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

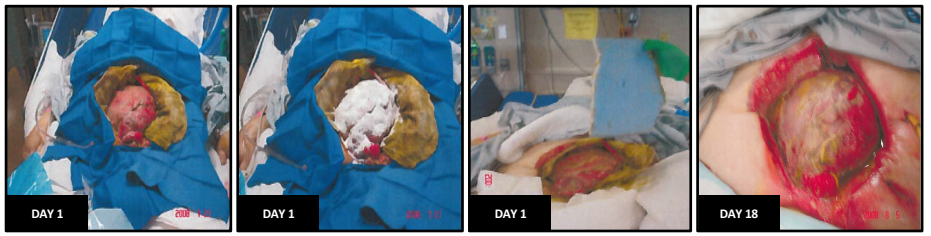
Three case studies incorporating treatment with Transforming Powder Dressing (TPD) to promote granulation in patients with complex wounds are reviewed. In each case, patients had extensive wounds with high levels of reported pain. Prior treatment in all cases failed to progress wounds to the stage to 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

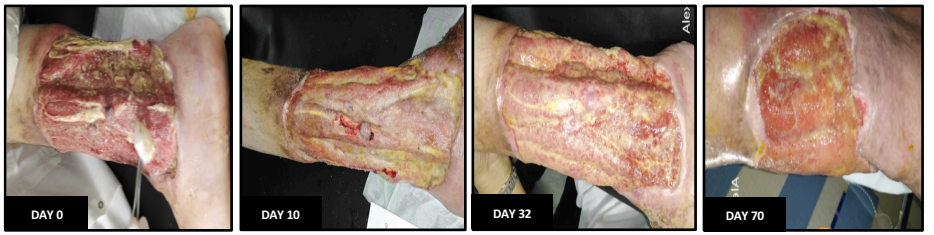
PATIENT 1: 40 y/o female with large complex abdominal wound resultant of car accident
Challenge: NPWT could not be placed due to risk of fistula
TPD Treatment: TPD applied to wound with foam for excess exudate absorption
Outcomes Post-TPD Treatment:

- Wound was ready for grafting by Day 18



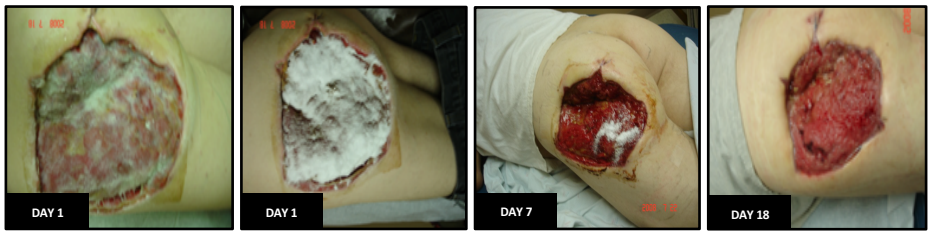
PATIENT 2: 42 y/o male with non-healing progressive venous ulcer, uncontrolled vasculitis, infection history, necrosis, exposed bone
Challenge: High pain score (9/10), failed SOC treatment
Treatment: TPD 2x/week in the first week and 1x/week after
Outcomes Post-TPD Treatment:

- 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.

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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

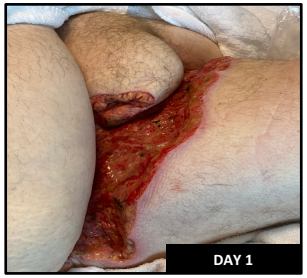
Three case studies incorporating treatment using a novel Transforming Powder Dressing (TPD) in patients with NF and other comorbidities were reviewed. In all cases, patients had extensive wounds with high pain scores, using Visual Analogue Scale (VAS), making NPWT or conventional dressing changes intolerable.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

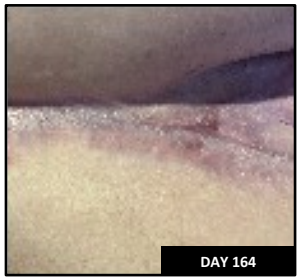
TPD is comprised primarily of biocompatible polymers (used in contact lenses). Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration. Once applied, TPD may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

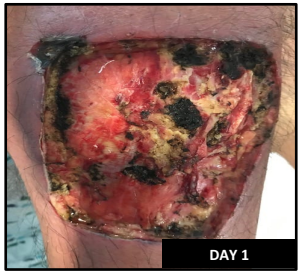
- VAS pain score reduced from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced home health visits (3x to 1x weekly)
- Reduced dressing encounters (<20 versus > 66 estimated with SOC)
- Avoided grafting, amputation & readmission

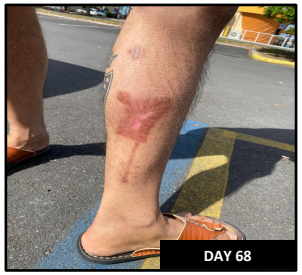




PATIENT 2: 51 y/o male with HIV
Wound Dimension: 72cm^2
Challenge: Painful daily gauze dressing changes
Treatment: Conversion to TPD
Outcomes Post-TPD Treatment:

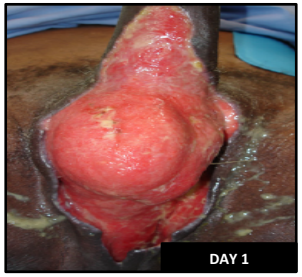
- VAS pain score reduction from 10/10 to 0/10
- Discontinued all pain and opioid medications
- Reduced dressing changes
- (11 vs. 60 estimated with SOC)
- and required visits from 3x to 1x weekly
- Avoided readmission for grafting

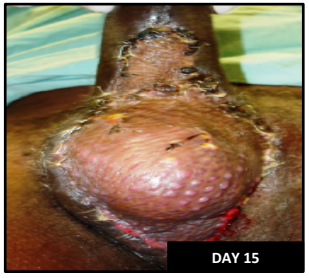




PATIENT 3: 71 y/o male with diabetes, Fournier's gangrene, penile implant malfunction4
Challenge: Painful, challenging location to conduct frequent dressing changes
Treatment: Wound was surgically debrided. Two meshed split-thickness skin grafts were applied, anchored using peripheral sutures covered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

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

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

BACKGROUND | RATIONALE

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

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

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

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

OBJECTIVE

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

METHOD

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

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

THE CHALLENGE: A CASE STUDY[1]

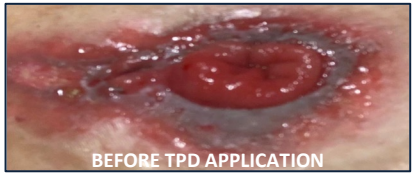
Female, 60 years old with:

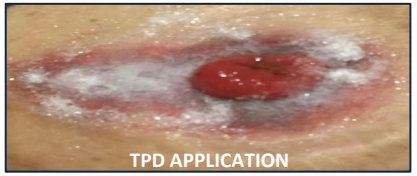
- **Crohn's Disease for 26 years with 27 hospitalizations**
- **Ileum resection, colostomy, loop colostomy revision secondary to hernia complication**
- Diagnosed with **peri-stomal PG 3** years ago
- **18%+ unintentional recent weight loss**
- **Excruciating pain (10/10 based on VAS score)** secondary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

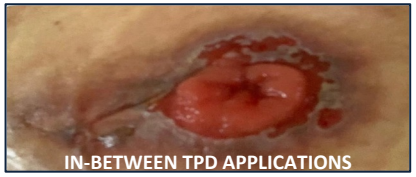
Failed Treatments: Tested **several devices and dressings.** In addition, injectable and topical steroids were tried without improvement. **Opioids** were taken every six hours to control pain.
Onerous Care Regime: Daily or **twice daily appliance changes** performed by the patient with **homecare nurse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

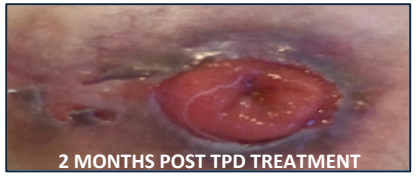
TREATMENT WITH TPD

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









REFERENCES | ACKNOWLEDGEMENTS

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

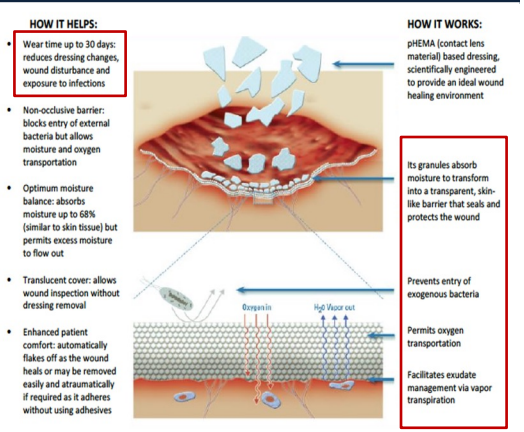
OUTCOMES | CONCLUSION

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

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

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

ABOUT TPD[2]



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).

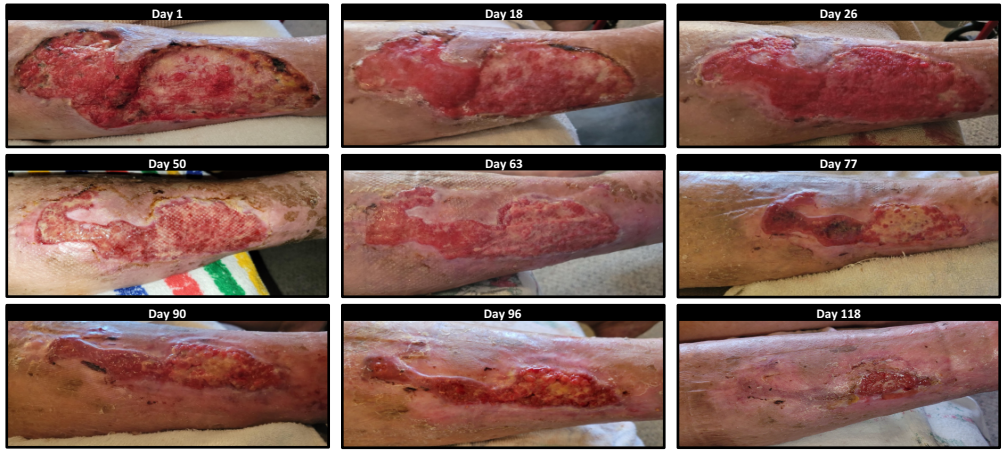
Material

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.

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

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:

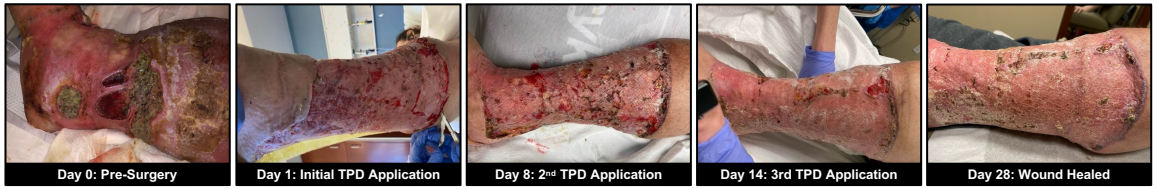
- Circumferential excisional debridement through muscular fascia was performed resulting in a wound area of 1,350 cm^2
- Negative pressure wound therapy (NPWT) was applied post debridement
- A second debridement was performed four days later and NPWT treatment was continued
- A Split thickness skin graft (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.

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

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

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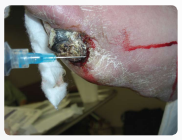
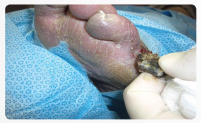


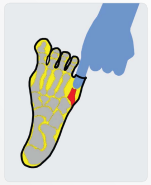
Stable L small toe dry gangrene in a high risk patient.
Problem list: hemodialysis x 8 years, ASPVD S/P 4 perifierial angioplasties with stents, anticoagulation with Coumadin and unstable ischemic cardiomyopathy, prior heel ulcer and finger amputations.
Anesthesia: 5mg of diazepam po, 20cc plain Lidocaine 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



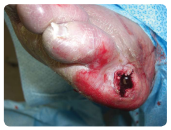
Planned small toe auto-amputation abandoned when wound drains foul smelling pyocyanic green suppurative exudate. Decision to proceed with Wound Center open amputation after patient is unable to be "cleared for surgery" by nephrology and internal medicine due to medical risks.
Working behind a large paper 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



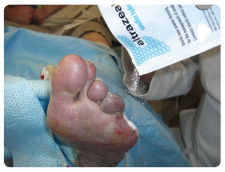
Removal of adequate metatarsal bone is a surgical challenge. One third of the distal 5th metatarsal has been removed with a double action rongeur. The surgeon's small finger guides the blind metatarsal resection by Braille. Repeat cavity palpation with the small finger assures that bone fragments are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

4



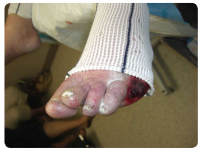
The resulting amputation cavity is 3.5 to 4.0 cm deep. Removing 1/3 of the 5th metatarsal bone is key to healing. To dependably heal, the transected bone end must be covered with adequate soft tissue. Note that the ragged cavity wall appears viable. Note bleeding is minimal because of tumescent Lidocaine.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

5



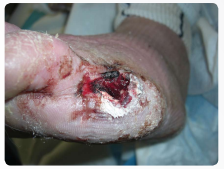
Open small toe amputation cavity is packed with powder using the surgeon's finger to pack the cavity open. The surgical principal of wide open packing keeps the skin edges open. An open wound allows time for the macrophages to deal with devitalized tissue and colonized bacteria. An open wound prevents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

6



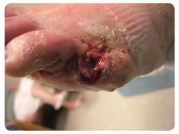
Note how well powder packs the cavity open. Early "stump cavity" packing is known to be an important surgical principal. Following the rongeur debridement, the cavity has a high burden of foreign material that will cause late infection if not removed.
After open amputation, the cavity contains a burden 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



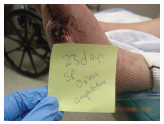
Open amputation cavity, POD # 6. Note absence of redness and excellent perfusion of the skin edge. Note that edema has been controlled by Longitudinal Yarn Compression textile. LYC has created corrrow furrows on the foot.

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.

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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

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Creighton University School of Medicine

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A novel treatment protocol for the management of nonhealing surgical wounds

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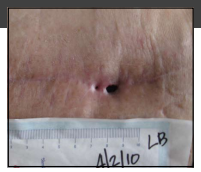
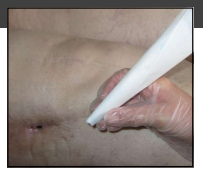
Purpose

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

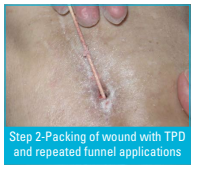
The study indicated that the use of the TPD[1] on nonhealing surgical wounds with a silicone mesh with adhesive border allows for applications of a moist wound dressing for periods of up to 7 days without dressing change. The technique to the right allows the TPD to be applied to a nonhealing surgical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



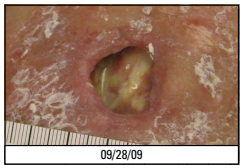
Step 2-Packing of wound with TPD and repeated funnel applications

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



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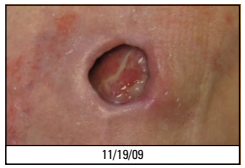

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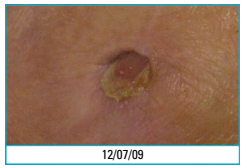

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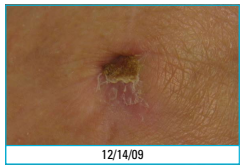

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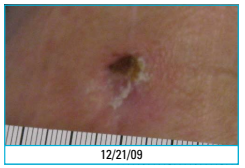

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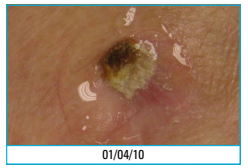

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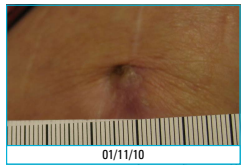

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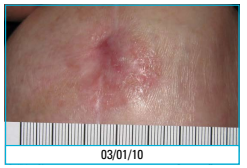
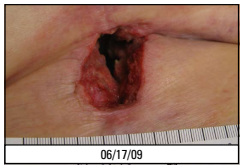


03/01/10

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.



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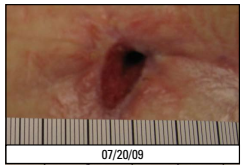

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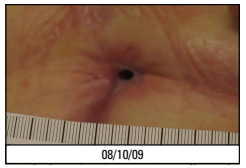

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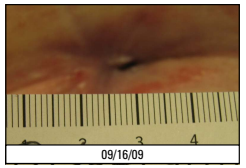

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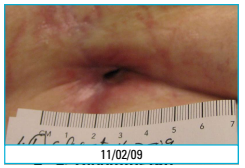

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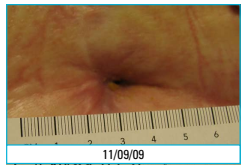

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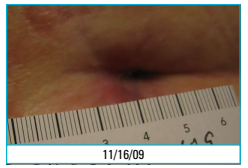

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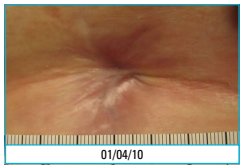

01/04/10

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.

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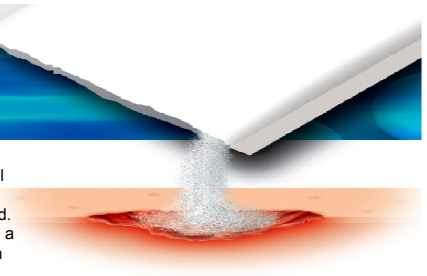
The Wound Healing Centers of Indiana Indianapolis, IN

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.

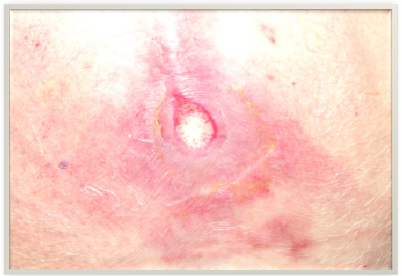
Attendees will also see the results of the application of a novel powder dressing which allows the coverage of these wounds in a region where torsion and strain can make retaining a dressing difficult.

Introduction

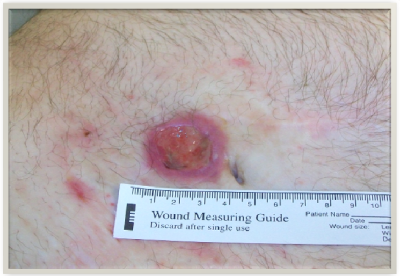
Healing postoperative wounds is problematic due to their location in positions not conducive to standard dressings, tendency towards dryness and the many etiologies of the failure to heal. Abdominal wounds pose their own set of problems in that they are on areas that are in constant motion which reduces 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

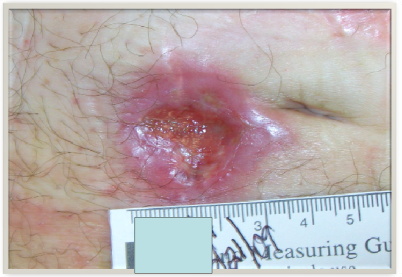
A 58 year old male patient presenting with an open draining wound of the abdomen which had been present for 6 months. The patient had undergone 4 previous ventral hernia repairs the last of which was 4 years prior and used mesh in the repair. The patient had a history of Staph infections of the wound 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.



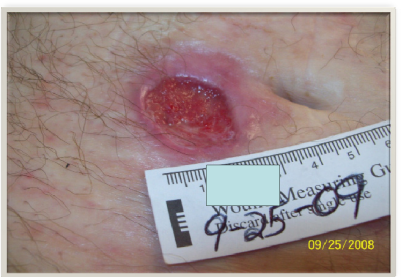
Initial Treatment



2 Months



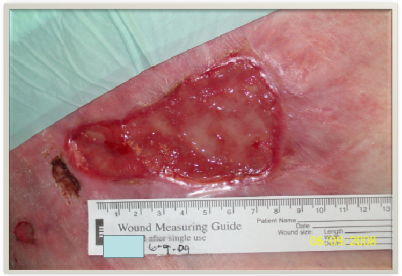
4 months



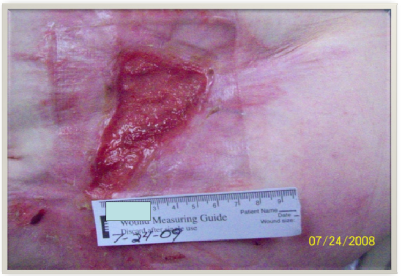
5 months

Case 2

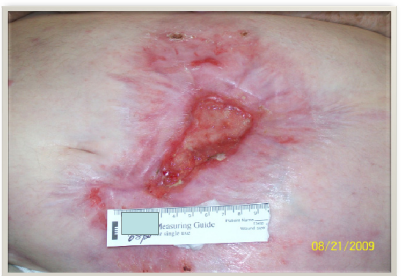
A 74 year old male patient presenting with an incisional dehiscience. The patient underwent repair of an abdominal aortic anyeurism 1 month prior and the dehiscence occured 1 month after surgery. The patient had been undergone treatments including VAC, topical antibiotics, and simple dry dressings with 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.



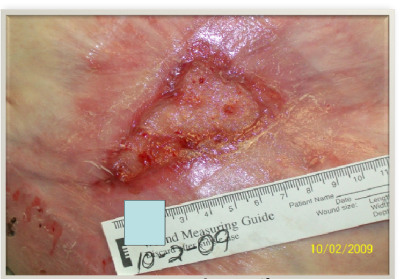
Initial Treatment



2 Months



3 months



4 months

2009 APWCA Conference
Philadelphia, PA.

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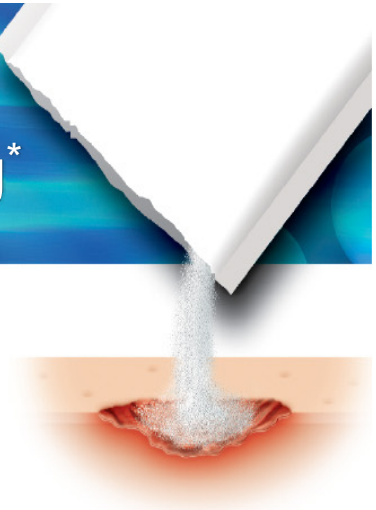
Treatment of a Rheumatoid Nodule Surgical Wound with a Novel Powder Wound Dressing*



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.

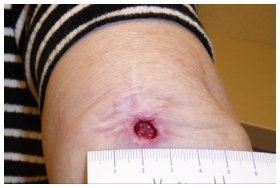
Background:

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.

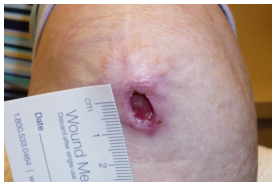
Upon examination, the wound was present on the right arm at the elbow on the lateral olecranon measuring 9 mm in length and 6 mm in width. The depth was 2 mm and there was undermining from 10 to 12 o'clock of approximately 10 mm. The undermining tissue was fibrous and the remaining tissue was red and 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:

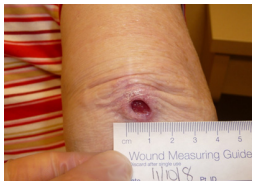
A novel powder dressing, was placed on the wound as treatment with an extended wear time based on the manufacturer claims. It was hoped that the ability of this dressing to stay in place for longer periods would allow the patient to have infrequent dressing changes between visits. The dressing is presented 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.



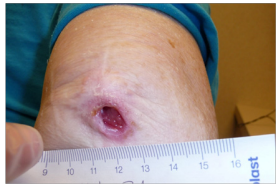
Day 0 of treatment



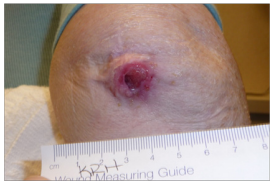
Day 4 of treatment



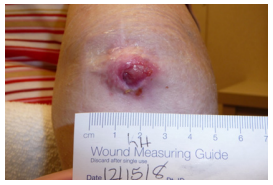
Day 11 of treatment



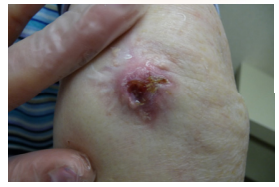
Day 21 of treatment



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