 0/10 post-TPD application
- Discontinued use of morphine and all pain medications
- Reduction in dressing changes due to TPD's extended wear time
  - Enhanced patient comfort while enabling tissue growth
  - Optimized resource utilization due to fewer dressing change requirements and reduced wound assessments
- Week 6: Significant reduction in wound size
- Week 11: Wound closed; patient was transitioned to another hospital for lung transplant


PRIOR TO TPD TREATMENT


WEEK 1


WEEK 11: FULL CLOSURE

REFERENCES

1. Harries, R. L., Bosanquet, D. C., & Harding, K. G. (2016). Wound bed preparation: TIME for an update. International wound journal, 13 Suppl 3(Suppl 3), 8–14.
2. Upton, D., & Andrews, A. (2015). Pain and trauma in negative pressure wound therapy: a review. International wound journal, 12(1), 100–105.
3. Hernandez MC, El Khatib M, Prokop L, Zielinski MD, Aho JM. Complications in tube thoracostomy: Systematic review and meta-analysis. J Trauma Acute Care Surg. 2018;85(2):410-416. doi:10.1097/TA.0000000000001840.

Acknowledgements: This poster was presented in collaboration with ULURU Inc. All protocols and clinical assessments were conducted independently by AdventHealth without any compensation.

CONCLUSION

Although chest tube insertions are used routinely to drain pleural collections, these invasive procedures are associated with high complication rates (20-40%), including surgical site infections and bleeding, that can occasionally be life threatening.[3] SOC treatment, including NPWT, are often problematic in this patient population Patient comfort and safety are the ultimate priorities in the care of patients with challenging surgical wounds. Alternative treatments must be considered due to the current limitations of SOC.

Based on the clinical observations and outcomes of this case study, we conclude that TPD presents a safe and effective modality for the treatment of challenging surgical wounds, resulting in decreased patient-reported pain and pain medications, improved patient comfort, rapid reduction in wound size and facilitation of wound closure.

*Altrazeal® Transforming Powder Dressing (USA).

Effective Treatment of Anticoagulated Patients with Novel Transforming Powder Dressing (TPD)

Tammy Lichtman, RN, BSN, CWON; Jeffrey Chiu, MD; Ron Sotomayor, BA, RN, CWOCN; AdventHealth System, Orlando, FL | Symposium on Advanced Wound Care (SAWC) Spring Meeting, April 2022

Background

Anticoagulants can contribute to wound healing complications by accelerating bleeding and exudation. Even minor injuries may evolve into severe soft tissue damage with increased risk of hematomas. Resulting wounds may be extensive, painful, and debilitating with high risk of infection and tissue necrosis, imposing a significant wound care challenge with limited treatment alternatives.[1] Conventional dressings require frequent changes exacerbating wound trauma and patient discomfort. Another routine therapy, negative pressure wound therapy (NPWT), has been associated with bleeding complications. Between 2009 and 2011, the FDA reported six deaths and 77 injuries associated with NPWT; bleeding complications were prevalent in all six deaths and 17 injuries, including certain patients on anticoagulant therapy.[2] Alternative therapies, therefore, must be evaluated.

Case Overview: Methodology

We present a complex case involving a patient treated with a novel transforming powder dressing (TPD*). An 88-year-old male with multiple comorbidities including atrial fibrillation was being treated with apixaban to reduce the risk of stroke and systemic embolism. The patient reported a fall, wounding his right lower extremity (RLE). His pain increased and the wound worsened despite standard of care therapy. Computed Tomography Angiography revealed a large, superficial hematoma in the lateral aspect of the right calf. Acute blood loss and anemia secondary to the hematoma was observed. DVT prophylaxis was discontinued. Excisional wound debridement and evacuation of the hematoma was performed eleven days after the initial injury. TPD was applied to the wound post-surgery and continued during home healthcare visits. The patient was observed weekly for removal of contact layer and outer dressing to assess the wound. For the first 5 weeks, the wound dressing was changed (topped off) 1 time per week. The following 8 weeks, the wound dressing was changed 1 time every other week. The final 6 weeks, the wound dressing was changed 1 time every third week (11 TPD dressing changes over treatment course).

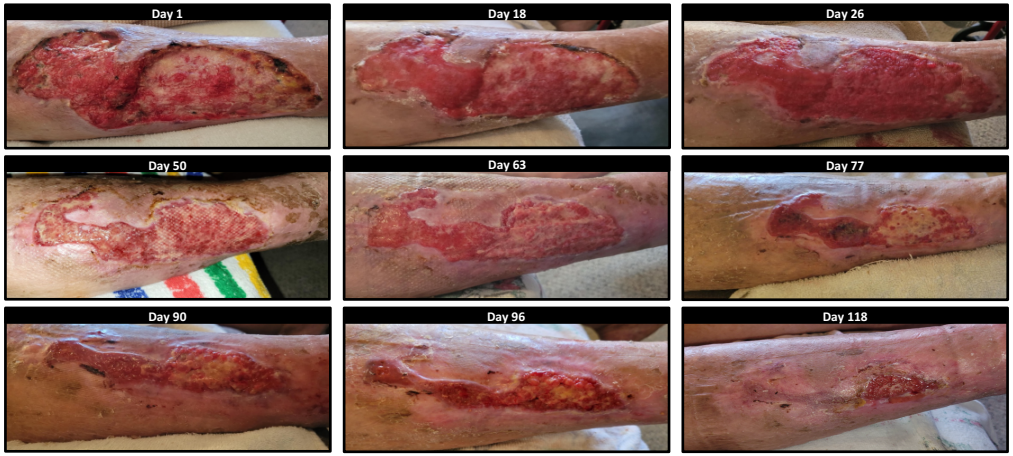
Material

TPD is a novel 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 matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration, as well as some negative pressure effects on the wound. Once applied, TPD may be left in place for up to 30 days and additional powder may be added ("topped off") as needed. Simple secondary dressings are used and changed in areas with high exudation or friction. TPD dries and flakes off as the wound heals.

**Altrazeal® Transforming Powder Dressing (USA)*

Results

- After treatment with TPD our team observed the following results:
- Reduced pain, minimal wound bleeding and a significant decrease in sanguineous drainage
- Expedited granulation: wound was ready for grafting 35 days after initial application of TPD (clinical team elected not to perform grafting)
- Significant reduction in wound size and dressing changes
- From 155 cm3 to 1.2 cm3 within 118 days
- Dressing change frequency reduced relative to standard of care dressings
- Changes every 10.7 days on average
- Homecare nursing visits reduced to once per week instead of thrice per week (standard of care)



Conclusion

After treatment with TPD, we observed a significant reduction in sanguineous drainage and overall wound size. Dressing change frequency and home health visits were reduced relative to standard of care therapies.

The wound care team recommended secondary intention wound healing with TPD as grafting was no longer required.

Based on the results of this complex case, we conclude that patients who are at high risk for stroke and embolism and are being treated with anticoagulants should be considered for wound care treatment with TPD.

References

1. Cole, W; The Impact of Oral Anticoagulants on Wound Healing and Development in an Aging Population; Podiatry Today; June 2021; Accessed 16December 2021; https://www.hmpglobalearningnetwork.com/site/podiatry/case-study/impact-oral-anticoagulants-wound-healing-and-development-aging-population
2. Livingston, M; (November 20, 2009); FDA Preliminary Public Health Notification: Serious Complications Associated with Negative Pressure Wound Therapy Systems (Shuren JE); https://woundblog.wordpress.com/2009/11/20/fda-preliminary-public-health-notification-serious-complications-associated-with-negative-pressure-wound-therapy-systems/

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

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

Janie Hollenbach DNP, RN, WCC, OMS, DWC, CHRN[a] and Susan Rolniak St. John[b] MSN, APRN-NP

[a]Wound and Ostomy Nurse, Department of Colon and Rectal Surgery, Allegheny Health Network, Pittsburgh, PA | [b]Clinical Consultant, ULURU Inc.

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]

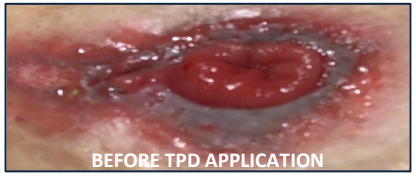
Female, 60 years old with:

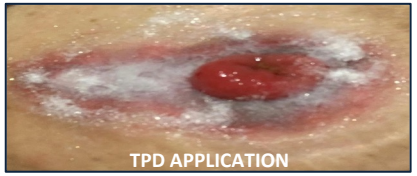
- **Crohn's Disease for 26 years with 27 hospitalizations**
- **Ileum resection, colostomy, loop colostomy revision secondary to hernia complication**
- Diagnosed with **peri-stomal PG 3** years ago
- **18%+ unintentional recent weight loss**
- **Excruciating pain (10/10 based on VAS score)** secondary 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

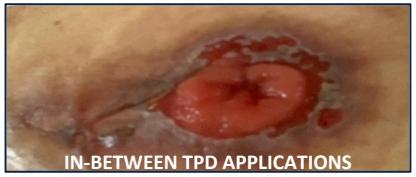
Failed Treatments: Tested **several devices and dressings.** In addition, injectable and topical steroids were tried without improvement. **Opioids** were taken every six hours to control pain.
Onerous Care Regime: Daily or **twice daily appliance changes** performed by the patient with **homecare nurse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

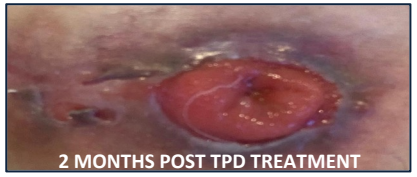
TREATMENT WITH TPD

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.

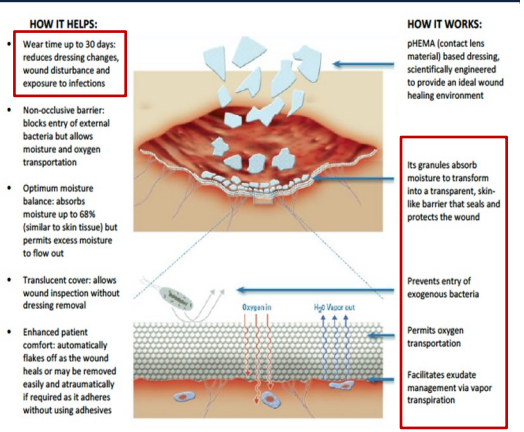
OUTCOMES | CONCLUSION

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 an Enteroatmospheric Fistula with Transforming Powder Dressing

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

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

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 be 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 colo-cutaneous fistula extending from the right colon into the right pelvic wall. Post-operative 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.

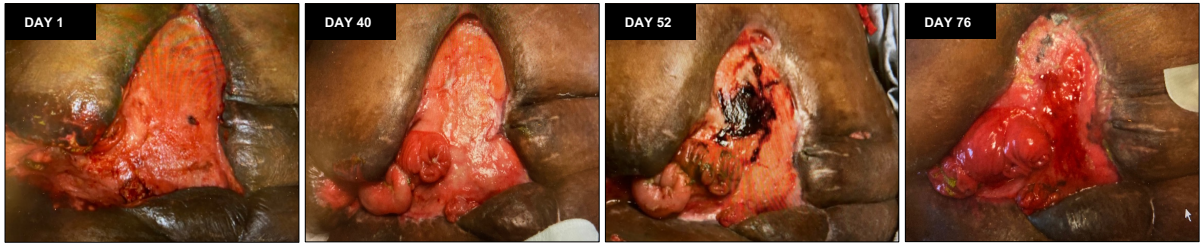
The patient was discharged home and returned to the clinic three weeks later. The wound had decreased in size (9cm x 8cm x 1.2cm), and the stomatized fistulae were able to be isolated with a smaller, less costly patient management appliance. Within 10-days of initial TPD treatment, the patient was able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

Altrazeal® Transforming Powder Dressing (USA).

RESULTS

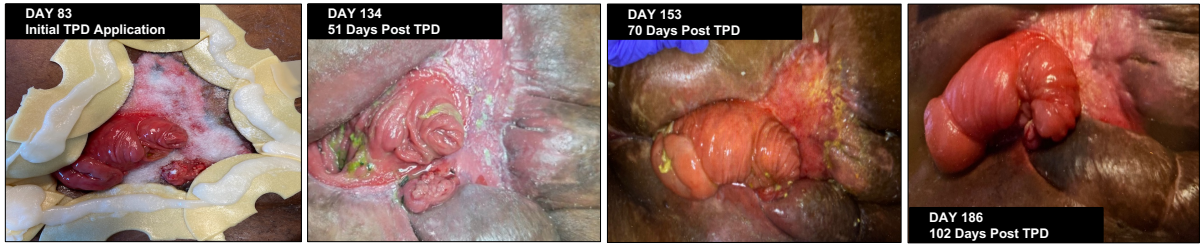
SOC Treatment Course for First 11 Weeks (Prior to TPD Application):

- 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 excoriated 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.

REFERENCES & ACKNOWLEDGEMENTS

(!) Meshikhes AW, Al-Hariri A, Al-Zahir AA, Al-Nahawi M. A rare approach to entero-atmospheric fistula. Am J Case Rep. 2013;14:476-480. Published 2013 Nov 13. doi:10.12659/AJCR.889638. | (2) Ludlow E. What is an Entero-cutaneous Fistula and Entero-atmospheric Fistula? https://www.insidescompany.com/blog/what-is-an-enterocutaneous-fistula-and-enteroatmospheric-fistula; Published online 2020 Nov 9. | (3) Terzi C, Egeli T, Canda AE, Arslan NC. Management of enteroatmospheric fistulae. Int Wound J. 2014;11 Suppl 1(Suppl 1):17-21. doi:10.1111/iwj.12288. **Acknowledgements:** This poster was presented in collaboration with ULURU Inc. All protocols and clinical assessments were conducted independently by AdventHealth without any compensation. For application instructions and risks of this device refer to Altrazeal Instructions for Use.

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

Purpose:

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 techiques.
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:

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 discharge. Enterostomal soilage will exacerbate the skin condition making management even more difficult. The end result is a painful stomal or fistula site 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 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 patients with peristomal skin wounding and mucocutaneous separation. Transforming powder dressing not only allowed them to heal, but helps extend wear time of the appliance. 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 monitored.

A second patient developed a high output abdominal fistula. 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.

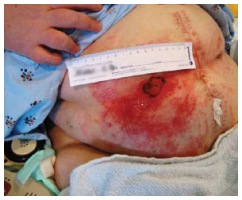
Results:

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.

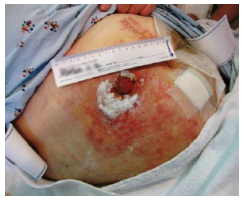
Transforming powder protected the skin in a case of difficult to control high output fistula and allowed the patent to be successfully managed. Without the powder dressing, the patient had pain and irritation from the skin exposure from enteric contents. The Transforming Powder Dressing worked well to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

CASE 1

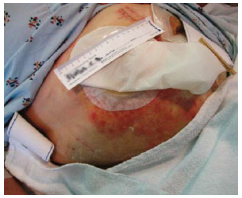
Damaged peristomal skin and mucocutaneous separation



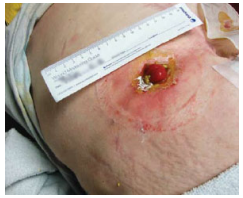
Transforming Powder Dressing applied



Stomal appliance applied over powder dressing

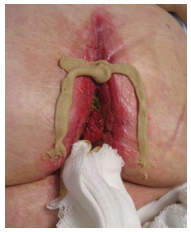


Peristomal Skin and mucocutaneous separation healed

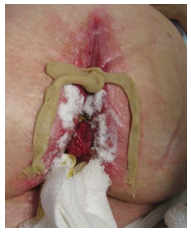


CASE 2

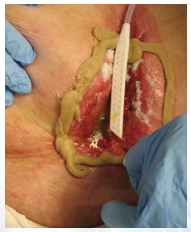
Small Bowel Fistula developed in midline wound



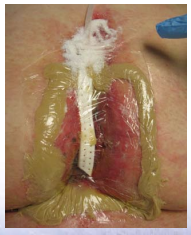
Transforming Powder Dressing applied to protect skin



Powder covering skin and fistula walled off with stoma paste



Film applied to cover suction and control fistula effluent



Discussion:

When skin breakdown and mucocutaneous separation occur, ostomy leakage becomes more likely. Repeated skin injury may result in damaged skin and a weeping stoma area that will not accept an appliance. Prompt attention and effective treatment will more likely heal the condition and avoid lasting complication. Management of the moisture is imperative to fitting and securing the appliance footplate. Appliance leakage and failure becomes a result of repeated skin injury and can become cyclical, impacting on the patients self esteem and quality of life. Transforming Powder dressing manages moisture and protects the wound bed from external contamination. We found that the stomal appliance can be placed over the powder dressing and remain in place to heal and protect the skin.

Small bowel fistulas when high output, are difficult to control. The surgeon is reluctant to re-operate within the first 12 weeks so as to avoid a "difficult abdomen" situation and run the risk of further complication. Having a management strategy that is effective in controlling the fistula and allow time to resolve the hostile post-operative abdomen is essential. Transforming Powder Dressing controlled the complicated skin issues that occurred with this difficult fistula. Enterostomal Therapists may find this technique useful in caring for their stomal and complex wound patients.

References:

1.) Baranoski, S. & Ayello, E. Wound Care Essentials: Practice Principles. (2nd ed.) Walters Klower/Lippincott Williams & Wilkins (2008).

2.) McCann, E. Common Ostomy Problems. In Milne, C., Corbett, L., Dubue, D.: Wound, Ostomy & Continence Nursing Secrets: Hanley & Belfus, Inc. (2003) pp. 319-325.

3.) St. John, JV, Brown, SA., Hatef, DA, Unzeitig, AW, Noble, D, Waller, LK, and Ponder, BC. Formulation development and in vivo testing of a novel powder wound dressing employing dehydrated technology. The University of Texas Southwestern Medical Center at Dallas, Department of Plastic Surgery, 1801 Inwood Rd., Dallas, TX 75390

4.) Fiers, S. & Thayer, D. Management of Intractable Incontinence. In Doughty, D.: Urinary & Fecal Incontinence: Nursing Management; Mosby, Inc. (2000) pp. 183-207.

5.) Pittman, J., Rawl, S., Schmidt, C.M. et.al. (2008) Demographic & Clinical Factors Related to Ostomy Complications and Quality of Life in Veterans with an Ostomy. Journal of Wound, Ostomy & Continence Nursing, 35(5), 493-503.

TRINITY
IOWA HEALTH SYSTEM

A better experience.

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

Chitang Joshi[1], Shin Young Yu[1], Joshua Weissman[1], Peter Ullrich[1], Reagan Taylor[2], Safwat El Hoseney[3], Robert Galiano[1]

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

Symposium of Advanced Wound Care (SAWC) | Fall 2021 Meeting

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.

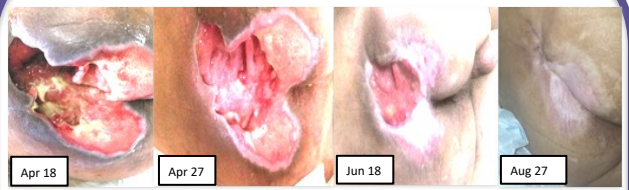
Transforming powder dressing (TPD) forms a non-occlusive barrier on the wound bed that helps optimize wound moisture to promote healing. Extended wear time reduces dressing changes, infection risk and complications, presenting a promising new wound treatment modality

Materials and Methods

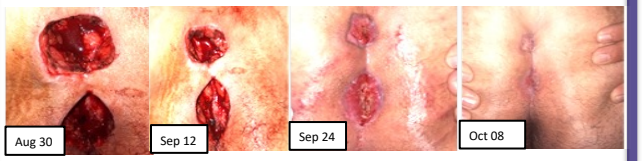
We used a novel methacrylate-based transforming powder dressing, which transforms in-situ to a shape-retentive wound matrix once in contact with moisture. (Altrazeal® TPD, ULURU Inc.).

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.

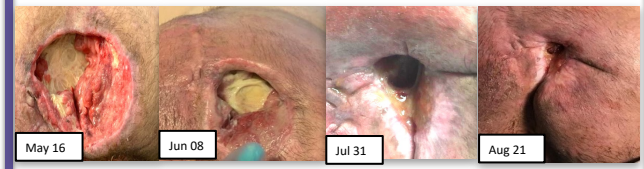
Results



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 PrIs; significantly reducing the duration of healing, patient pain and number of dressing changes.

References

1. Anders, J., Heinemann, A., Leffmann, C., Leutenegger, M., Pröfener, F., & von Renteln-Kruse, W. (2010). Decubitus ulcers: pathophysiology and primary prevention. *Deutsches Arzteblatt international*, *107*(21), 371–382. https://doi.org/10.3238/arztebl.2010.0371
2. Lyder CH, Ayello EA. Pressure Ulcers: A Patient Safety Issue. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 12
3. J K Szor, C Bourguignon. Description of pressure ulcer pain at rest and at dressing change. J Wound Ostomy Continence Nurs. 1999 May;26(3):115-20.

Northwestern

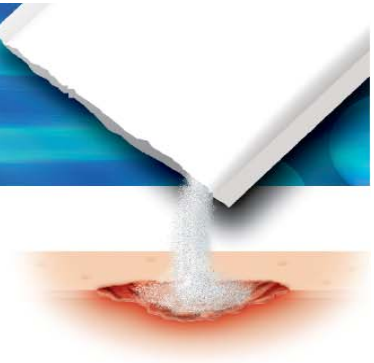
Contact: chitang.joshi@northwestern.edu

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

2010 SAWC Meeting
Orlando, FL

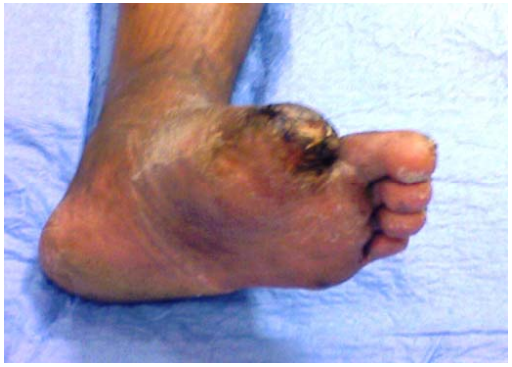
Kelly A Mauro, PT, CWS
Diabetic Foot Clinic
Comprehensive Diabetes Lower Extremity Amputation Prevention
New Orleans, LA

Development of a Protocol for the Treatment and Resolution of Diabetic Foot Ulcers with Clinical Complications

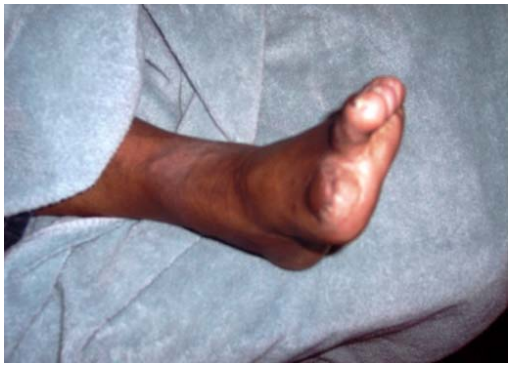


Purpose: The purpose of this evaluation was to test a novel powder wound dressing in the development of a protocol for the treatment of diabetic foot ulcers with mixed concomitant etiologies.
Methods: Wounds with clinical complications including post-op amputation, underlying osteomyelitis, arterial insufficiency and immunosuppression arising from HIV or HCV were studied to determine if a single primary wound dressing can be applied in a protocol that allowed protection of the wound with 7 or 14 day intervals between dressing changes.
The case study presents wounds ranging from 2 years to 4 months in stasis with closure occurring at an interval of 5-10 weeks vs 8-12 weeks in a similar patient population without the application of the primary powder dressing.
The wounds were treated using the novel powder dressing as the primary dressing in contact with the DFU. Th product is applied witha sterile tongue blade. Cadexomer iodine was applied with the powder if the wound had biofilm. The product is used under contact casting with a silicone mesh product used as a secondary dressing between the powder and the cast.
Findings: The case shows shows that the protocol developed with and without offloading allows the application of the powder dressing on the surface of a diabetic foot ulcer. Data is shown for time to healing and photographs of wound progression with dressing changes at 7 or 14 days is shown through healing for all cases.

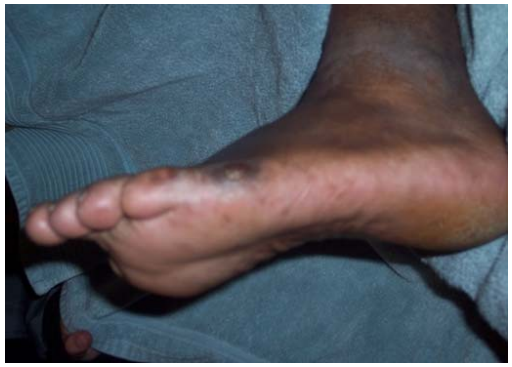
1. Fitzgerald, R, Bharara, M, Mills, J, Armstrong, DG (2009); " Use of a Nanoflex powder dressing for wound management following debridement for necrotising fasciitis in the diabetic foot" International Wound Journal, 6(2): 133-139.



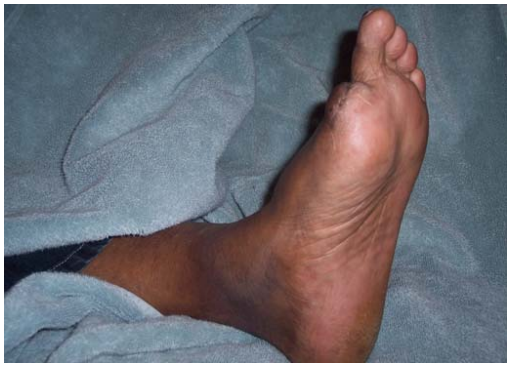
Patient Post Left Distan Hallux Amputation



Hallux Amputation Closed at 5 Months



5th Metatarsal Ulcer Arose 4 Months Post Hallux Amputation



Hallux Amputation Closed at 5 Months

Clinical Treatment:

59 year old patient treated for two months in HBO wound care department. Patient received s/p left distal hallux amputation one month after treatment for ingrown toenail. The patient was presented to the ER with a wound consisting of 80% devitalized tissue, 20% exposed bone and underlying osteomyelitis. Patient received an arteriogram to assess arterial status due to TBI on LLE 0.35 suggesting severe micro vessel disease and critical limb ischemia. Patient was referred to ortho service for rongeur of exposed proximal phalanx of left hallux and Tenoachilles lengthening to provide gait and pressure relief to enhance healing. Patient's offloading was revised due to the onset of a new ulcer prior to surgery at lateral 5th metatarsal head. Post operatively left hallux wounds measured:(1) 0.3x0.6x0.2 cm (2) 0.5x0.9x0.1cm. The 5th MTH measured:0.8x0.7x0.4 cm probing to tendon. The patient was seen every 7-14 days for selective debridement, application of powder dressing, offloading and self-care, and disease management injury and prevention skills. The hallux post operative wounds closed in three months. At month 6, MTH wound was recultured and were positive. The patient was put on oral antibiotics. Cadexomer iodine gel was added to the powder dressing and a second vascular intervention was performed successfully at month 9. The lateral 5th MTH wound closed at month 10.

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

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

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

BACKGROUND

The prevalence of chronic wounds continues to increase to epidemic proportions in the world and currently affects 6.7 million people in the United States.[1] Chronic wounds are challenging for many complicated reasons, and often do not respond to standard of care (SOC) treatments.[2]

OBJECTIVE

The aim of this product evaluation was to evaluate a novel, biocompatible, nonocclusive transforming powder dressing (TPD*) to determine its impact on chronic wounds that were refractory to healing using SOC therapies.

METHODOLOGY

Setting: Four outpatient wound healing centers at University of Pittsburgh Medical Center, a large integrated academic health system with over 20 wound care centers.

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

Procedure:

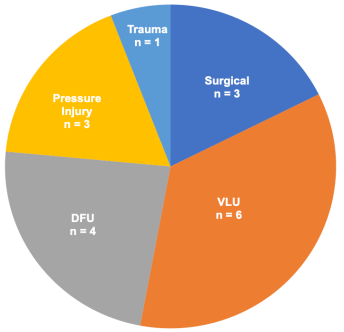
- The product evaluation was first reviewed by and approved by the Value Analysis Team (VAT).
- Each site was able to choose up to 6 patients and provide up to 3 treatments per patient.
- All preselected patients were informed of the product evaluation and consented to participation.
- All wounds were prospectively treated with methacrylate-based TPD, sprinkled into the wound, and hydrated with saline until it aggregated to form a moist, flexible, oxygen-permeable film that contoured and adhered to the wound.
- TPD was covered with a contact layer and secured with rolled gauze. Some patients also received compression wraps or offloading devices as prescribed.
- TPD was topped off or reapplied weekly for 3 weeks and patients were followed for a total of 4 weeks.
- Post TPD application, change in percent volume reduction (PVR) was measured on a weekly basis.

MATERIALS

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

**Altrazeal® Transforming Powder Dressing*

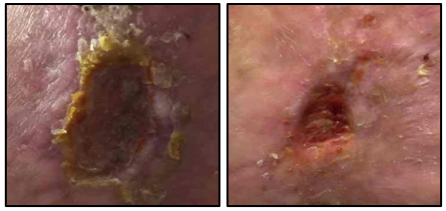
Wound Distribution by Etiology



		Week 0	Week 1	Week 2	Week 3	Week 4	Overall
Patient	Type	Wound Size (cm^3)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)	% Reduction (-) or Increase (+)
1	DFU	97.9	-57%	-86%	0%	-45%	-97%
2	DFU	0.5	-15%	153%	-59%	26%	26%
3	DFU	0.2	-56%	0%	400%	-18%	100%
4	DFU	1.5	33%	7%	-3%	-75%	-87%
5	PRESSURE	0.4	36%	-50%	43%	-44%	-46%
6	PRESSURE	1.6	61%	-31%	-58%	-71%	-86%
7	PRESSURE	0.2	-59%	0%	0%	87%	300%
8	SURGICAL	8.3	-32%	-32%	-9%	-25%	-68%
9	SURGICAL	19.2	-88%	50%	50%	0%	-97%
10	SURGICAL	3.5	-66%	-83%	-50%	0%	-97%
11	TRAUMATIC	1.51	0%	-56%	0%	9%	-52%
12	VLU	1.1	-60%	-57%	0%	-42%	-91%
13	VLU	0.6	-35%	0%	0%	-89%	-83%
14	VLU	1.5	-47%	-25%	0%	-17%	-67%
15	VLU	0.3	40%	-20%	0%	0%	33%
16	VLU	0.6	-17%	20%	17%	-14%	0%
17	VLU	3.9	-0.179	-0.5	-0.375	-10%	-77%
						Mean	-29%
						Median	-68%

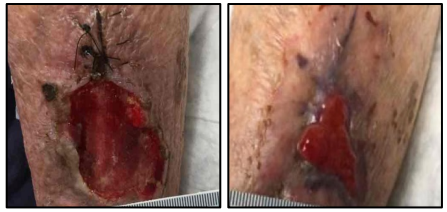
CASE STUDIES

Diabetic Foot Ulcer



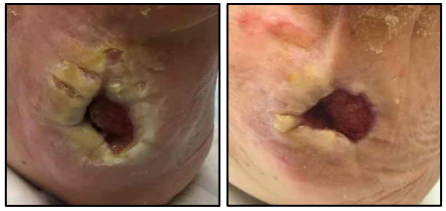
Before TPD | After 3 TPD Weeks

Surgical Wound Considered for Amputation



Before TPD | After 3 TPD Weeks

Diabetic Foot Ulcer



Before TPD | After 3 TPD Weeks

RESULTS AT WEEK 4 (3 TREATMENT WEEKS)

- 19 patients consented to participation; 17 completed the study
  - **Median wound volume reduction (WVR) = 68% in three treatment weeks**
  - WVR reduction observed in 12 patients (71%) / 50% or more patients in each etiology
  - Seven patients (41%) with > 80% WVR
  - 11 (65%) patients with > 50% WVR
- **One 90-year-old patient was deemed "limb salvage:"**
  - Wound volume reduced from 19.2 cm^3 to 0.6 cm^3 in four weeks
  - Wound healed after the study
- **No adverse effects related to the product were reported.** Five patients (29%) had wounds that increased in size for reasons unrelated to TPD

DISCUSSION

The results support that TPD may be a useful therapy for chronic wounds that have failed SOC. A longer evaluation would have been helpful to determine the full impact of TPD on overall healing outcomes.

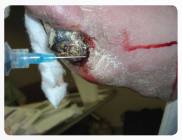
REFERENCES AND ACKNOWLEDGEMENTS

(1) Wound Care Awareness Week Highlights of the Chronic Wound Epidemic in U.S. Businesswire.com/news/home/20160607006326/en/Wound-Care-Awareness-Week-Highlights-Chronic-Wound. Accessed 11/5/2020. (2) Han G, Celery R. Chronic Wound Healing: A review of current management and treatments. Adv. There 2017; 34 (3): 599-610. Ncbi.nim.nih.gov/pmd/articles/PMC5350204/Accessed online 11/5/2020.

Acknowledgements: This poster was developed in collaboration with Altrazeal Life Sciences. No compensation was paid to the authors and all protocols and evaluations were conducted independently. For application instructions and risks of this device please refer to Altrazeal Instructions for Use. | EDU-0042, REV 02

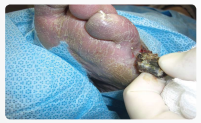
Wound Center Open Toe Amputation: "Stump" Cavity Management with Hydroxyethylmethacrylate Powder Dressing

1



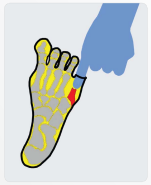
Stable L small toe dry gangrene in a high risk patient.
Problem list: hemodialysis x 8 years, ASPVD S/P 4 perifierial angioplasties with stents, anticoagulation with Coumadin and unstable ischemic cardiomyopathy, prior heel ulcer and finger amputations.
Anesthesia: 5mg of diazepam po, 20cc plain Lidocaine injected as a digital nerve block and as a wide field tumescent block. Tumescent Lidocaine acts to decrease bleeding. Patient is fully anticoagulated with Coumadin.

2



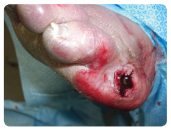
Planned small toe auto-amputation abandoned when wound drains foul smelling pyocyanic green suppurative exudate. Decision to proceed with Wound Center open amputation after patient is unable to be "cleared for surgery" by nephrology and internal medicine due to medical risks.
Working behind a large paper drape the digit is removed with #15 blade at the metatarsal joint capsule. While the #15 blade remains sharp, a circumferential incision is made through viable skin. Traction of the small toe is maintained in line with the 5th metatarsal bone to minimize pain caused by motion. First step is to transect the small toe at the metatarsal join. Second step is to resect one third of the metatarsal bone with a rongeur.

3



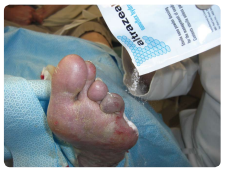
Removal of adequate metatarsal bone is a surgical challenge. One third of the distal 5th metatarsal has been removed with a double action rongeur. The surgeon's small finger guides the blind metatarsal resection by Braille. Repeat cavity palpation with the small finger assures that bone fragments are removed and that the bone end is "smooth."

4



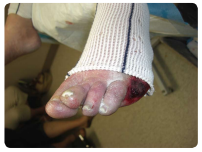
The resulting amputation cavity is 3.5 to 4.0 cm deep. Removing 1/3 of the 5th metatarsal bone is key to healing. To dependably heal, the transected bone end must be covered with adequate soft tissue. Note that the ragged cavity wall appears viable. Note bleeding is minimal because of tumescent Lidocaine. Direct pressure on the wound quickly controls bleeding in spite of anticoagulation with Coumadin.

5



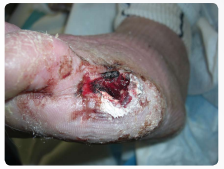
Open small toe amputation cavity is packed with powder using the surgeon's finger to pack the cavity open. The surgical principal of wide open packing keeps the skin edges open. An open wound allows time for the macrophages to deal with devitalized tissue and colonized bacteria. An open wound prevents anaerobic conditions. Macrophages are able to survive.

6



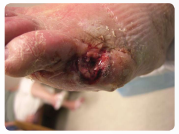
Note how well powder packs the cavity open. Early "stump cavity" packing is known to be an important surgical principal. Following the rongeur debridement, the cavity has a high burden of foreign material that will cause late infection if not removed.
After open amputation, the cavity contains a burden of devitalized fat, clot, joint capsule, tendon, and fragments of bone. Powder forms a rubbery gel in the cavity. The gel has adequate tensile strength to be removed in one piece. Each time the cavity is repacked with powder, necrotic tissue is removed.
The white textile is Longitudinal Yarn Compression** (LYC). LYC textile controls edema that accompanies the considerable surgical trauma resulting from the 5th metatarsal osteotomy. Edema decreases skin perfusion. As hand surgeons know, edema is the enemy of healing after digital amputation.

7



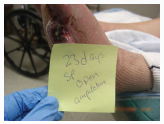
Open amputation cavity, POD # 6. Note absence of redness and excellent perfusion of the skin edge. Note that edema has been controlled by Longitudinal Yarn Compression textile. LYC has created corrrow furrows on the foot.

8



Stump cavity POD #14. Granulation tissue now covers the bone in the base of the amputation cavity. This is remarkable in the face of bacterial colonization, profound arterial ischemia, devitalized tissue in the cavity walls and the daily blunt trauma resulting from ambulation. Note the lack of peri-wound edema and the presence of skin corrrow furrows resulting from the yarn focused textile.

9



POD #23. Cavity is now closed, remarkably, over the 5th metatarsal bone osteotomy. No further powder packing is required. Patient died shortly after this photo due to heart failure.

Laura Landon-RN
Manager, Bergan Mercy Hospital Wound Care Clinic-Omaha, Nebraska

Pam Chelesvig-BS
Director of Human Research, Kohll's Corporation-Omaha, Nebraska

Martin Winkler-MD FACS
Creighton University College of Medicine-Omaha, Nebraska
University of Nebraska College of Medicine-Omaha, Nebraska

Behavioral Objectives:
- Define advantages of open toe amputation in the face of infection and ischemia.
- Review anesthesia and surgical technique, step by step, for wound center open toe amputation.
- Understand options to manage post operative "cavity" healing in the face of exposed metatarsal bone.

Background
Open toe amputation is easy to perform in the wound center environment. (1) A three centimeter deep cavity results from resection of the distal third of a metatarsal bone. This "stump cavity" heals slowly creating a considerable management challenge. Open amputations dependably heal in spite of profound ischemia and infection because devitalized fat, tendon, cartilage, clot and bone are not trapped beneath suture line. Skin edge perfusion is not decreased by suture tension. Anaerobic conditions do not occur.

Negative Pressure Wound Therapy (NPWT) has improved "stump cavity" healing at the cost of limiting patient ambulation. Device necrosis, technical problems and high cost remain significant complications of NPWT.(2)

NPWT draws # sol from the wound surface via a mechanical vacuum.
Hydroxyethylmethacrylate 78 nm , a novel powder wound dressing, packs nicely into the cavity forming a durable gel that draws water from wound interface via capillary, not osmotic, action. Said another way, the geometry generates a high Moisture Vapor Transpiration Rate (MVTR).
(3, 4) This anecdotal study supports the hypotheses that is an effective dressing for open amputation cavity.

Methods: Step by step operative technique and stump cavity healing over time are illustrated with photos in one ambulatory dialysis dependent patient with dry gangrene due to ischemia.

Outcomes: Photographs document healing.

Conclusions: Hydroxyethylmethacrylate 78 nm is a novel, cost effective, therapy for stump cavity management after ambulatory open toe amputation.

References:

(1) Kaufman, Jeffrey L., Stark, Karl, Shah, Dhiraj M., Chang, Benjamin B., Kadros, Alan S. and Leather, Robert P. "Local anesthesia for surgery on the foot: Efficacy in the ischemic or diabetic extremity." Journal Annals of Vascular Surgery, Volume 5, Number 4, July, 1991

(2) Andros, George MD, Neogoda, Jeffrey A, MD, FACHM, FACEP. "Consensus Statement on Negative Pressure, Wound Therapy (V.A.C.® Therapy) for the Management of Diabetic Foot Wounds: Should small, superficial wounds be considered for V.A.C.® Therapy?" Supplement, Ostomy Wound Management, June 2006.

(3) Fitzgerald, R., Bharara, M., Mills, J., Armstrong, DG. "Use of a Nanofiber powder dressing for wound management following debridement for necrotizing fasciitis in the diabetic foot." International Wound Journal (2009), 6(2): 133-139.

(4) Martin, Barry D. MD, FACS, LTC(R), Medical Corps, USA. "Comparison in Management of Large, Open Combat Wounds in Service Personnel Using Negative Pressure Wound Therapy and a Novel Powder Dressing." Poster Presentation 2009 SAWC Meeting Grapevine, Texas

***Altrazeal™ Uluru Corporation-Addison, TX 75001**
****EdemaWear" Compression Dynamics-Omaha, Nebraska 68132**

National Science Foundation Grant Award Number: 0650233

University of Nebraska Medical Center

Creighton University School of Medicine

www.CompressionDynamics.com
www.UluruInc.com

A novel treatment protocol for the management of nonhealing surgical wounds

Authors:
Jennifer Eingle, PT, DPT
Advanced Wound Care Team Leader
Peoplefirst Rehab. Indianapolis, IN

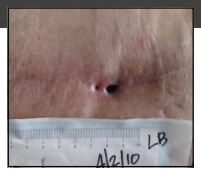
Jodie R. Harper, MD, CWS
Wound Care Specialists of Indiana
Indianapolis, IN

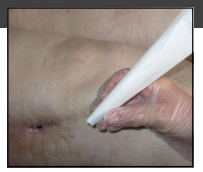
Purpose

The purpose of this evaluation was to test a novel protocol in the management of nonhealing surgical wounds using a novel transforming powder dressing (TPD) to decrease the frequency of dressing changes.

Conclusions

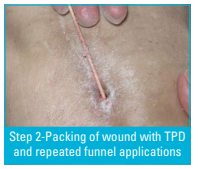
The study indicated that the use of the TPD[1] on nonhealing surgical wounds with a silicone mesh with adhesive border allows for applications of a moist wound dressing for periods of up to 7 days without dressing change. The technique to the right allows the TPD to be applied to a nonhealing surgical wound with depth and retained in place using an adhesive border dressing:





C-Nonhealing surgical wound with depth
1-Nonhealing surgical wounds with depth can be treated by packing the wound with TPD[1]. This is typically accomplished using a modified funnel.
2-Packing the TPD with a sterile probe between applications as the powder aggregates.

Step 1-Transfer of TPD into deep wound using "funnel technique"



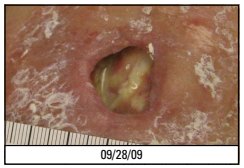
Step 2-Packing of wound with TPD and repeated funnel applications

Step 3-protecting periwound

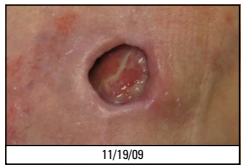
Step 4-Application of adhesive border dressing with breathable foam pad

3-The periwound is cleaned and treated with a protective skin barrier[2].
4-An adhesive border dressing[3] is applied over the wound insuring that the adhesive does not contact the aggregated TPD. Typical dressing changes including TPD is weekly.

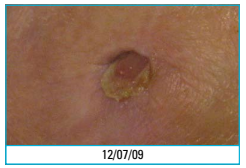
Products
[1]-Altrazeal[tm] Transforming Powder Dressing - ULURU, Inc.
[2]-Prep Protective Skin Barrier - Coloplast, Inc.
[3]-Mepilex[tm] Border - Molnlycke Healthcare



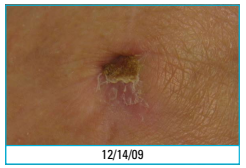
09/28/09



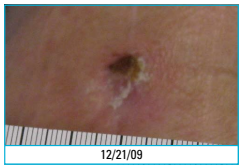
11/19/09



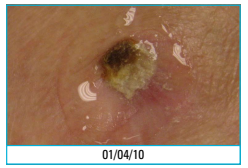
12/07/09



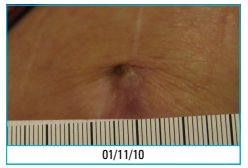
12/14/09



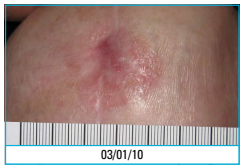
12/21/09



01/04/10



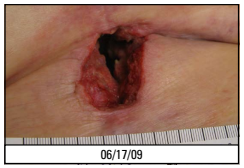
01/11/10



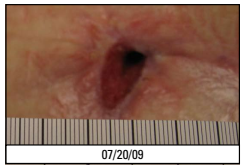
03/01/10

PATIENT: 80 yo female presented to wound center on 9/21/09 with nonhealing surgical wound to left knee following trauma requiring I&D of the prepatellar bursa in March 2009. The wound measured 2.0 x 1.8 x 1.2 cm with undermining at 12 to 12 o'clock, deepest to 2.7 cm. **PMH:** CHF, hypertension, hypthyroidism, osteoarthritis.

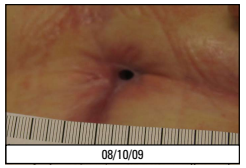
WOUND CENTER COURSE: The Patient required excisional debridement and enzymatic debridement with Santyl® for 4 weeks and then changed to Prisma™ collagen daily using NU GAUZE® to fill in the dead space (1.5 x 1.5 x 0.7 cm with u/m from 10–12 to 2.8 cm). The Patient wasn't improving so 4 weeks of OASIS® and Iodoflex™ from 11/9–11/20 improved wound to 0.8 x 0.5 x 0.5 cm with u/m to 1.0 cm. 12/7/09: First application of the TPD[1], the wound measured: 0.8 x 0.5 x 0.2 cm with u/m at 12 o'clock to 1 cm. 12/14/09: Second application of the TPD with measurements of 0.5 x 0.3 x 0.2 cm with u/m at 12 o'clock to 0.3 cm. 12/21/09: Third application of the TPD with measurements of 0.4 x 0.2 x 0.1 cm with u/m at 12 o'clock to 0.2 cm. 12/28/09: f/u visit, the TPD in place and dry, left intact: 0.5 x 0.5 x 0 cm, no depth, no u/m. 1/4/10: Forth application of the TPD the wound measured 0.2 x 0.2 x 0.1 cm, no u/m. 1/11/10: The Patient healed. At f/u visit on 3/1/10, wound remained healed with no complications.



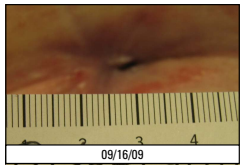
06/17/09



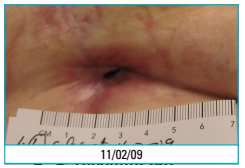
07/20/09



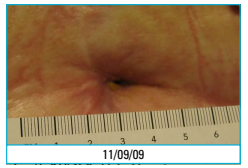
08/10/09



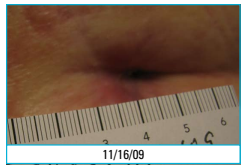
09/16/09



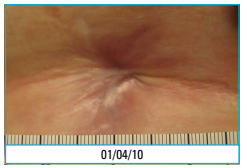
11/02/09



11/09/09



11/16/09

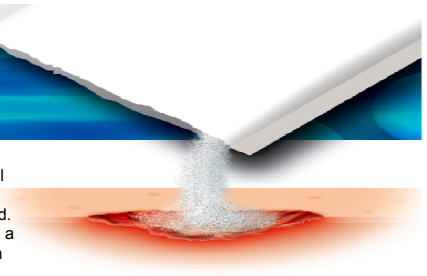


01/04/10

PATIENT: 72 yo female on 3/19/09 with nonhealing surgical wound to her anterior chest wall. The Patient was s/p coronary artery bypass in 9/08 that was complicated by sternal wound infection requiring surgical debridement followed by complete reconstruction of her sternum covered with flap in 10/08. Despite treatment with KCI Wound VAC, the Patient required further surgical debridement including infected bone on 6/11/09 and also received 6 weeks of IV daptomycin. **PMH:** CAD s/p CABG (as above), DM, type 2 on insulin. **WOUND CENTER COURSE:** Initial visit after surgery on 6/17/09, the wound measured 5.2 x 3.4 x 4.2 cm with undermining at 12 o'clock to 2.9 cm and at 3 o'clock to 3.0 cm. We resumed KCI VAC therapy. The wound improved with KCI VAC therapy which was d/c'ed on 7/20/09 due to size limitations (2.0 x 1.2 x 1.3 cm with u/m at 2 o'clock to 4.8 cm). Between 7/20/09–10/5/09, multiple wound products including Mesalt® packing strips, Hydrofera® Blue rope, Fibracol® Plus collagen, PolyMem Silver® WIC rope, and Multidex® powder were used with minimal improvement (1.0 x 1.1 x 1.0 cm with u/m at 2 o'clock to 3.2 cm). Since the wound had stalled at that size, OASIS was used weekly x 4 from 10/5/09–10/26/09 with measurements improving slightly to 1.0 x 0.5 x 1.0 cm with u/m to 3.2 cm. First application of the TPD[1] was 11/2/09 and in 1 week wound measurement decreased to 0.3 x 0.2 x 1.0 cm with u/m to 1.5 cm. The TPD as reapplied on 11/9/09 and the Patient was healed at her next visit on 11/16/09. F/u visit on 1/04/10 revealed well healed scar.

Michael S. Miller DO, FACOS, FAPWCA, CWS
The Wound Healing Centers of Indiana Indianapolis, IN

Treatment of Post-Operative Chronic Abdominal Wounds Using a Novel Powder Wound Dressing



Objectives

Upon viewing this poster, attendees will have observed the treatment of post-surgical abdominal wounds that have shifted from an acute postoperative stage to a chronic-non-healing stage.

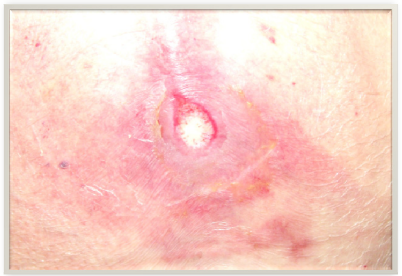
Attendees will also see the results of the application of a novel powder dressing which allows the coverage of these wounds in a region where torsion and strain can make retaining a dressing difficult.

Introduction

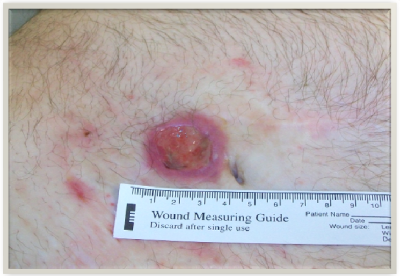
Healing postoperative wounds is problematic due to their location in positions not conducive to standard dressings, tendency towards dryness and the many etiologies of the failure to heal. Abdominal wounds pose their own set of problems in that they are on areas that are in constant motion which reduces the adherence of the dressings, and their position makes application and adherence difficulty due to gravity. A typical patient with a non-healing post-operative abdominal wound can also have fragile skin in this location so minimal adhesive and fewer changes are desirable traits in the choice of dressing. Pain is also a significant factor in patient care. We report on the use of a novel powder dressing in the treatment of two cases involving non-healing post operative wounds in the abdomen.

Case 1

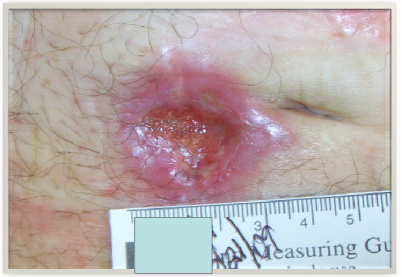
A 58 year old male patient presenting with an open draining wound of the abdomen which had been present for 6 months. The patient had undergone 4 previous ventral hernia repairs the last of which was 4 years prior and used mesh in the repair. The patient had a history of Staph infections of the wound which necessitated treatment with IV antibiotics. Previous treatments to this wound included topical antibiotics, dry gauze and topical steroids and the wound remained in stasis for the 6 month period. He reported pain as a "6" on a 0 to 10 scale when initially presenting. Sharp debridement of the wound was performed and one week later, the wound was covered with a novel powder dressing. The 4.1 cm X 3.4 cm X .4 cm. Pain decreased to a 1 on the same scale since initiation of Altrazeal. The wound has shown a decrease in depth with some improvement in granulation bed.



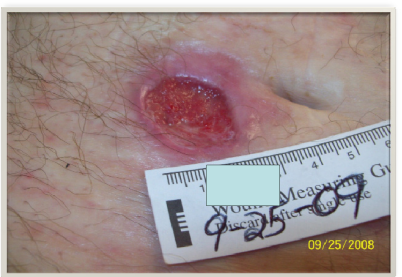
Initial Treatment



2 Months



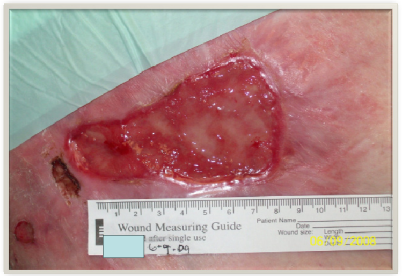
4 months



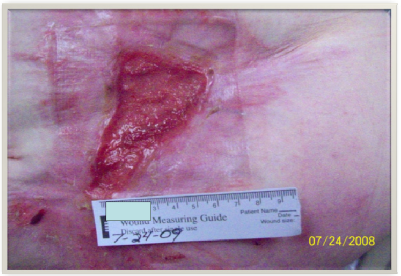
5 months

Case 2

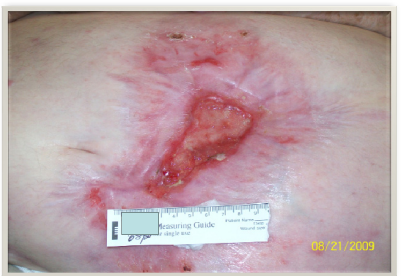
A 74 year old male patient presenting with an incisional dehiscience. The patient underwent repair of an abdominal aortic anyeurism 1 month prior and the dehiscence occured 1 month after surgery. The patient had been undergone treatments including VAC, topical antibiotics, and simple dry dressings with the patient doing his own care for the 4 months prior to referral. After initial evaluation, aggressive debridement of the wound was performed with initiation of treatment with the powder wound dressing commencing one week later. Initial measurements of the wound were 10.6 cm X 6.0 Cm X .5 cm. Pain prior to treatment was a "4" on a scale of 0 to 10 and decreased to a "0" after two weeks of treatment. The periwound has shown some decrease in erythema and the wound depth has decreased with improvement in the granulation bed appearance.



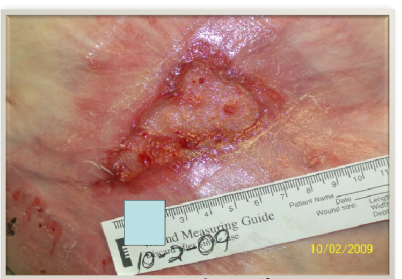
Initial Treatment



2 Months



3 months

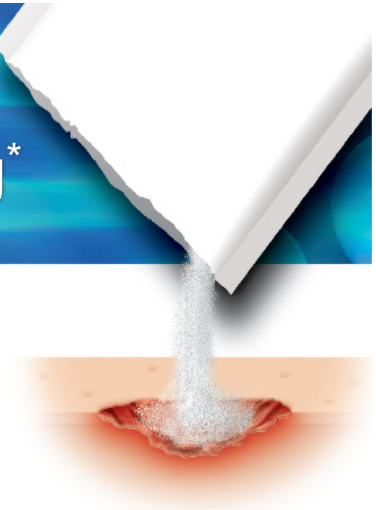


4 months

2009 APWCA Conference
Philadelphia, PA.

Stephanie Bixler,
MSN, CANP, CWCN,AAPWCA
Wound Care Nurse Practitioner
Marshfield Clinic Rice Lake Center
Rice Lake, Wisconsin

Treatment of a Rheumatoid Nodule Surgical Wound with a Novel Powder Wound Dressing*



Introduction:

A rheumatoid nodule is a local swelling or tissue lump which occurs almost exclusively in association with rheumatoid arthritis. The nodules are usually subcutaneous especially over bony prominences such as the tip of the elbow or olecranon or over the finger knuckles. In some cases the nodules can be painful, especially if the overlying skin breaks down and patients opt to have the nodule removed surgically.

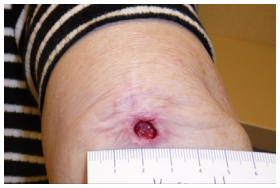
Background:

A 57 year old Caucasian female was referred to the wound care clinic for a non-healing surgical wound of the right elbow created during removal of a rheumatoid nodule. The surgical wound dehisced and remained open 5 weeks post surgery. The patient had a history of similar non-healing surgical wounds from nodule resections in the past complicated by osteomyelitis. The patient was on chronic steroids for rheumatoid arthritis. Treatment was complicated by difficulties in compliance with dressing changes. The wound had been treated with daily dressing changes using triple antibiotic and gauze.

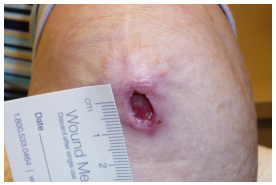
Upon examination, the wound was present on the right arm at the elbow on the lateral olecranon measuring 9 mm in length and 6 mm in width. The depth was 2 mm and there was undermining from 10 to 12 o'clock of approximately 10 mm. The undermining tissue was fibrous and the remaining tissue was red and granulating. There was no evidence of infection. The patient complained of discomfort and pain while sleeping. The patient was treated with a woven hydrocolloid dressing that was covered with an adhesive secondary dressing which was to be changed every three days. Dressing changes were difficult due to discomfort and the wound location.

Treatment:

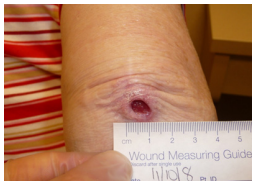
A novel powder dressing, was placed on the wound as treatment with an extended wear time based on the manufacturer claims. It was hoped that the ability of this dressing to stay in place for longer periods would allow the patient to have infrequent dressing changes between visits. The dressing is presented as a powder and was applied by pouring the powder directly onto the wound. The powder transforms into a solid, flexible dressing in the presence of exudate or normal saline. More powder was added alternating with saline until a plug formed filling the wound to the surface of the skin. The patient was sent home for one week prior to another dressing change and this procedure was repeated with each office visit until the wound completely healed.



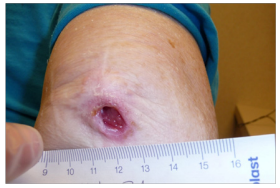
Day 0 of treatment



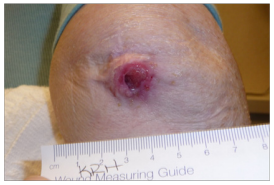
Day 4 of treatment



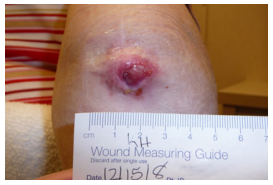
Day 11 of treatment



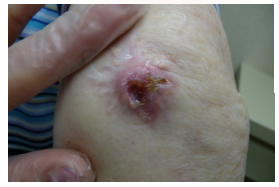
Day 21 of treatment



Day 40 of treatment



Day 47 of treatment



Day 61 of treatment
Wound Healed

Visit	Examination	Treatment	Patient Comments
1-Day 0 of treatment	Wound measures 0.9 x 0.6 cm with depth of 0.2 cm and undermining of 1 cm. No infection	Sharp debridement, irrigation, powder dressing applied	Dressing comfortable and in place
2-4 days of treatment	Wound measures 0.8 x 0.5 cm with depth of 0.2 cm and undermining of 0.8 cm. Granulation bed robust, some new epithelialization, and no infection present	Wound irrigated, powder dressing applied	Patient did not need to change the dressing , no strikethrough dressing noted, decrease in pain
3-12 days of treatment	Wound measures 0.7 x 0.5 cm with depth of 0.1 cm and undermining of 0.5 cm. Contracture and epithelialization present	Wound irrigated, powder dressing applied, contact layer used to cover powder, secured with tape.	Patient notes better sleep with decreased pain. Patient would like to extend periods between dressing changes.
4-21days of treatment	Wound measures 0.5 x 0.6 cm with no depth and undermining of 0.8 cm.	Wound irrigated, powder dressing applied, contact layer used to cover powder, secured with tape	Patient did not change dressing, noted no drainage, and has been pain free
5-26 days of treatment	Wound measures 0.5 x 0.5 cm with no depth and undermining of 0.8 cm. New granulation tissue noted in undermining area	Wound irrigated, powder dressing applied, contact layer used to cover powder, secured with tape	patient noted no drainage and the dressing stayed in place. Patient did note some itching at wound margins
6-35 days of treatment	Wound measures0.5 x 0.3 cm and undermining of between 0.2 and 0.4 cm. Undermining track filled with granulation tissue. Dressing was dry and some redness around the wound with crusting on cover dressing. Possible microbial contamination	Wound irrigated, powder dressing applied. Ag mesh applied fixed with tape.	Dressing remained in place. Patient reports some pain at wound site between visits.
8-47 days of treatment	Wound measures 0.3 x 0.4 cm with undermining of 0.4 cm. Wound is 50:50 granulating and epithelialized tissue.	Wound irrigated, powder dressing applied. Ag mesh applied fixed with tape.	Dressing is comfortable with no pain.
10-54 days of treatment	Wound is insignificant with small area of granulating bed. Remainder of wound epithelialized	Wound irrigated, powder dressing applied. Ag mesh applied fixed with tape.	Patient reports no pain and complete freedom of movement. Patient hopes this is last visit. Patient reports that this is faster healing than previous nodule surgical wounds
11-61 days of treatment	Wound healed	Wound healed. Skin washed and covered with gauze and tape. Patient agreed to protect new skin for 2-4 weeks.	Patient wound has remained healed for nearly four months post treatment.

* Altrazeal Transforming Powder Dressing

Gregory Bohn MD, FACS
Medical Director
Trinity Center for Wound Care
and Hyperbaric Medicine

Graft Fixation and Wound Moisture Management with Transforming Powder Dressing*

TRINITY IOWA HEALTH
A better experience.

Introduction

Skin grafting is a fundamental method to repair skin defects and heal chronic wounds. Graft fixation and maintaining the wound environment is essential to the success of split or full thickness skin grafting. Skin grafts survive the first 24-48 hours as the result of serum imbibition. The graft is bathed in serum from the wound that supplies its nutrients via capillary action keeping the graft alive. Fixation methods prevent shear and slipping of the graft so as to hold it secure on the wound bed. Fixation allows the process of inosculation to occur as capillary buds in the wound bed align and grow into the vascular channels of the graft. Both of these processes are important for graft success and prevent graft loss.

Hypothesis

A new powder wound dressing technology can be utilized to "anchor" a meshed autograft or bio engineered skin substitute** in place on a wound without the use of fixation such as sutures or staples.

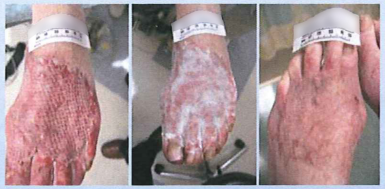
Materials and Methods

Transforming powder dressing was used to fix split thickness skin grafts and bio engineered skin substitutes. Skin grafts were harvested at 0.012 to.015 inch. The grafts were messed 1:1.5 and applied to the wound bed. Transforming powder was applied and aggregated fixing the grafts in place. Skin grafts were checked at weekly intervals until graft take was assured and documented.

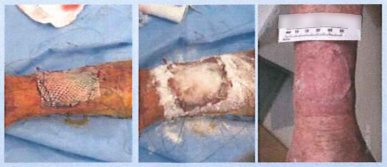
Bio engineered skin substitute was meshed 1.5:1 and applied to wounds. The graft was fixed with transforming powder dressing. Wounds were followed at weekly intervals. If necessary, Bioengineered skin substitutes can be re-applied at 2 week intervals.

The technique was tested on two cases involving autologous mesh grafts harvested as 0.015 inch thick split thickness grafts. One case was a debrided third degree burn on the dorsal left foot. The second case involved a surgical excision where the graft did utilize limited suture fixation. In both cases with autologous grafts, the transforming powder dressing was not changed after application.

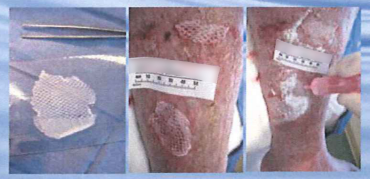
The technique was tested on two cases where living skin equivalent was meshed and applied directly to a debrided venous ulcer or DFU. In these cases, the powder dressing was left in place over the living skin equivalent for two weeks then the wound was cleaned and a new application of living skin equivalent was applied to the wound with another application of transforming powder dressing.



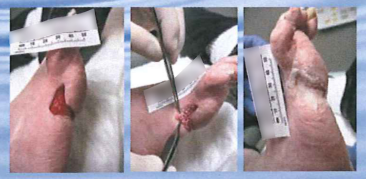
Case 1: Third degree burn debrided and treated with 0.0015 in ch split thickness skin graft meshed 1:1.5. Sutures and clips were not applied to this graft.



Case 2: Surgical excision site grafte with 0.015 inch autologous split thickness skin graft meshed 1:1.5. Sutures were used to anchor the edges of the graft.



Case 3: Venous Stasis Ulcer treated with Living Skin Equivalent fixed in place using Transforming Powder Dressing.



Case 4: Diabetic foot Ulcer treated with Living Skin Equivalent fixed in place with Transforming Powder Dressing. Patient was offloaded with a contact cast.

CONCLUSIONS

Transforming powder dressing can be employed as a method of graft fixation for both split thickness skin grafts and bioengineered skin substitutes. Whether applied in the operating room using split thickness skin grafts or in the clinic with bio engineered skin substitutes, the material remained in place with the grafts. The grafts were meshed and the powder material filled the spaces in the graft and securing it in place.

This method simplifies the use of bioengineered skin substitutes in the clinic setting and avoids problems with disturbing the grafts with dressing changes. Maintaining the moist wound environment without fluid build up is an important aspect of grafting and a material that optimizes the wound moisture while securing the graft in place can be beneficial. Graft take can be improved and optimize the effectiveness of these commonly used wound care products.

One other important finding from this study is that this technique of graft fixation can be used under compression wraps or in conjunction with contact casting.

REFERENCES

1. Siemionow M, Nasir S. Immunologic responses in vascularized and nonvascularized skin allografts. *J Recon Microsurg*. 2008;24:497-505.
2. MacFarlane DF. Current techniques in skin grafting. *Adv Dermatol*. 2006;22:125-38.
3. Schneider AM, Morykwas MJ, Argenta LC. A new and reliable method of securing skin grafts to the difficult recipient bed. *Plast Reconstr Surg*. Sep 1998;102(4):1195-8.
4. Zaulyanov L, Kirsner RS. A review of a bi-layered living cell treatment (Apligraf) in the treatment of venous leg ulcers and diabetic foot ulcers. *Clin Interv Aging*. 2007;2(1):93-8
5. Donohue KG, Carson P, Iriondo M, et al. Safety and efficacy of a bilayered skin construct in full-thickness surgical wounds. *J Dermatol*. Aug 2005;32(8):626-31.

*Altrazeal ®Transforming Powder Dressing-ULURU, Inc.
** Apligraf ®-Organogenesis Inc.

Comparison in Management of Large, Open Combat Wounds in Service Personnel Using Negative Pressure Wound Therapy as Standard of Care and a Novel Powder Dressing

Barry D. Martin, MD, FACS, LTC(P), Medical Corps, USA
Chief, Integrated Plastic Surgery Service, Consultant to The Surgeon General in Plastic Surgery
Walter Reed Army Medical Center/ National Naval Medical Center Washington, DC/ Bethesda, MD

2009 SAWC Meeting
Grapevine, Texas

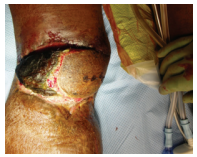
Home of Warrior Care
WALTER REED ARMY MEDICAL CENTER

Introduction

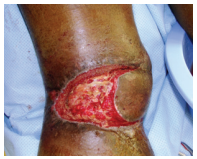
Combat trauma produces wound patterns that are seldom observed in civilian hospitals and require complicated surgery and post-operative care. The damage created by explosive devices depends on a number of factors, including the type of explosive, and the environment within which the detonation takes place. Injuries are dependent on the power of the explosion, the proximity of the casualty to the explosion and the environment (open or confined). When the energy of an explosion is directed towards tissue it creates a wound that is catastrophic to deep tissue and that will require surgical reconstruction until fully healed. In addition, this type of wound is universally accompanied by penetrating shrapnel which carries bacteria deep into the wound. Currently blast wounds in Uniformed Services Hospitals are managed uniformly with negative pressure wound therapy (NPWT), which is used to stabilize the wound, remove bacteria from tissue, and ultimately provide a well-vascularized granulation bed suitable for subsequent grafting.

This set of cases details the post-operative management of three combat trauma wounds where a combination of NPWT and a novel powder dressing are used to achieve closure.

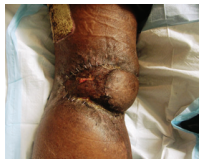
Saphenous artery fasciocutaneous flap coverage of a posterior popliteal wound with exposed nerve from a rocket-propelled grenade attack in Iraq.
Patient is a healthy 38 year old male with a concominant closed head injury.
Initial treatment was serial debridements with VAC coverage for ten days. The procedure was complicated by superficial skin necrosis which was managed by debridement and NPWT (4 days) followed by skin grafting covered with the powder dressing for 10 days.
Patient is now five months post-injury with a healed wound pending secondary nerve grafting.



Partial Flap loss
Pre-debridement



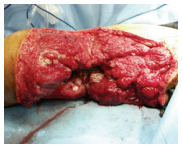
Post-debridement



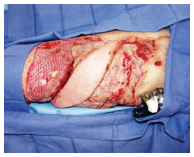
2 weeks post grafting

Latissimus dorsi myocutaneous free-tissue transfer with large skin grafts to the wound 2 weeks following injury.
Patient is a 26 year old male healthy medic who suffered an open fracture of his anterior knee/thigh with large soft tissue loss.
Initial pre-flap management was serial debridement and VAC dressings. Post-flap dressings were NPWT as a bolster over the recipient graft sites and the powder dressing to his skin-graft donor sites and the recipient site following removal of NPWT. The graft sites required two additional applications of the powder dressing until complete re-epithelialization occurred at 3 weeks following flap procedure.

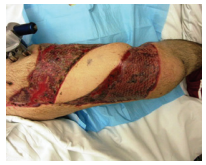
Patient is now 3 months post-op with a healed wound and ambulatory. He is also currently being treated by osseous distraction/lengthening of his femur fracture. Patient will require subsequent tendon grafting to improve knee extension power.



Initial Wound following debridement
NPWT, and external distractor

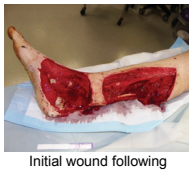


Flap inset with
Surrounding Skin Grafts

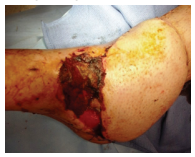


Three weeks post-op

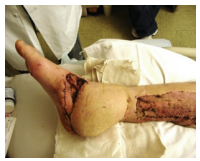
Anterolateral thigh free-tissue transfer and large skin grafting five months ago.
Patient is a 22 year old male healthy infantry soldier who suffered an IED blast injury to his lower leg and ankle with an open ankle fracture, exposed tendons and a segmental nerve deficit. The other injury was a traumatic below-knee amputation of the opposite leg.
Initial management was serial debridement, NPWTfor 10 days prior to free flap.
Post-op management was NPWT bolster over skin grafted areas with transition to powder dressing for two weeks (three applications required).
Patient is completely healed, ambulatory and awaiting nerve grafting



Initial wound following
debridement, and NPWT,



One week post free flap, powder
wound dressing in place



Three Weeks
Post Grafting

Discussion

Complicated trauma cases involve detailed assessment and planning prior to reconstructive surgery. The choice of techniques for post-operative management is critical and can often be overlooked after the surgical procedure is completed. For trauma cases involving reconstructive surgery with flaps or skin grafts, the conventional choice is NPWT or bolster dressing(s). These techniques are viable and functional options. A novel powder dressing was evaluated as a choice for covering and protecting a flap or mesh STSG after the application of NPWT. This technique was evaluated to determine if it was possible to transition from NPWT to the use of a unique powder dressing for closure. The data set is limited, however, the powder dressing does appear to cover and protect a wound during closure with dressing changes at intervals between 3 and 7 days.

Conclusions

It is possible to transition from NPWT to the use of a novel powder dressing in post operative care of combat trauma cases involving reconstructive surgery. Further studies as to the timing of the transition would benefit the development of best clinical practice for the use of this novel dressing.

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

Brett Arnoldo, MD, Associate Professor, Department of Surgery, University of Texas Southwestern Medical School

Gary Purdue, MD, Professor, Department of Surgery, University of Texas Southwestern Medical School

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

John V. St. John, PhD, Vice President, Research and Development, ULURU, Inc.

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

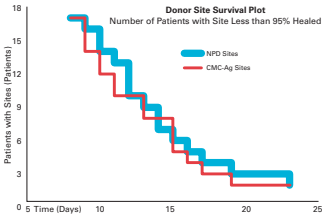
	PWD	CMC-Ag
Number of Subjects	19	19
Size (cm²)		
Mean (SD)	264 (281.9)	229 (157.3)
Median (Min-Max)	154 (36, 1008)	197 (64, 759)

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	

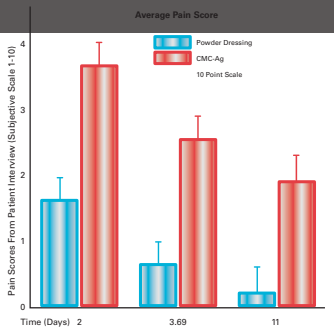
a p-value from matched-pair t-test.

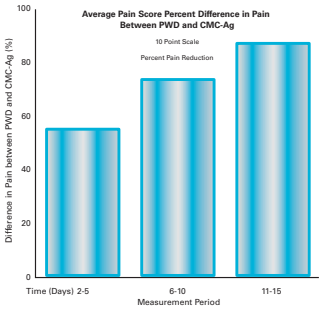
Pain Scores

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.

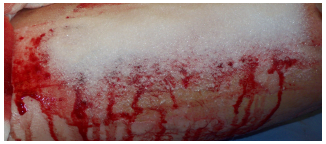
The clinical study personnel instituted a "second check" procedure to confirm site A and site B and which packet was to be applied to each. This deviation was not expected to impact either the safety of the subjects, or the validity of the data collected from these 2 subjects.

Donor Sites as Wound Healing Model

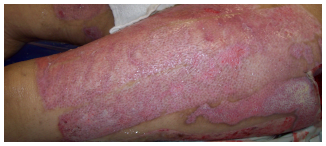
The use of donor sites as wounds in a healing model provides for a reproducible wound but also makes wound healing endpoint comparisons difficult for comparative treatments since the wound is partial thickness and acute. Thus the result of equivalent healing timepoints was not unexpected.

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

This study was funded by ULURU, Inc., Addison, Texas.

*Altrazeal™ Transforming Powder Dressing

2009 SAWC Meeting
Grapevine, Texas

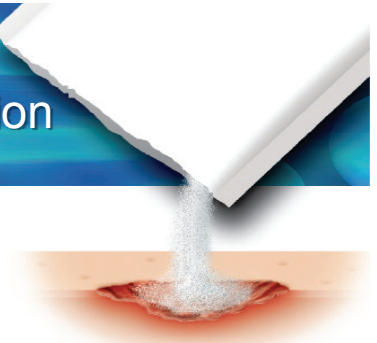
James Gleaves, MD, FACS

Kim Eldridge, RN, CNOR, RNFA, CFCN, WCC

Rush Hospital
Wound Care, Hyperbaric and Limb Salvage Center

Meridian, Mississippi

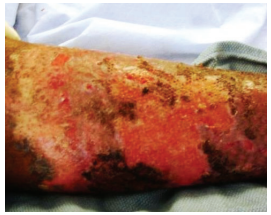
A New Treatment in Mesh Skin Graft Procedures Using A Novel Powder Dressing for Clipless, Sutureless Graft Fixation

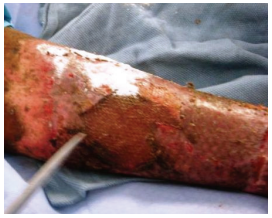


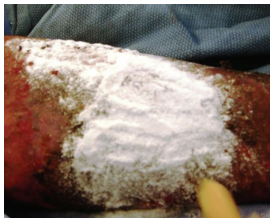
Objective
The objective of this presentation was to evaluate a technique for the fixation of a split thickness skin graft (STSG) using a novel powder dressing with different graft locations and different methods of external fixation including a sutureless, clipless graft.

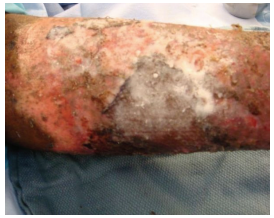
Patient History
72 year old male with history of hypertension, arthritis, urinary incontinence, heavy tobacco usage, deafness and low pain threshold.

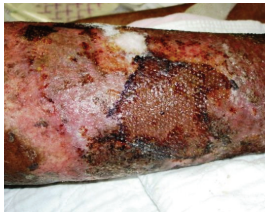
Wound History
Patient received burn to lower left leg. During ER visit, the burn was treated with silver sulfadiazine cream. Patient complained of severe pain; patient was prescribed hydrocodone pain reliever. Dressings were changed daily in Home Healthcare situation. Patient compliance and pain tolerance made dressing changes problematic. The burn showed no improvement for two weeks.

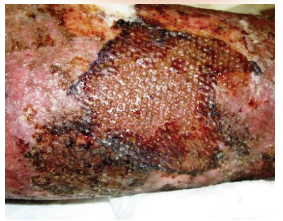

Burn Prior to STSG Procedure


Mesh STSG in Place


Powder Dressing Applied


Powder Dressing Hydrated and Transformed


Post Op Day 5, Dressing in place


Post Op Day 5, Dressing Removed, 100% Take

Introduction
The ability to cover and protect a STSG easily with few dressing changes while managing fluid and preventing infection represents a list of attributes that are a proverbial "gold standard" for a dressing over a mesh graft. The importance of proper wound bed preparation including sharps debridement and management of microbial contamination followed by good surgical technique in graft harvesting and placement can not be understated in terms of successful outcomes. However, following surgery the "take" of the graft on the underlying bed is impacted by the management of the fragile tissue and the interface between new tissue and the wound. In protecting the graft during take, two primary factors to consider are fluid and moisture management, and immobilization. Common techniques for managing both include bolstering with foam and other padded dressing materials, and negative pressure wound therapy systems. Both of these techniques manage fluid and provide necessary pressure but the graft is typically held in place with sutures or clips (staples) and each technique has complications associated with dressing changes or equipment.
One other factor that is rarely considered in STSG is the use of clips or sutures. Although nearly ubiquitous in graft placement, the employment of these fixation devices does require an initial surgical technique, and following healing, the fastening devices must be removed which can be time consuming for the woundcare professional, and cause discomfort for the patient. A technique of mesh STSG fixation without sutures or clips is an important potential alternative to conventional graft application and management.

Methods:
We report on a case of a sutureless, clipless mesh STSG where fluid management and holding the graft in place are both achieved through the use of a novel powder dressing applied once and then monitored through the graft take and subsequent healing.

Graft Procedure
Patient was referred to woundcare clinic and low tolerance for pain was a factor in decision to attempt a sutureless, clipless mesh graft. Previous use of staple fixtures resulted in intolerable pain for this patient. In the OR, a conventional STSG was harvested and meshed 1:3 then applied to the wound bed. The STSG was pressed gently into place and good contact was formed at all graft locations through careful placement. No clips or sutures were used to secure the graft to the tissue or surrounding skin.

Dressing Placement and Post-Operative Care
The powder dressing was applied liberally using a tongue blade to transfer the powder from a sterile cup over the STSG surface. The powder was initially applied approximately 2 mm thick and was white in appearance as shown in Figure 3 above. Previous experience with this novel dressing has shown that the material consistently adsorbs wound fluid and changes from a powder into a thin, translucent flexible covering on the wound and graft surface. Our experience has shown that this transformation can be accelerated by applying saline through a mist or by dripping it on the surface of the powder. Figure 4 shows the intact, moist dressing. For further protection of the dressing and graft, a fenestrated silicone wound contact layer ** was applied over the intact, transformed powder dressing and the leg was wrapped in gauze. No clips or sutures were used to hold the covering and no tieover bolster was employed.

The gauze and silicone contact layer could be removed as needed to observe the underlying dressing. In this case, observations of the graft held in place with the transformed powder dressing were made daily. At no point was there any wound fluid management issues with maceration and at the same time, the dressing maintained a moist layer on the graft itself. By day 5 the graft showed 100% take. Some areas covered by the transformed powder dressing remained intact while areas with epithelialized skin were uncovered as the dressing lost adhesion.

To date, the graft remains closed with improving cosmesis (3 weeks)

Results and Observations
It is important to understand that no dressing or post-operative care for a STSG can replace proper clinical treatment including establishing vascular flow and surgical debridement of non-viable tissue. Proper graft handling and placement is also critical. In most procedures, the use of clips or sutures is employed without a thought. Following the graft surgery, however, critical factors to improve success include holding the graft in place (bolstering) and managing exudate. In this evaluation we employed a novel powder dressing to a conventional mesh STSG, however, the dressing was used both to secure the graft in contact with the wound bed and to bolster and prevent movement or shear forces. In this single study, the dressing performed well. The mesh STSG showed no sign of movement, and moisture control provided by the dressings inherent physical properties prevented both excess fluid and drying. The material did not allow tissue to integrate into the material and the graft epithelialized smoothly beneath the dressing.

Conclusions
STSG will remain an important technique for the closure of wounds and this technique has been well refined to achieve positive results. Simple means of fixing the graft without sutures or clips have not been widely studied simply because materials did not exist to provide that type of fixation. Similarly, few major advances have been made in bolstering the graft site while managing fluid. We believe that this technique offers promise both for patients and clinicians in providing positive outcomes for the management of mesh STSGs.

This work was sponsored by ULURU, Inc.

* Altrazeal Transforming Powder Dressing
** Mepitel fenestrated silicone

Poster CS-114

A Procedure Using a Single Dressing Application for the Bolstering and Protection of a Meshed Skin Graft

2009 SAWC Meeting
Grapevine, Texas

Kim Eldridge, RN, CNOR, RNFA, CFCN, WCN

James Gleaves, MD, FACS

Rush Hospital
Wound Care, Hyperbaric and Limb Salvage Center

Meridian, Mississippi

Objective
The objective of this presentation is to demonstrate a new procedure for the immobilization and isolation of a meshed skin graft without dressing changes, bolstering or negative pressure wound therapy.

Introduction
Split thickness skin grafts (STSG)s are a common and very effective surgical technique to quickly provide reepithelialization for well prepared wound beds The survival or "take" of a graft is dependent on numerous factors, however, the most frequent causes of STSG failure are dislodging or shear, and accumulation of wound fluid between the graft and wound bed. The two primary methods of providing immobilization of grafts during the take period are the use of a tieover bolster or application of negative pressure wound therapy. Both of which are successful treatments but present some complications with either difficulty in observing the underlying graft or in terms of equipment and personnel resources.

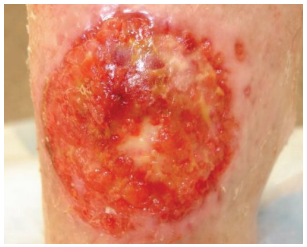
Methods
We present a treatment modality suitable for immobilizing, isolating and providing a moist wound healing environment for a meshed STSG. This treatment employs a novel powder dressing. When this powder dressing is applied to a mesh graft site, it transforms into a hydrating layer that adheres to the interstitial spaces between the graft. The material appears to fill in these spaces and behaves as a protective support bolster between the mesh graft and serves to anchor the mesh to the underlying wound bed. As new tissue begins to fill in the mesh spaces through contracture, the powder dressing sloughs off.

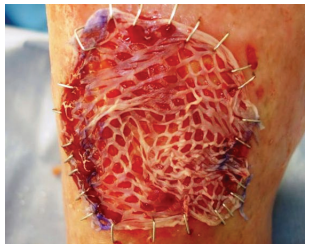
Patient History
81 year old female with history of diabetes, CHF, PAD, PVD

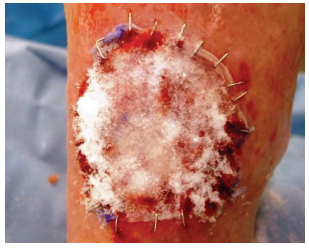
Wound History
Arterial ulcer on dorsal plantar of right foot. Wound was treated for several months prior to evaluation at Rush Hospital with little success. After evaluation of Vascular Status, she was found to have severe peripheral arterial disease and required vascular intervention.

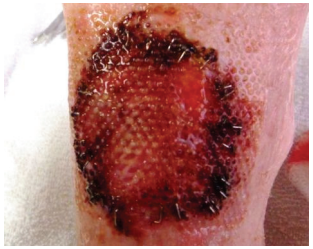
Wound Treatment
Vascular flow was established with angioplasty and stenting per vascular interventionist. This was performed with excellent results, then the patient was taken to the OR for sharp debridement and STSG. The STSG was harvested from the right thigh donor site, meshed 1:3 and then applied to the wound bed and anchored with staples.

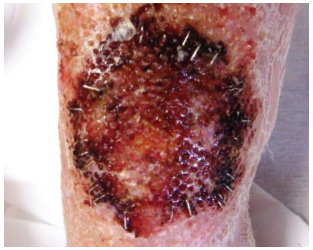
Powder Dressing Application and Follow-up
- The powder dressing was applied immediately post- op to a thickness of 1-2 mm
- A fenestrated wound contact layer** was applied over the graft site and covered with gauze
- The contact layer was changed at day 5 and 10.
- The powder dressing was removed at day 12 with greater than 90 % reepithelialization.

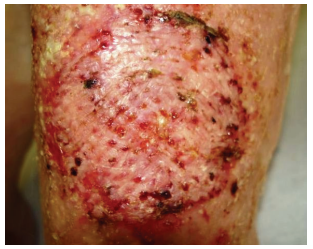

Ulcer Post Sharp Debridement

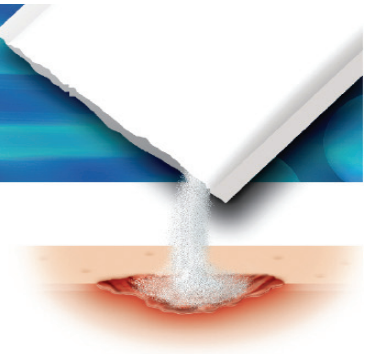

Mesh STSG in Place on Wound


Novel Powder Dressing on Wound


Day 5-No Dressing Changes


Day 10-No Dressing Changes


Day 12-Powder Dressing Removed



Results and Observations
The novel powder dressing described in this technique was initially evaluated as a covering for skin graft donor sites. Following evaluation in donor sites, the product was applied to a STSG with the hope that it could provide a convenient and comfortable treatment to protect a mesh graft during the period of "take" while the graft adheres to underlying tissue and reepithelializes across interstices.

The powder is applied with a procedure that is dramatically different from most films or pads using sprinkling rather than laying or stapling a pad in place. This application lends itself to covering the uneven surfaces of a mesh STSG. Additionally, the powder can be pressed into the spaces as it is applied over the surface. The resulting transformation from powder initially yields a white covering that gradually darkens in appearance with blood and wound fluid. The material does not resorb but does flatten somewhat over the graft surface and does not appear to allow shear forces to pull or dislodge the graft tissue as the mesh knits to the underlying wound. The chosen silicone mesh contact layer is easily removed from the powder dressing surface. Removal of the powder dressing if necessary can be accomplished by soaking the dressing in saline for several minutes after which pieces remaining on the wound can be peeled away without strong adhesion to the underlying tissue.

Conclusions
Results from this treatment were better than expected. The dressing provided a flexible, immobile surface that penetrated the gaps in the mesh graft and had strong adhesion to the underlying wound bed. The wound surface remained hydrated and the dressing did not dry or flake away from the moist tissue during the 12 day treatment. This technique appears to be a viable method of easily securing a STSG with a single dressing. The technique should be explored further to determine the best clinical practice and full benefits of this application.

This work was sponsored by ULURU, Inc.

* Altrazeal Transforming Powder Dressing
** Mepitel fenestrated silicone

Poster CS-022

2009 CSAWC
San Antonio, TExas

Gleaves, Jim, MD. Surgeon, Rush Hospital, Meridian, Mississisppi

Eldridge, Kim, RN, Rush Hospital, Merrdian, Mississippi

Treatment of a severe Fournier's necrotizing fasciitis involving the scrotum and volar penile skin associated with a malfunctioning penile prosthesis affixed in the erect position with a delicate split thickness skin graft anchored with a powder dressing

Objectives

Understand the significant complications following a Fournier's necrotizing fasciitis of a male perineum and its treatment with a meshed split thickness skin graft on the scrotum and volar surface of a penis which was incidentally associated with a damaged penile implant.

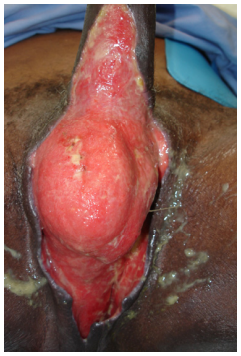
Be exposed to the delicate nature of graft suturing and affixation when attempting to apply a meshed split thickness skin graft in one setting to the penile and scrotal skin.

Introduction

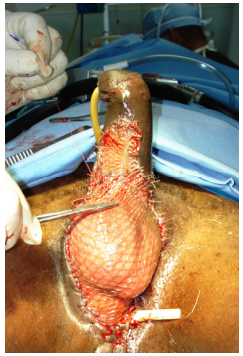
Simple geometry reveals that any one singular infintesimal point on the scrotal surfaces of two spheroidal masses can be assoiciated with only one plane. A spheroid surface has a multiplicity of planes throughout its surface extending to the periphery of the graft. It is very difficult to affix the graft without multiple sutures and/or clips throughout the grafts surface and not just at the periphery of the graft. This type of procedure typically requires multiple grafting procedures.

Methods

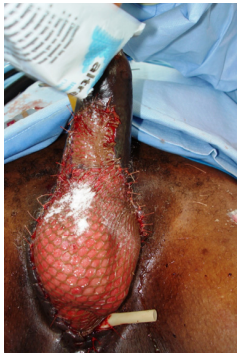
This case study presents the treatment of a 71 year old diabetic, African American male, who had a penile implant which became damaged and was malfunctioning with his penis in a permanent erect state ("bent" superiorly in the standard 90 degrees perpendicular to the patients body frame in a "functional position"). The damaged penile implant complicated the treatment after onset of the infection that had developed six days earlier, as Fournier's necrotizing fasciitis with severe systemic sepsis. This necrotizing faciitis involved the entire scrotum traveling along the volar surface of the penis toward the base of the glands. Immediate initial treatment included: broad spectrum antibiotics, treatment with hyperbarics prior to the urologist taking the patient to the operating room where under general anesthesia the entire scrotal skin was removed up to the base of and including that of the penis. He was treated for approximately two weeks with intravenous antibiotics, aggressive local care, and hyperbarics for two weeks prior to grafting. Grafting the scrotum is particularly difficult due to its shape and it usually requires multiple trips to the operating room to get adequate coverage due to the double spheroidal structure of the scrotum. The skin on the base of the penis is essentially perpendicular in relation to skin found on the scrotum. This tissue is quite delicate; pain and sensation can be extraordinarily excruciating and exceptionally miserable for the patient. One large graft (400 to 500 cm^2) was applied and this was meshed 3:1, sutured at the periphery where the scrotum had reached the base of the thighs and perineal area posteriorly and onto the penis using absorbable vicryl stitches; fewer than normal were used due to the Powder Wound Dressing* (PWD) fixation. No additional stitches were used in the bed of the graft nor in the area where an additional piece of graft was placed to cover the volar penile skin. The graft was covered with a PWD and aggregated with saline mist, which then affixed and anchored the graft to the underlying deep scrotal and penile wound surface. A light secondary dressing of 4x4's and net gynecology underwear was applied but no significant affixation to the secondary dressing was necessary. On one occasion in the following two weeks an additional dose of PWD was applied and aggregated again with saline.



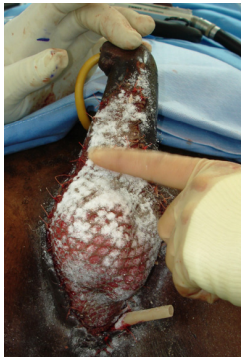
Gently Debrided Wound



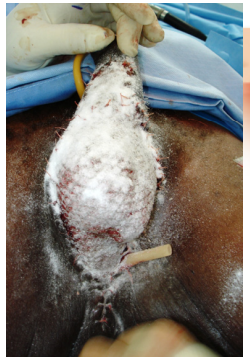
Application of Mesh Graft and Suturing



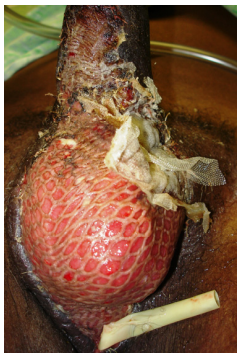
Graft in place with Application of Powder as Primary Graft Fixation



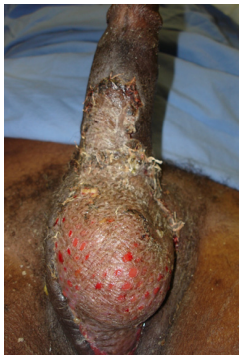
Gentle Spreading of Powder Dressing Over Graft and Tissue Surface



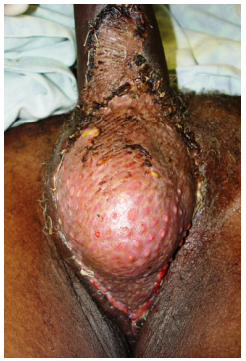
Powder Dressing in Place with Hydration and Aggregation Occurring



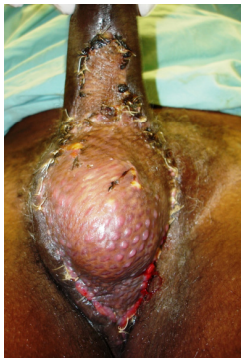
Day 5: Dressing Change. Powder Dressing has been removed from the scrotum. Some of the intact dressing and wound veil used to cover the primary dressing is visible on the dorsal skin of the penis.



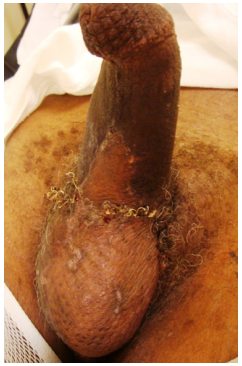
Day 12: Primary dressing left in place with tissue ingrowth visible at graft interstices.



Day 15: Graft in place with substantial ingrowth of new skin. Primary dressing no longer present.



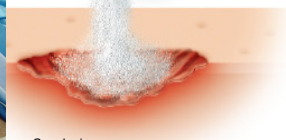
Day 19: Graft at nearly 100% take with new skin through all interstitial spaces.



6 Weeks Post Operative: Complete take of graft with excellent cosmesis.

Findings

The wound continued to show ongoing improvement following the grafting procedure. The skin graft began to turn obviously pink over its entire bed covering the scrotum and penis by the third day and it could be seen through the light layer of PWD as it was translucent. By the end of 14 days not only did the entire graft had a 100% take of all skin that was applied but the interstitial spaces between the webs were epithelialized. The graft remained anchored and "took" completely showing total epithelialization by the fourth week. It should be added that the PWD was also used on the donor site without a second dressing. The donor site was 24 cm x 8 cm. The donor site produced no pain post operation.



Conclusions

This case demonstrates that meshed STSG can be held in position and anchored to the bed with PWD that reconstitute themselves into a congealed "superstructure". Numerous areas on the graft that would have normally been sutured, were not sutured nor clipped at all, thusly decreasing pain. For the novel and unusual wound, dressing and treatment of the site following surgery requires delicate care and obviously in this case, minimal dressing changes and handling markedly improving the patients comfort. It also shows the scrotum which is a very difficult area to graft particularly when associated with a penile skin loss injury can be quite well handled with a PWD to help affix the graft to the wound bed. This is consistent with other studies where we have been successful in areas that are planar and flat or gently curved to be able to completely affix a skin graft without any other fixation including clips or sutures.
A secondary conclusion was that donor sites have very little to no pain when treated with the PWD.

The complications following a Fournier's necrotizing fasciitis of a male perineum and the treatment with a meshed STSG on the scrotum and volar surface of the penis associated with a damaged penile implant can be an exceptional challenge to both the patient and the surgeon.

This case study, reveals that delicate grafting of surfaces with complex geometry can be accomplished by fixation of a graft to a well perineum using a powder wound dressing. There was less pain as a minimal number of sutures were placed and dressing changes were minimized. There were no dressing changes for the donor site and powder wound dressing (PWD) was used as a the dressing, which also relieved pain in the donor site.

References

Fitzgerald, R, Bharara, M, Mills, J, Armstrong, DG (2009): "Use of a Nanoflex powder dressing for a wound management following debridement for necrotizing in the diabetic foot" International Wound Journal 6(2); 133-139.

Eldridge, K. E.; Gleaves, J. M. (2009) "A new treatment in Mesh Skin Graft Procedures Using a Novel Powder Dressing for Clipless, Sutureless, Skin Graft Fixation" Poster Presentation, Society for Advanced Woundcare Meeting, Grapevine, Texas.

*Altrazeal™ Transforming Powder Dressing