A TRANSFORMING POWDER DRESSING (TPD) TO IMPROVE HEALING OF DEEP PARTIAL THICKNESS BURN WOUNDS

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INTRODUCTION

Burn wound care is a major socio-economic problem in the United States (1-2). According to the American Burn Association's National Burn Repository, approximately half a million people in the United States are severely burned each year (3). The current standard of care (SOC) for burn wound management is application of gauze and/or antimicrobial treatments (4). Unfortunately, these limited options to treat acute burn wounds do not address common comorbidities seen in burn patients associated with frequent dressing changes, infection prevention, and tissue preservation (5). Therefore, there is a requirement to optimize burn wound treatment using a 'temporizing', yet cost-effective wound dressing. To address this problem, we evaluated a commercially available, transforming powder dressing (TPD) that improves wound healing and can stay on a wound for extended periods of time (up to 30 days).

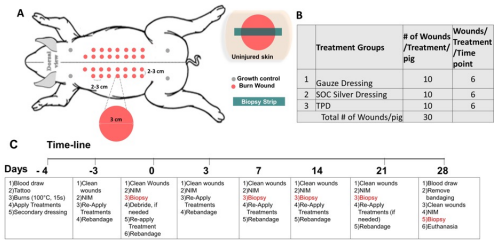
OBJECTIVES AND HYPOTHESIS

The objective of this project was to evaluate the efficacy of TPD wound dressing using a porcine deep partial thickness burn wound model.

Hypothesis: Early initial treatment of acute burn wounds with TPD will reduce time for complete wound closure and improve healing outcomes.

METHODS

Deep partial thickness (DPT) 3cm diameter burn wounds were created on the dorsum of anesthetized Yorkshire pigs (n=3, 30 wounds/pig). Three treatment groups (TPD, a silver-based dressing and gauze) were randomized across three pigs (10 wounds/pig/treatment). Treatments were applied one-hour post-injury, reapplied on days 7 and 14, and redressed as needed. Wound re-epithelization and contraction were measured over time using a 3D imaging system and a digital camera.



	Treatment Groups	# of Wounds /Treatment/ pig	Wounds/ Treatment /Time point
1	Gauze Dressing	10	6
2	SOC Silver Dressing	10	6
3	TPD	10	6
	Total # of Wounds/pig	30	

Figure 1: TPD evaluation with a 3cm diameter porcine DPT burn model:
A: Experimental design with 3cm diameter deep partial porcine burns and biopsies
B: Treatment groups
C: Experimental timeline

On days 0, 7, 14, 21 and 28, biopsy strips were harvested through the center of the wound bed histological analysis. Hematoxylin and Eosin (H&E) staining was used to observe re-epithelialization, and the epithelial gap in different groups. Further, slides were stained for necrosis and viability analyses using vimentin antibodies. A biotinylated avidin/horseradish peroxidase enzyme was used as secondary antibody and detected using a DAB (3,3' Diaminobenzidine) substrate kit.

RESULTS

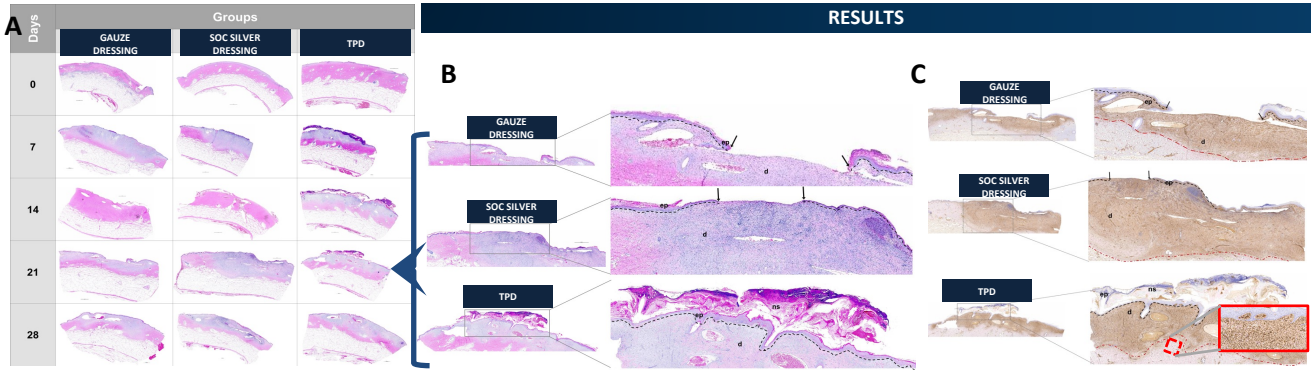


Figure 2: **(A)** Representative H&E images of the entire biopsy strip spanning wound bed with adjacent normal skin, harvested at different post-treatment days (scale bars = 2mm). **(B)** Representative H&E images of biopsy samples harvested at day 21. Images on left are the entire biopsy strip (scale bars = 2mm). The area indicated by the black box is the enlarged image on the right (100 µm). **(C)** Vimentin stained biopsy section on day 21 confirms complete re-epithelialization of TPD treated groups. The tissue that is stained brown above the red dotted line are positive for vimentin. The image inset within the red box is a magnified section showing cell-associated vimentin indicating re-organizing dermis. Black arrows in figure 2B and 2C indicate the re-epithelializing wound edges present on both sides of the tissue section.
ep = newly formed epidermis; **d** = dermis; **ns** = residual necrotic slough.

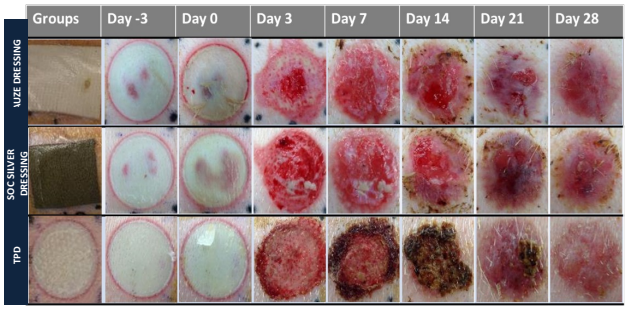


Figure 3: Representative time-course digital images of DPT wounds treated with gauze dressing, SOC silver dressing and TPD.

DISCUSSION

- TPD adhered to the burn wound bed after initial application on day 0 and flaked-off as the wound healed (days 7 & 14) with complete re-epithelialization by day 21
- H&E stained biopsy sections (day 21) confirmed complete re-epithelialization of wounds treated with TPD, whereas wounds using gauze and silver-based dressings still had open wound areas. For the TPD treated wounds, the dermal layer of the wounds had a more organized collagen structure
- The quality of healing was monitored using vimentin stained tissue sections. Day 21 sections indicated vimentin in TPD treated wounds conferred with proliferating dermal cells, illustrating the formation of an organized cytoskeletal network, critical to providing cell structure and resulting in re-organized wound dermis
- In summary, TPD presented an easy-to-use dressing that created a favorable microenvironment that improved wound healing with reduced frequency of primary dressing changes relative to SOC therapies

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Disclaimer: This study has been conducted in compliance with the Animal Welfare Act, the implementing Animal Welfare Regulations, and the principles of the Guide for the Care and Use of Laboratory Animals.

TREATMENT OF PARTIAL THICKNESS BURNS IN OUTPATIENT SETTINGS WITH ALTRAZEAL

Dhaval Adhvaryu, MD, FACS, Baton Rouge General Hospital | Jonathan Saxe, MD, FACS, MAR, Altrazeal Life Sciences Inc.

Military Health System Research Symposium (MHSRS) 2023 | Kissimmee, FL

altrazeal®
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Baton Rouge General

COMPANY MISSION | ACHIEVEMENTS TO DATE

OVERVIEW: Small business enterprise based in Addison, TX specializing in development of wound care and drug delivery technologies

MISSION: To improve the lives of patients the world over by delivering comprehensive solutions that optimize outcomes for patients, providers and payers

ALTRAZEAL STATUS: Patent granted / market launch initiated

Used in several prominent health systems across the United States and internationally

DOD / VA EFFORTS: DAPA listed. SAM registered. Approved for use in several VAMCs

DOD FUNDED R&D PROJECTS: DoD funding awarded for three post-marketing clinical studies and pre-clinical studies for new products:

- MTEC-NAMD: Pre-clinical and clinical studies in burns and diabetic foot ulcers
- CDMRP-PRMRP-DHA: Clinical study in pressure injuries
- SBIR Phase I & II-DHA-WRAIR: Pre-clinical studies for drug delivery combinations
- MIDRP (contract pending): Pre-clinical studies for drug delivery combinations

UNIQUE EXPERTISE: Partnerships with global wound care experts / centers of excellence

ALTRAZEAL® TRANSFORMING POWDER DRESSING

Altrazeal is comprised primarily of two biocompatible polymers (similar to those used in contact lenses). Upon hydration, its granules aggregate into a moist, oxygen permeable barrier that protects the wound from contamination while helping manage excess exudate through vapor transportation. Once applied, Altrazeal may be left in place for up to 30 days. Powder may be added ("topped off") as needed without requiring primary dressing changes. As the wound heals, Altrazeal dries and flakes off. Simple secondary dressings may be used in areas of high friction or exudation.

INTRODUCTION AND CASE OVERVIEW

Burn injuries are common; over 11 million casualties are recorded annually[1]. Protocols to treat burn injuries are well-defined and typically incorporate wound debridement, moist wound dressings, antimicrobials for infection management, and pain medications, all which are vital for successful re-epithelialization of the wound.[1,2,3] Management of acute burn pain is particularly critical, as frequent dressing changes and exposure to air currents or any perception of contact can induce intense pain and anxiety, limiting a clinician's ability to provide adequate wound management.

This prospective case series summarizes the results from management of 9 patients, 6-32 years old, with acute partial thickness burns [1-12% total body surface area (TBSA)] who presented to the burn center and outpatient clinic for initial or follow up management of their burn injuries. All patients were treated with a single application of Altrazeal secured with a nonadherent layer and gauze. Patients were monitored for 30 days for wound healing, pain reduction (including pain medications) and dressing change frequency.

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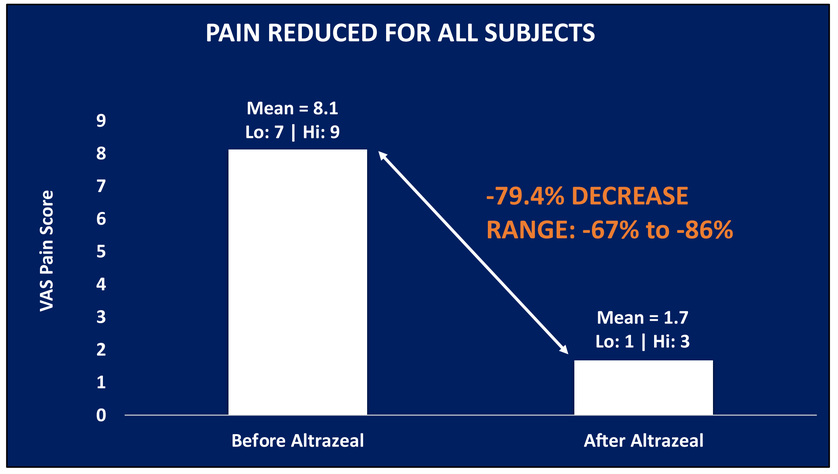
SUMMARY RESULTS

Age (Yrs) Sex (M/F)	Type	Location	TBSA (%)	Days to Heal	Pain Before Treatment	Pain After Treatment	Pain During Treatment
17 | M	Flash Burn	Hand	2	14	9	2	1
6 | F	Flash Burn	Lower Legs	12	9	9	2	1
21 | M	Grease Burn	Hand	2	16	9	1	0
26 | F	Scald Burn	Ankle	2	11	7	3	0
10 |F	Hot Surface Burn	Hand	1	9	8	2	0
32|M	Scald Burn	Arm	4	14	8	1	0
27 | M	Gunpowder Burn	Hand	2	14	8	2	0
31 | M	Grease Burn*	Arm	3	10	8	1	1
29 | M	Grease Burn	Hand	1	12	8	1	1
		Average		**12.1**	**8.1**	**1.7**	**0.4**
		Sdev		2.5	0.6	0.7	0.5
		Min		**9**	**7**	**1**	**0**
		Max		**16**	**9**	**3**	**1**



*A percentage of original burn had dressing removed early and this was the only assessed as 70% re-epithelialized. The area covered by the Altrazeal was 95% re-epithelialized or better at 10 days.

CONCLUSION

All patients healed with a single application and no reported complications, including infections. There was a rapid decrease in pain reported by all patients after Altrazeal application. The patients did not have any significant scarring and did not lose range of motion. Altrazeal presented an easy to use and cost-effective alternative to conventional methods for management of partial thickness burns.

ILLUSTRATIVE CASES

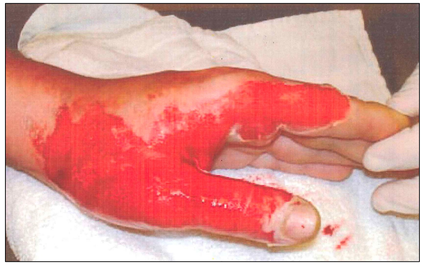
INITIAL TREATMENT

26 y/o male with 2% TBSA grease burn on left hand

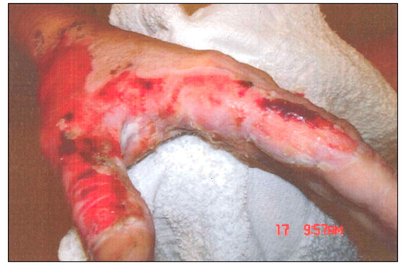
- Silver sulfadiazine used 2x daily for 2 days
- Treatment stopped due to pseudo eschar formation and pain during dressing changes

POST ALTRAZEAL

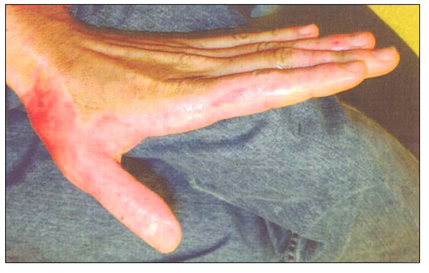
- Wound healed in 11 days with one application
- No loss of flexibly or range of motion
- Pain subsided from 9/10 to 0/10 (-89%)



Day 1



Altrazeal Application



Day 11

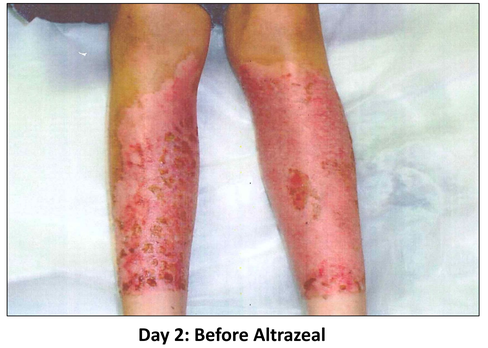
INITIAL TREATMENT

6 y/o male, 12% TBSA fire burn to both legs

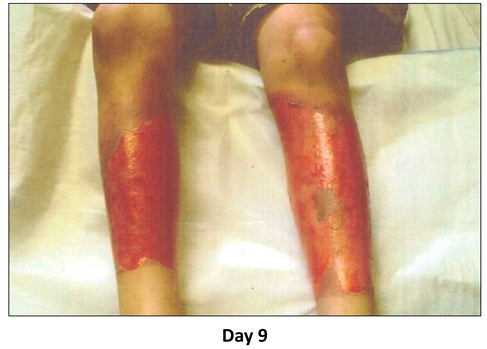
- Silver sulfadiazine used 2x daily initially for 2 days
- Child uncooperative with clinicians due to extreme pain
- Pain medications 4x/day

POST ALTRAZEAL

- Wound healed in 9 days
- Single application of Altrazeal
- Pain subsided from 8.5/10 to 1/10 (-77%)



Day 2: Before Altrazeal



Day 9

Quality Improvement Project: Management of Complex Painful Postoperative Wounds

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Rosalyn Barnabee, BSN, RN, WOC; Tracy Decker, DNP, RN; Daniel Farinas Lugo, MD; Marcus Darrabie, MD, FACS; AdventHealth System, Orlando, FL

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

INTRODUCTION

Management of painful postoperative wounds is difficult and expensive[1]:

- Medicare estimated costs for treatment of acute and chronic wounds range from $28 to $97 billion annually with surgical wounds contributing the largest 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 wound therapies, including NPWT and conventional dressings, require frequent dressing changes that can be painful and increase the need for opioids and risk of dependency

There is a critical need for a multidisciplinary collaboration and quality initiatives to identify alternate modalities for management of painful acute and chronic postoperative wounds.[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 standard of care (SOC) practices for the management of painful postoperative wounds. TPD is comprised primarily of biocompatible polymers. Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping manage excess exudate through vapor transpiration. Once applied, TPD may be left on for up to 30 days. More powder may be added as needed without requiring primary dressing changes. Simple secondary dressings may be used in areas of high exudation or friction. TPD dries and flakes off as the wound heals.

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

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

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

RESULTS

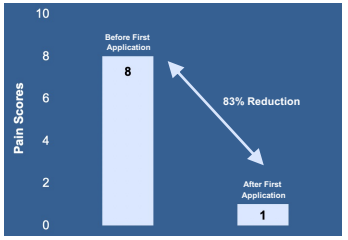
Sample Population (n=12):

- **Gender:** Male: n= 6; Female: n= 6
- **Age:** 21 - 95 years (mean: 49.1)
- **Wound Etiologies:** Diverse debrided or excised wounds - necrotizing fasciitis, hidradenitis suppurativa, burn, pilonidal cyst, peri-stomal, pressur injury, abscess, hematoma
- **Wound Size:** 7.5 - 1,350 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

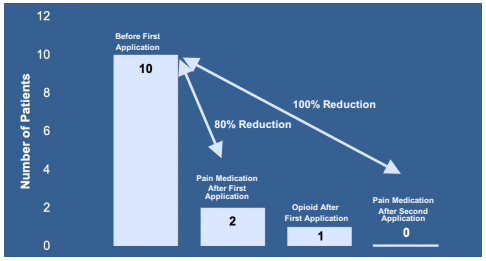
QIP SAMPLE POPULATION

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%

PAIN SCORES



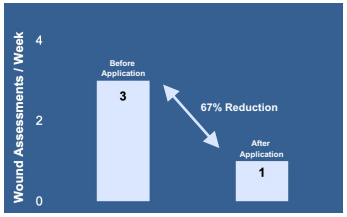
PAIN MEDICATION



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

WOUND ASSESSMENTS



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CONCLUSION

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

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

**Altrazeal® Transforming Powder Dressing (USA)*

Treatment of Non-Healing Radiation Injury Using Novel Extended-Wear Transforming Powder Dressing

Jo Ann Thompson, RN, BSN, CWOCN; Home Health Department, CWOCN; Baptist Health Home Care
Laura L. Polson, BSN, RN-BC, CVAHP; Clinical Quality Value Analysis; Baptist Healthcare
WOCNext 2023 Meeting, Las Vegas, NV | June 4-7, 2023

BACKGROUND

Over half of all cancer patients receive radiation therapy, resulting in skin injuries in approximately 95% of those treated.[1] Further complications occur in up to 60% of treated patients[2] and include compromised wound healing, chronic ulceration, pain, secondary infections, and psychological distress.[2,3] Established standard of care (SOC) strategies for treating radiation wounds primarily utilize antimicrobial dressings which require frequent and painful dressing changes and consume significant human and material resources.

CASE OVERVIEW

This case study describes a 76-year-old female with metastatic cancer, s/p T8 laminectomy, tumor debulking, and radiation therapy with a nonhealing radiation wound on the thoracic spine. The wound was refractory to SOC therapy for a period of three months. Multiple topical agents were used including silver and other antibacterial dressings without any improvement in wound healing. Palliative care and home health nurses were required to perform daily dressing changes.

CURRENT CLINICAL APPROACH

A novel transforming powder dressing (TPD) was applied and covered with a contact layer and gauze. TPD was "topped off" three times over the 33-day treatment period and secondary dressings were changed prn. TPD is an extended wear dressing that covers and protects the wound while releasing excess exudate through vapor transpiration.

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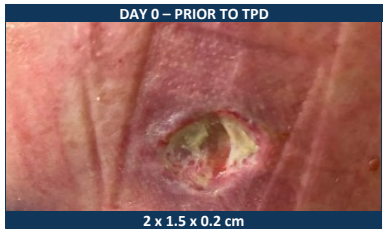
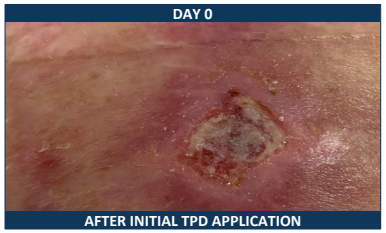
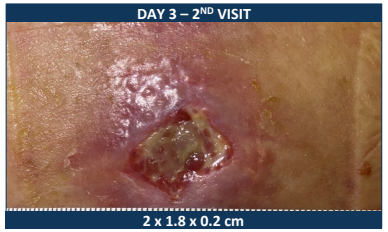
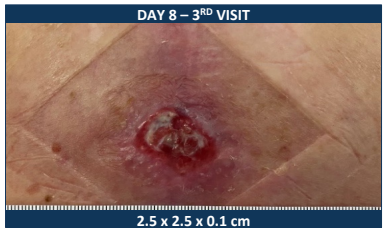
PATIENT OUTCOMES

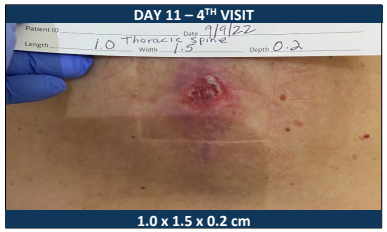
Prior to TPD, patient's non-healing wound measured 2.5 x 1.5 x 0.2 cm (0.6cm^3). TPD treatment resulted in full wound healing in 33 days. Patient reported pain and psychological relief after TPD application and was discharged from home health services.

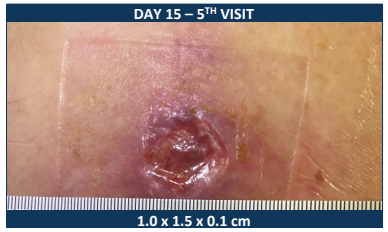


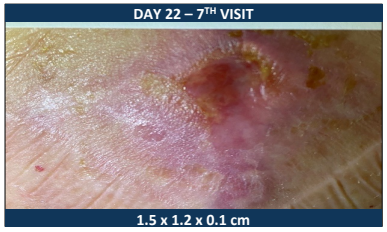


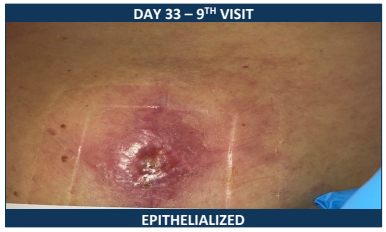












CONCLUSION

Radiation wounds are highly challenging, hard-to-heal wounds. The case demonstrated TPD's effectiveness in healing a three-month-old refractory wound within 33 days. The patient also reported reduced pain and no complications were observed. Nursing visits were reduced from daily to once a week with TPD. We conclude that TPD should be considered as a viable, alternative therapy for patients with chronic radiation injuries with poor prognoses.

EDU – 0070, REV O1

A Novel Transforming Powder Dressing for Healing Chronic Wounds of Multiple Wound Etiologies

David Bickers CRNP, CWOCN-AP | University of Pittsburgh Medical Center, Altoona PA

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

CHALLENGE

Delayed wound healing results from an imbalance occurring during healing stages, often resulting in conversion of an acute wound to a chronic non-healing wound.[1,2] Chronic wounds are significantly more complicated to heal than acute wounds.[2] In the US alone, chronic wounds currently affect 6.7 million people, with annual healthcare costs exceeding 50 billion dollars.[3]

Evidenced based clinical principles for optimizing wound healing include: (1) maintaining a moist (but not wet) wound environment, (2) permitting gaseous and fluid exchange while providing mechanical and bacterial protection, and (3) utilizing a dressing that is non-adherent to the wound, easy to use, comfortable and pain-free for the patient. When standard of care (SOC) therapy fails to heal a wound, alternate treatment strategies must be considered.

METHOD AND MATERIALS

We present a case series which evaluates the clinical outcomes of 3 patients with chronic wounds of different etiologies which were refractory to prescribed SOC therapy (burn, 2 diabetic foot ulcers and trauma wound).

All wounds had deteriorated or showed no clinical progress prior to conversion from SOC dressings to Transforming Powder Dressing (TPD). For purposes of consistency in our assessment, the conversion of the primary dressing from SOC to TPD was the only wound treatment factor modified.

TPD is a novel powder dressing comprised primarily of biocompatible polymers (same as those used in contact lenses). Upon hydration, 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.

SUMMARY RESULTS

- In the cases presented, each of which was refractory to SOC therapy, all wounds healed and came to complete closure after treatment with TPD.
- Average time to heal for all 4 wounds after initial treatment with TPD was 47 days.

PATIENT 1: BURN

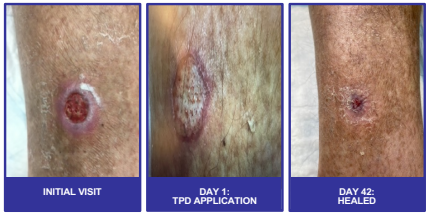
- **History:** 62 y/o male with DMT2, venous insufficiency, mild lymphedema, and deep partial thickness burn on ankle / LLE after catching sock on fire while welding
- **Wound Size:** 1.5cm x 1.5cm x 0.2cm
- **Wound Duration:** > 8 weeks (60 days)
- **Prior Treatment:** Silver Sulfadiazine 1% cream and non-adherent dressing multiple times a week
- **TPD Treatment**: Weekly applications
- **Outcome:** Fully healed in 42 days with TPD

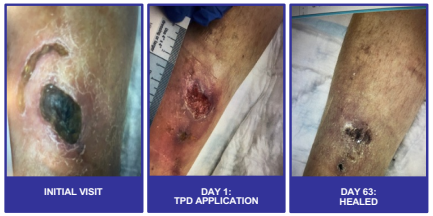
PATIENT 2: DIABETIC FOOT ULCER

- **History:** 62 y/o female with IDDM T2, lymphedema,
- neuropathy, BMI 45.6, and two plantar DFUs
- **Wound Size:** 0.5cm x 0.5cm x 0.7cm (heel) | 1.6cm x 1.2cm x 1.2cm (5th metatarsal)
- **Wound Duration**: ~1.5 to 2 years
- **Prior Treatment**: Total contact cast with foam dressings
- **TPD Treatment**: Weekly applications
- **Outcomes**: Both ulcers fully healed within 35 days (average)
  - **Heel Ulcer:** Closed in 33 days with TPD
  - **Submetatarsal 5 Ulcer:** Closed in 37 days with TPD

PATIENT 3: TRAUMA

- **History:** 52 y/o male with CAD, renal disease, smoking disorder, and trauma wound to anterior knee
- **Wound Size:** 2.5cm x 2cm (eschar)
- **Wound Duration:** > 6 weeks (45 days)
- **Prior Treatments:** Mupirocin calcium ointment, medical grade honey, cortisone applied multiple times a week
- **TPD Treatment**: Weekly applications
- **Outcomes:** Fully healed in 63 days





CONCLUSION

The use of TPD as a universal primary dressing on non-healing wounds of different etiologies significantly improved healing times with reduced frequency of dressing changes and brought each of the non-healing wounds to complete closure. No adverse events were reported.

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

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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 10-20 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 wounds-at 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 preoperatively 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 a wound eschar

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Efficacy Analysis

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 sides using a mixed model repeated measures ANOVA analysis that accounted for the treatments being observation 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 nonwoven material containing 1.2% lonicalcium. 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 (25-28 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. Ages ranged from 5 to 79 years and averaged 38.6. 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)	38.6 (21.7)
Median (Min-Max)	36.0 (5, 79)
Gender	
Male	15 (79%)
Female	4 (21%)

Source: Master SAS

Donor Site Characteristics

Table 02 summarizes the donor sites characteristics. The mean BSA size was 284 cm² (SD 138.8) for PWD sites and 329 (173.8) for CMC-Ag sites.

Table 02 – Summary of Donor Site Characteristics

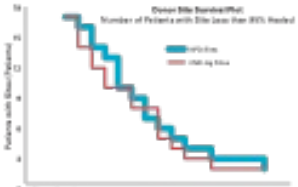
	PWD	CMC-Ag
Number of Subjects	19	19
Size (cm²)		
Mean (SD)	284 (138.8)	329 (173.8)
Median (Min-Max)	198 (36, 1000)	187 (64, 768)

Source: Master SAS

Efficacy Results

Twenty-five (25) trials, 4 failed and were enrolled into the study and 19 received study devices. Twelve subjects (60%) 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 side minus CMC-Ag)	p-value a
N	11	11	11	
Mean (Minute)	14.2	13.36	1.1	0.56
Standard Error	0.85	0.94	(0.97)	
Minimum	10	9	-1	
Maximum	23	20	3	
95% Confidence Interval	12.3, 15.9	11.3, 14.6	-0.9, 2.9	

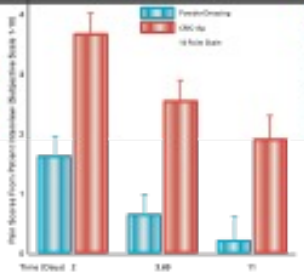
a p-value from modeled pain data

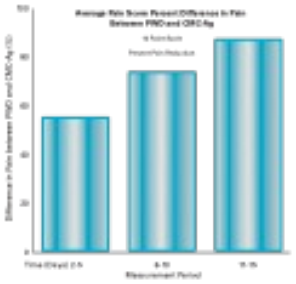
Pain Scores

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 2.09 on the CMC-Ag side versus 1.00 on the PWD side (p<0.0001). Similarly on days 6 to 10, the average pain score was 2.63 on the CMC-Ag side compared with 0.67 on the PWD side (p<0.0001).

Average Pain Score





Subject's Satisfaction Survey

Table 04 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 8.8 versus 5.8; 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 remained in place after applications as both dressings performed well on that measure (average score of 8.8 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 Response:		17	17	
Q1 – On a scale of 1 to 10, with 1 being total all and 10 being very secure, did the dressing remain in place after application?	Mean (SD)	9.3 (0.94)	8.6 (1.51)	0.05
	Median	10	10	
	(Min-Max)	7 to 10	5 to 10	
Q2 – On a scale of 1 to 10, with 1 being very uncomfortable and 10 being very comfortable, did you find the edges of the dressing to be comfortable?	Mean (SD)	8.8 (2.17)	5.8 (1.87)	<0.001
	Median	10	6	
	(Min-Max)	2 to 10	2 to 8	
Q3 – On a scale of 1 to 10, with 1 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 (2.32)	<0.001
	Median	1	5	
	(Min-Max)	1 to 10	2 to 9	

a p-value from modeled pain data

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. For the randomization 1 or, in both cases, PWD should have been applied to donor site B, but was applied to donor site A instead.

The 2 initial study personnel instituted a "second check" procedure to confirm which one site B and which patient 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.

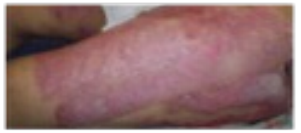
Donor Sites as Wound Healing Model

The use of donor sites as wounds in a healing model provides for a reproducible wound bed; also makes wound healing endpoint comparisons difficult for comparative treatments since the second 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 8 and day 23 (p=0.56) 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=0.0094 at 11-15 days).

For patient comfort, there was a statistically significant difference in comfort with the NPD having greater comfort levels 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.

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Acknowledgements

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Gregory Bohn MD, FACS
Medical Director
Trinity Center for Wound Care
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Graft Fixation and Wound Moisture Management with Transforming Powder Dressing*

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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.

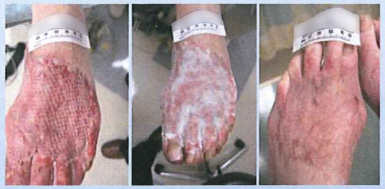
Materials and Methods

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.

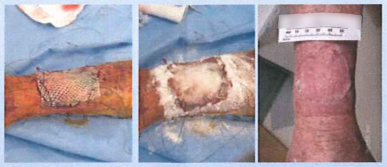
Bio engineered skin substitute was meshed 1.5:1 and applied to wounds. The graft was fixed with transforming powder dressing. Wounds were followed at weekly intervals. If necessary, Bioengineered skin substitutes can be re-applied at 2 week intervals.

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.

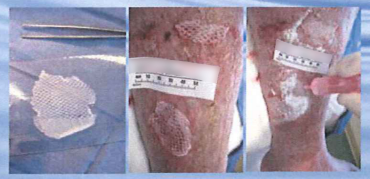
The technique was tested on two cases where living skin equivalent was meshed and applied directly to a debrided venous ulcer or DFU. In these cases, the powder dressing was left in place over the living skin equivalent for two weeks then the wound was cleaned and a new application of living skin equivalent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



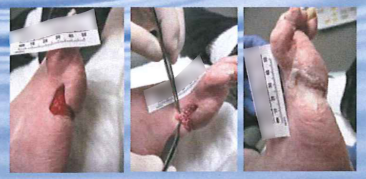
Case 1: Third degree burn debrided and treated with 0.0015 in ch split thickness skin graft meshed 1:1.5. Sutures and clips were not applied to this graft.



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.

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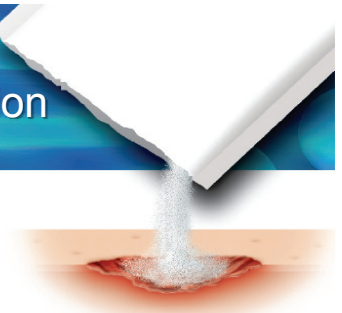
Meridian, Mississippi

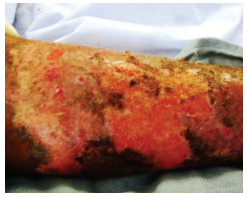
A New Treatment in Mesh Skin Graft Procedures Using A Novel Powder Dressing for Clipless, Sutureless Graft Fixation

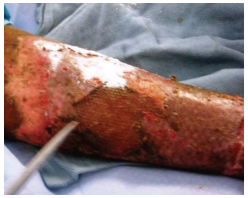


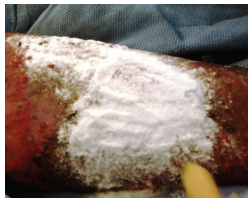
Objective
The objective of this presentation was to evaluate a technique for the fixation of a split thickness skin graft (STSG) using a novel powder dressing with different graft locations and different methods of external fixation including a sutureless, clipless graft.

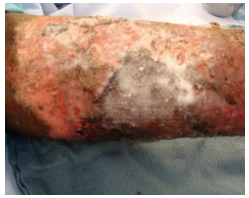
Patient History
72 year old male with history of hypertension, arthritis, urinary incontinence, heavy tobacco usage, deafness and low pain threshold.

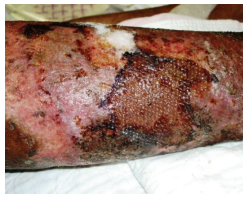
Wound History
Patient received burn to lower left leg. During ER visit, the burn was treated with silver sulfadiazine cream. Patient complained of severe pain; patient was prescribed hydrocodone pain reliever. Dressings were changed daily in Home Healthcare situation. Patient compliance and pain tolerance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

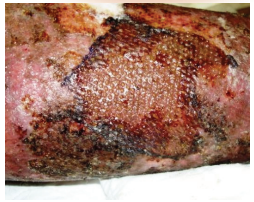

Burn Prior to STSG Procedure


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

altrazeal®
transforming powder dressing

Simplify Wound Healing - Skin 2.0

TRANSFORMING POWDER DRESSING WITH EXTENDED WEAR TIME RETROSPECTIVE EVALUATION IN TRAUMA INJURIES

Jonathan M Saxe, MD, MAR, MBA, FACS; Vice Chair of Surgery; Ascension St. Vincent Medical Center, Indianapolis, IN; Medical Director, ULURU Inc.

MTEC Annual Membership Meeting, Baltimore, MD | May 2022

COMPANY MISSION | ACHIEVEMENTS TO DATE

OVERVIEW: Based in Addison, TX, we are committed to developing and commercializing innovative wound care and drug delivery systems based on our patented technologies.

MISSION: To improve the lives of patients the world over by delivering comprehensive solutions that optimize outcomes for all key stakeholders: patients, providers and payers.

ALTRAZEAL STATUS: Patent granted, FDA registered, and market launch initiated. Used in prominent hospital systems: AdventHealth, Northwestern, Northwell Health, NYU, Plaza Medical (HCA), Providence Health (LifePoint), St. Vincent's (Ascension), UPMC.

DOD / VA EFFORTS: DAPA listed. SAM registered. Introduced to MRMC, CCCRP, USAISR, USUHS, WRAIR, NMRC, 59th Wing. Approved for use in several VAMCs including Boston, Chicago, Charleston, Dallas, Sacramento and Tampa.

DOD FUNDED R&D PROJECTS: Received grant funding from the Department of Defense related to three post-marketing clinical studies as well as a number of pre-clinical studies for product development:

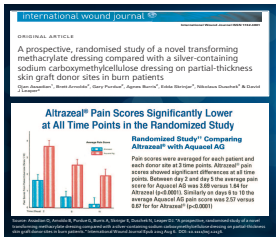
1. MTEC-NAMD: Clinical studies in diabetic foot ulcers and acute partial thickness burns
2. CDMRP-DHA: Clinical study in pressure injuries
3. SBIR-WRAIR-DHA and MIDRP-BDRD: Development of Altrazeal combinations for drug delivery

UNIQUE EXPERTISE: Clinical partnerships with global wound care experts and centers of excellence.

ABOUT ALTRAZEAL® TRANSFORMING POWDER DRESSING

Altrazeal powder is comprised primarily of two biocompatible polymers (same as those used in contact lenses). Upon hydration, Altrazeal granules aggregate to form a moist, oxygen-permeable barrier that protects the wound from contamination while helping to manage excess exudate through vapor transportation. Once applied, Altrazeal may be left in place for up to 30 days. Additional powder may be added ("topped off") as needed without requiring primary dressing changes. Simple secondary dressings may be used in areas of high friction or exudation. If clinically necessary, the dressing may be removed atraumatically by lifting off with a pair of forceps. As the wound heals, Altrazeal dries and flakes off.

EASY TO USE | ENHANCED PATIENT COMFORT

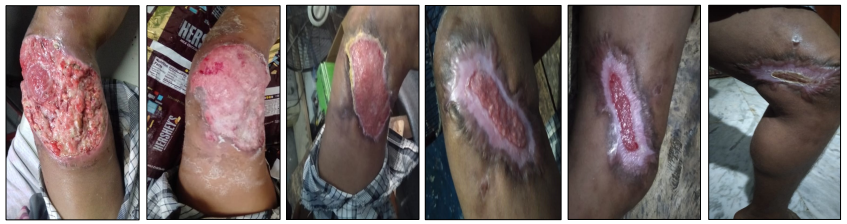


CASE SERIES OVERVIEW: FULL THICKNESS TRAUMATIC INJURIES (N=10)

A retrospective analysis of data from 10 patients with complex, full thickness traumatic wounds with elements of exposed bones, tendons and muscle was performed. All wounds were treated with Altrazeal until complete wound closure was achieved or the wounds were ready for grafting. Time to healing as well as frequency and number of dressing changes were tracked.

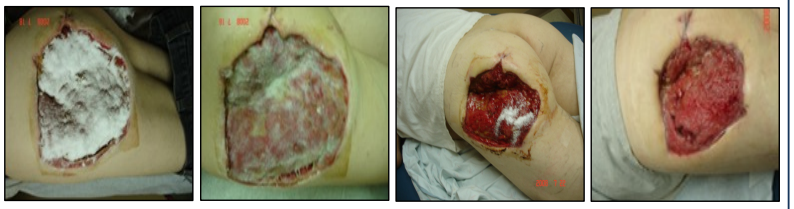
CASE 1: TRAUMA INJURY FROM MOTORCYCLE ACCIDENT

- **Patient:** 31-year-old female
- **Wound Size:** 35cm x 17cm x 17cm
- **Challenge:** Extensive wound with dressing changes required multiple times a week
- **Dressing Changes:**
  - Total: Six changes
  - Average: Once every eight days
- **Outcomes:**
  - Wound healed in 45 days
  - Avoided grafting



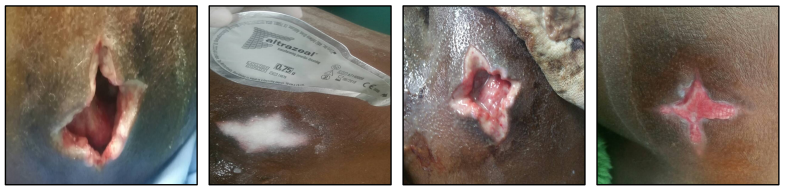
CASE 2: IMPROVISED EXPLOSIVE DEVICE WOUND DUE TO M-80 ACCIDENT

- **Patient:** 40-year-old male
- **Wound Size:** 25cm x 25cm x 5cm
- **Challenge:** NPWT discontinued due to pain. Porcine matrix failed to stimulate granulation
- **Dressing Changes:**
  - Total: Two changes
  - Average: Once every nine days
- **Outcomes:**
  - Depth reduced from 5cm to 2cm by Day 7 with single application
  - Wound ready for grafting by Day 18



CASE 3: GUN SHOT WOUND

- **Patient:** 24-year-old male
- **Challenge:** Deep wound in combat situation with few medical and material resources
- **Dressing Changes:**
  - Total: Two changes
  - Average: Once every five days
- **Outcomes:**
  - Wound healed in 10 days with two applications
  - Avoided grafting



CONCLUSION

A marked acceleration in healing was observed in all ten cases with reduced frequency of dressing changes relative to standard of care (once every 6.5 days on average versus daily or three times a week for standard of care). Six patients achieved complete healing without requiring grafting. Mean healing time was 23 days with three applications on average, or once every seven days. Four patients received successful grafting treatments once sufficient granulation had been achieved with Altrazeal. Average treatment time was 33 days with dressing changes every six days on average. **Clinical observations and outcomes indicate that Altrazeal presents a safe, effective and resource-efficient modality for the treatment of patients with traumatic wounds.**

UPMC LIFE CHANGING MEDICINE

Novel Technique for Management of Painful Road Rash Injuries

Lori O'Shea, BSN, RN, WCC; Jenny A. Ziembicki, MD, FACS | UPMC Mercy Hospital Burn Center

Symposium on Advanced Wound Care (SAWC) | April 2022

BACKGROUND

Road rash injuries include painful skin abrasions, burns or wounds resulting from trauma accidents on cemented or tarred surfaces. Wounds vary in severity, depth, and degree[1, 2]

- Complications include infection, sepsis, wound progression, pain (often significant, resulting from wounds and wound related treatments[3,4]), embedded road debris, and devitalized tissue.
- Routine Standard of Care includes topical antibiotics, petroleum dressings, or moisture retaining therapies, and requires frequent and painful dressing changes.

CASE OVERVIEW: METHODOLOGY

20-year-old male sustained multiple injuries in a motorcycle accident, including:

- Subarachnoid head bleed
- Multiple mixed partial deep and superficial thickness wounds on his arm and legs

Initial treatment:

- Primarily focused on patient head injury and maintenance of neurological stability, which precluded use of pain medications. Because cleaning of wounds was reported as highly painful, all wounds were initially managed conservatively with simple petroleum-based contact layers and absorbent pads.

Upon hospital discharge 4 days later:

- He was treated at home by his caregiver, a wound care nurse. Due to the high level of pain, his caregiver elected to utilize TPD* to treat the wounds instead of application of topical antibiotics. Mechanical and autolytic debridement was performed to manage the exudate and remove the remaining embedded road debris.
- TPD was applied (sprinkled on the wounds), followed by a contact layer and gauze after the wounds were cleaned.

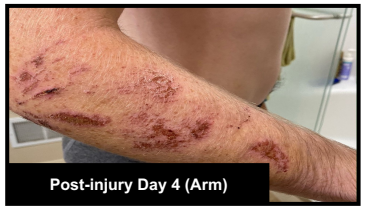
MATERIALS

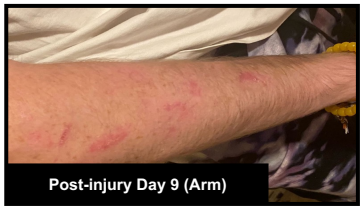
TPD is a novel powder dressing comprised primarily of biocompatible polymers. Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration, as well as some negative pressure effects on the wound. Once applied, TPD may be left in place for up to 30 days and additional powder may be added 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.

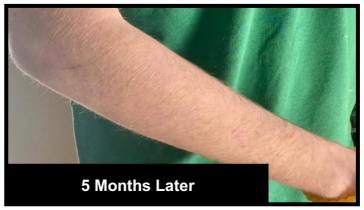
**Altrazeal® Transforming Powder Dressing (USA)*

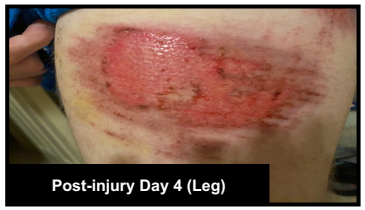
TPD APPLICATION AND RESULTS

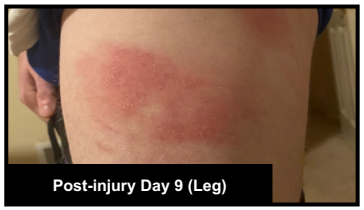
- TPD was topped off as needed, secured with contact layers, absorbent pads and a net dressing.
- On post-injury day nine, five days after initial TPD application, all wounds were epithelialized.
- Immediate pain relief was reported by the patient following TPD application.
- There were no complications of infection or wound progression.
- Post-healing scarring was minimal to absent.











CONCLUSION

Based on the accelerated wound healing, and pain reduction results associated with this patient, we conclude that TPD offers a safe and effective alternative to Standard of Care for the management of painful road rash injuries.

REFERENCES AND ACKNOWLEDGEMENTS

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4. Upton D, Morgan J, Andrew A. et al. The Pain and Stress of Wound treatment in Patients With Burns: An International Burn Specialist Perspective. Wounds. August 2013; 25(8):199-204.

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Application of a Novel New Wound Conforming Dressing

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

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

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

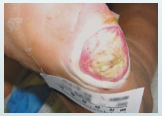
Case 1: A 47 yo Insulin dependent Diabetic white male presented with a neuropathic Wagner Grade 2 ulcer on the lateral aspect of his right foot. He had been treated with an offloading DH Walker and daily dressing with a currently available collagen silver dressing. Wound healing progress had stalled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

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

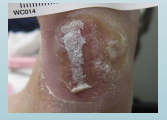
Case 3: A 57 yo white male undergoing active chemotherapy and radiation for intra-cranial metastatic melanoma lost his balance and fell against a steam heat radiator and suffered 3rd degree burn wounds to his right thigh. Concerned that the patient's debility while undergoing active chemotherapy would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

CASE 1

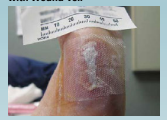
Diabetic Wagner Grade 2 Neuropathic Ulcer



Application of Powder Dressing

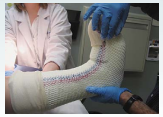


Powder Dressing Covered with Wound Veil



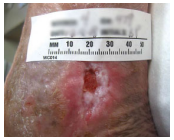
Diabetic Ulcer with Foam Before Contact Cast

Application of Contact Cast

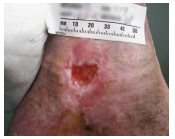


CASE 2

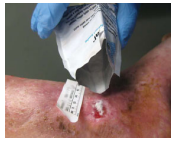
Right Leg Venous Ulcer



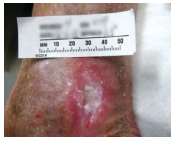
Left Leg Venous Ulcer



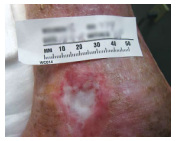
Powder Application



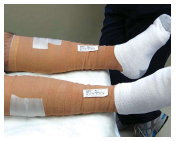
Powder Dressing Right Leg Venous Ulcer



Powder Dressing Left Leg Venous Ulcer

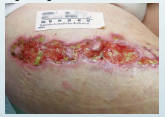


Compression Wraps Applied After Powder Dressing

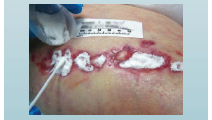


CASE 3

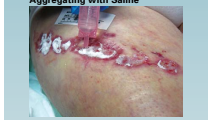
3rd Degree Durn Wound to Right Thigh



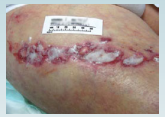
Application of Powder Dressing



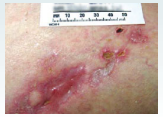
Dressing on Right Leg Burn Wound Aggregating with Saline



Powder Dressing in Place



Third Degree Burn Wound Healed



Powder Dressing and Diabetic Ulcer

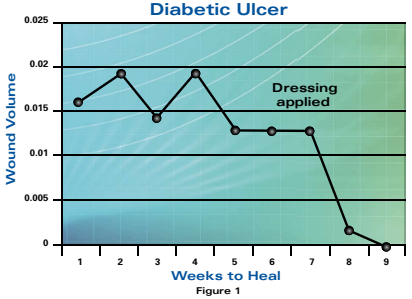
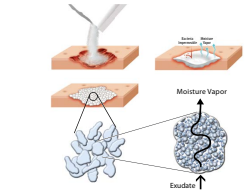
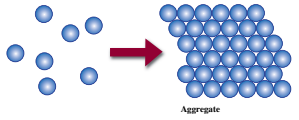


Figure 1



The dressing components consist of polymer particles. The polymer particles are composed of 85% poly-2-hydroxyethylmethacry-late (pHEMA) and 15% poly-2-hydroxypropyl methacrylate (pHPMA). The polymers pHEMA and pHPMA are both non-resorbable, non-degradable, hydrophilic crosslinked polymers that are in the ratio of 85:15 by weight and maintain a fluid content of approximately 68% by weight of the matrix. The powder aggregates (coalesces) immediately and irreversibly from polymer particles into an intact dressing. There is no chemical reaction during dressing formation. The dressing binds together physically and not chemically and remains bound together with the wound exudate through hydrophilic/hydrophobic interactions, hydrogen bonding and VanDerWaal forces. An illustration of the dressing displaying the mechanism of action is shown.



Aggregate

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

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

Purpose:

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

Objectives:

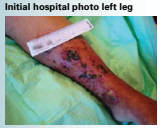
At the conclusion of this presentation the participant will be able to:
1. Realize that pain from wounds impacts on quality of life for patients with wounds.
2. Identify that nociceptive pain can be Procedural; related to dressings and their changes, Incident; related to movement with activity, and Background;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

Abstract:

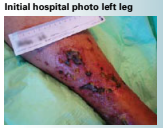
Pain has been categorized as Operative (debridement or surgically related), Procedural (related to dressing removal and application), Incident (related to movement, dressing slippage, etc.) and Background (persistent and underlying pain due to wound etiology). While Operative pain is managed by anesthetic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

CASE 1

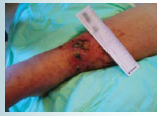
Initial hospital photo left leg



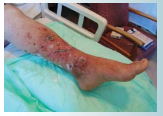
Initial hospital photo left leg



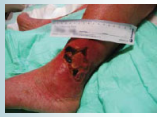
Initial hospital photo right leg



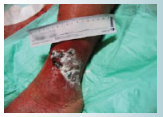
Transforming Powder Dressing applied



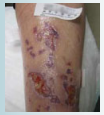
Left leg wound



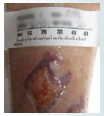
Left leg wound with powder



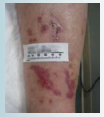
Outpatient wounds



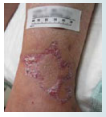
Outpatient wounds



Outpatient healed

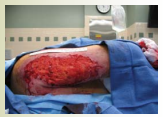


Outpatient healed

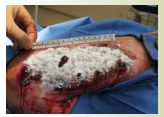


CASE 2

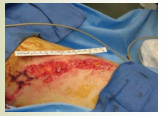
Arm wound



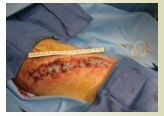
Arm wound



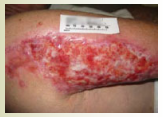
Thigh wound



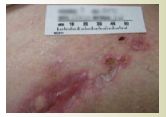
Thigh wound



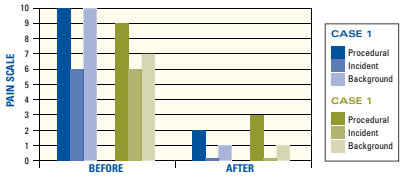
Arm wound healing



Thigh wound healed



Pain Reduction with Transforming Powder Dressing



Methods:

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

Case Studies:

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

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

Results:

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

Conclusion:

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

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