

# Treatment of Large Refractory Atypical Buttock Wound from Systemic Fungal Infection with Novel Transforming Powder Dressing: Case Study of Critically Ill Nine-Year-Old Male

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Symposium on Advanced Wound Care (SAWC) Fall 2023 Meeting | November 3 – 7 | Las Vegas, NV

## INTRODUCTION

Wounds and resulting complications are challenging, especially when standard of care (SOC) therapies fail, prompting clinicians to think "out of the box." This case study involves a 9-year-old male with multiple medical conditions including antibody autoimmune hemolytic anemia. He was admitted with shortness of breath and jaundice, requiring dialysis, ECMO and emergent intubation. The Wound Care team was consulted for what appeared to be a deep tissue injury on the buttocks but was ultimately determined to be a systemic fungal infection (*Rhizopus*). Complications resulting from SOC treatment highlight the need for incorporating new technologies, like transforming powder dressing (TPD\*) into our wound care regimen.

## METHODS

The wound required serial surgical wound debridements involving bilateral buttocks and posterior thigh. The wound circumscribed the anus and uncontrolled stooling necessitated multiple dressing changes per day. Negative pressure wound therapy (NPWT) was applied after a diverting colostomy. However, painful dressing changes necessitated premedication with conscious sedation and bleeding complications prompted NPWT discontinuation. TPD was initiated to treat the 2,794.5 cm<sup>3</sup> buttock wound (27 × 23 × 4.5 cm with a 6 cm tunnel).

TPD is a novel, extended wear (up to 30 days) dressing comprised of polymer granules that transform into a moist, protective matrix to cover the wound surface when hydrated with saline. TPD was applied and secured with a non-adhesive contact layer, gauze, and an egress system to manage drainage initially and then transitioned into a foam dressing.

## RESULTS

Within 10 days of TPD treatment, new granulation tissue was observed over the muscle and grafting/multilayer closure was performed. However, the graft failed and TPD applications were resumed until ready for closure. However, the wound incision dehiscd and TPD was restarted until granulation was complete. No complications were observed from TPD.



## DISCUSSION

Conversion to TPD eliminated bleeding complications, the need for conscious sedation and all pain medications. Wound care assessments were reduced from multiple times a day to 2x/week for the initial 10 days and to weekly thereafter. TPD stimulated granulation and the wound was transitioned to SOC dressings. The wound healed without further complications. TPD provided a viable course of treatment where conventional SOC and surgical interventions failed while reducing clinician time and material cost.

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# Utilization of Transforming Powder Dressing for Managing Peristomal Wounds and Mucus Fistula in a Neonate after Omphalocele Repair

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Symposium on Advanced Wound Care (SAWC) Fall 2023 Meeting | November 3 – 7 | Las Vegas, NV

## INTRODUCTION

Omphalocele is a congenital condition where a portion of the intestine protrudes through the abdominal wall near the navel, affecting approximately one in 4,200 births in the United States.<sup>1</sup> The current standard of care (SOC) involves surgical intervention, including the application of a silo pouch to contain the omphalocele, followed by repair and ostomy creation. However, complications such as wound infection, delayed healing, fascial separation, patient discomfort, and loss of abdominal domain can occur. Novel approaches to optimize wound healing, minimize dressing changes, and alleviate associated pain are needed.

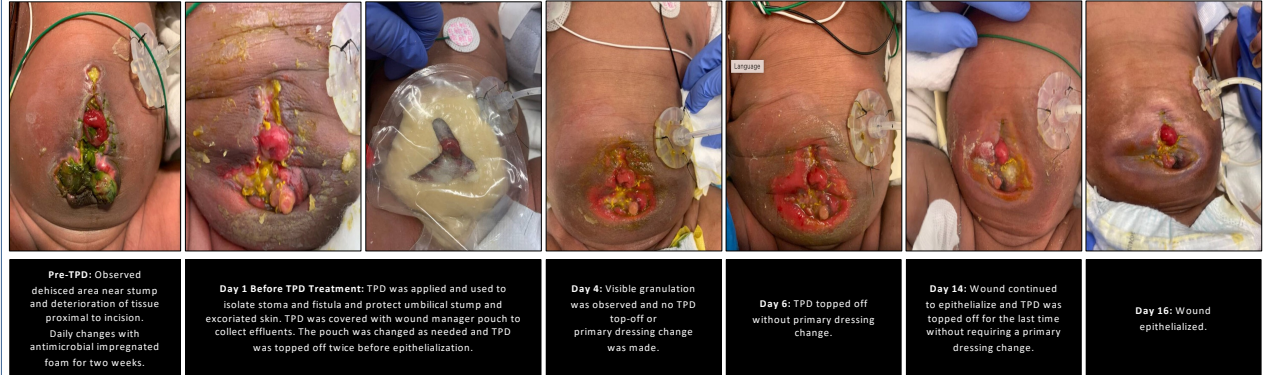
In this case study, we present the use of an extended wear (up to 30 days) transforming powder dressing (TPD\*), composed of polymers similar to those used in contact lenses, to expedite wound healing and improve patient care.

## METHODS

Following omphalocele repair, a 2-month-old boy experienced surgical wound dehiscence and developed moisture-associated skin damage (MASD). Various standard of care dressings were utilized in combination with jejunostomy pouching to isolate the stoma from the umbilical stump wound, and a mucous fistula was created to minimize further wound and skin complications. However, the pouching and dressings proved inadequate as effluent repeatedly undermined the barrier ring several times a day. The neonate experienced restlessness, worsening tachycardia, and increased pain due to MASD and frequent wound care. Consequently, the clinical team determined the need for an alternative treatment modality. After careful consideration, the entire area was managed as a fistula, employing a larger pouching system, while the wounds were protected with TPD to shield them from moisture and effluent.

## RESULTS

TPD was applied and topped off twice over 16 days. The MASD resolved, tachycardia improved, and all wounds achieved epithelialization. The neonate no longer required pain medication before treatment, and successful pouching was achieved.



## DISCUSSION

Upon hydration with saline, TPD polymers congeal to form an oxygen permeable, moist matrix that covers and protects the wound. The TPD matrix provides a non-occlusive barrier that allows fluid exchange through vapor transpiration, while protecting the wound from contamination. TPD may be left on the wound for up to 30 days and topped off as required in the interim, thereby reducing the trauma and infection risk associated with primary dressing changes. In this case study, utilizing TPD facilitated wound healing by offering a protective barrier against effluents and isolating the stoma and fistula. This approach resulted in reduced frequency of dressing changes, pain and pain medications while increasing patient comfort and nursing efficiency. Introducing TPD enabled the implementation of a suitable pouching option for a complex abdominal wound with MASD in a neonate following omphalocele repair.

## REFERENCES & ACKNOWLEDGEMENTS

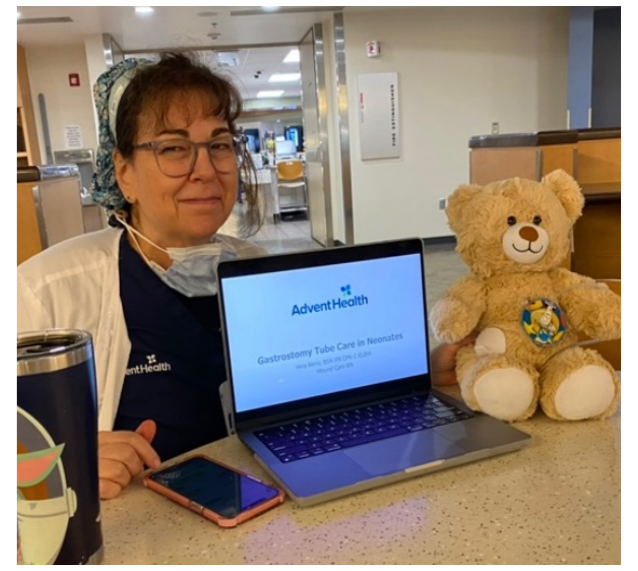
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# Managing Skin Breakdown in Extremely Low Birthweight Babies Using a Unique Transforming Powder Technology

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



## INTRODUCTION

Over 20 million newborns are low birth weight.<sup>1</sup> Micro-preemies, or extremely low birthweight infants, are born at less than 26 weeks and are one of the most vulnerable patient populations. Their stratum corneum is only two cells thick and does not fully develop until late in the third trimester. The skin is especially fragile and easily traumatized by gentle adhesives, life support, monitoring equipment, and other necessary invasive procedures. “Touch-time” increases stress and exposure to infection through damaged or immature skin in an already immune-compromised host. Other skin related complications include energy demands from electrolyte imbalances, more evaporative heat loss and the toxicity risk from external substances. Significant morbidity and mortality can be attributed to practices that cause either trauma to skin or alterations in normal skin function.<sup>2</sup>

Approaches to skin care in pre-term neonates varies considerably with location and clinical experiences. There is no single established guideline for neonatal skin care. Topical emollients, petrolatum ointments, humidification, plastic wraps, and transparent adhesive dressings have been used to treat weak or damaged skin barriers. These therapies require frequent changes, increasing touch time, risks of infection and skin trauma.

## METHODS

This case series presents three micro-preemies born at 22 weeks gestation (lowest birth weight of < 500 grams), who had large areas of denuded skin from tape trauma and were not responding to basic humidification. A novel extended wear transforming powder dressing (TPD\*), comprising of polymers similar to those used in contact lenses, was sprinkled over the damaged skin areas, transformed with sterile saline, and covered with non-adhesive cover dressings. TPD was left in place, but the cover dressings were changed as needed.

## RESULTS

The skin on all three babies was fully epithelialized within an average period of 10 days without scarring and using two applications of TPD. Oxygen requirements improved and no adverse effects were reported.



## DISCUSSION

TPD presents a simple wound management technique for the treatment of skin trauma in premature neonates. Upon hydration, its granules aggregated to provide a moist, non-occlusive, oxygen-permeable barrier that facilitated wound healing while reducing dressing changes and touch time in the NICU.

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# Novel Technique to Overcome Challenges Associated With Management of Difficult Perineal Pediatric Wounds Using a Transforming Powder Dressing: A Case Series

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Symposium on Advanced Wound Care | April 26 – 30, 2023 | National Harbor, MD

## INTRODUCTION

On average, 3.9 million pediatric surgeries are performed annually in the USA.<sup>1</sup> Five percent of surgical wounds develop infections or other wound complications, resulting in poor wound healing, and increased pain, hospital stay and treatment costs.<sup>2</sup> Postoperative care, including adequate wound management, is critical to ensuring successful outcomes.<sup>3</sup>

## METHODOLOGY

This pediatric case series involves three patients with difficult-to-dress perineal wounds with post-operative complications. Ages ranged from five months to 18 years with diverse wound types including a vulvar tumor, perianal fistula-in-ano and pilonidal cyst. All wounds were treated with a Transforming Powder Dressing (TPD\*), an extended wear (up to 30 days) dressing, made from polymers granules that transform upon hydration to form a moist matrix that covers the wound.

We hypothesized that the addition of TPD would facilitate wound closure and reduce primary dressing changes and its powder form would facilitate ease of application in these difficult to dress areas.

## DISCUSSION

All wounds healed with less than expected healing times and reduced dressing change frequency, demonstrating the utility of TPD in treating these difficult-to-dress perineal pediatric wounds.

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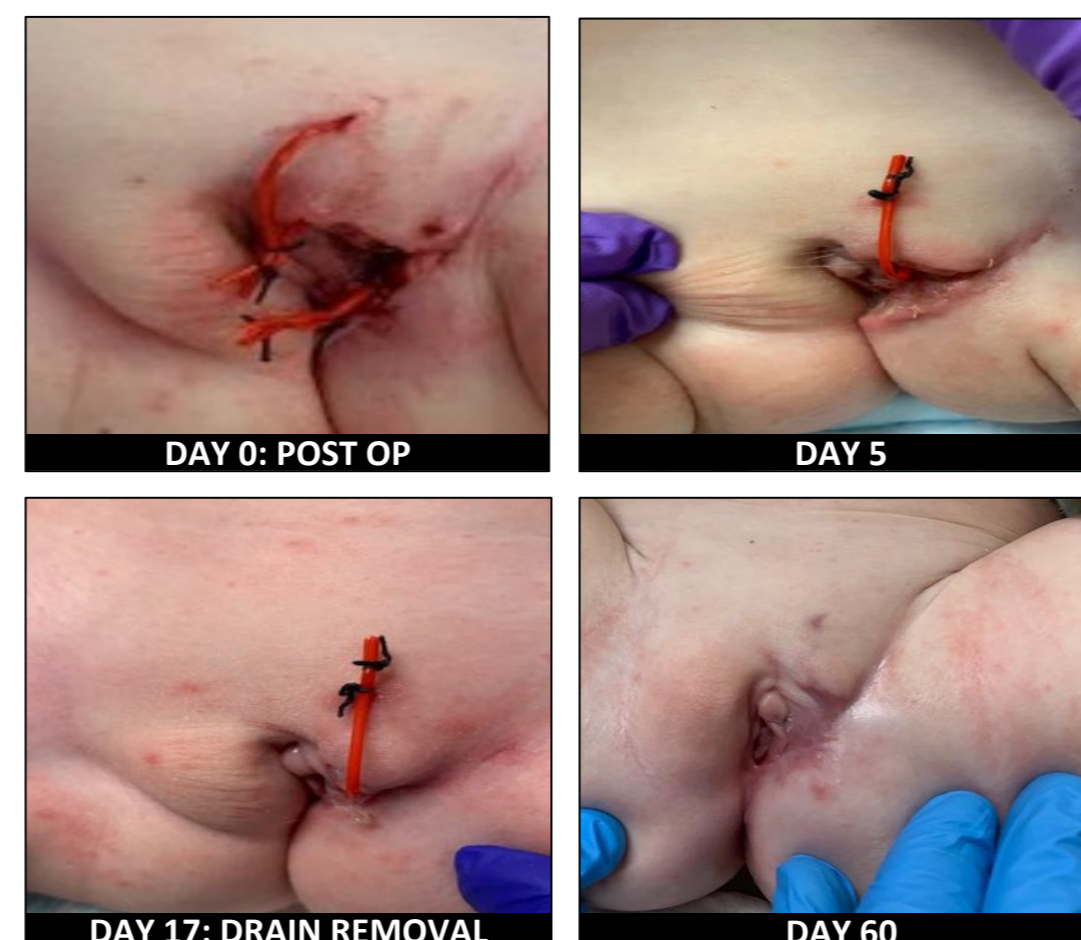
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\*Altrazeal® Transforming Powder Dressing

## RESULTS

### VULVAR TUMOR

- 14-month-old female with rapidly growing prepubertal tumor, s/p tumor excision and reconstruction with rhomboid rotational flap
- Post Op Day 5: 3.8 x 3.2 cm wound with undermining from c/b structure line disruption
- Patient to OR for placement of two silastic bands to allow drainage followed by TPD application
- TPD topped off 2x in the 1st week and then 1x every one to two weeks
- Complete epithelialization in 8 weeks**
- Six primary TPD changes over 60 days** versus 60-120 (1-2x daily) with conventional dressings in this clinical practice



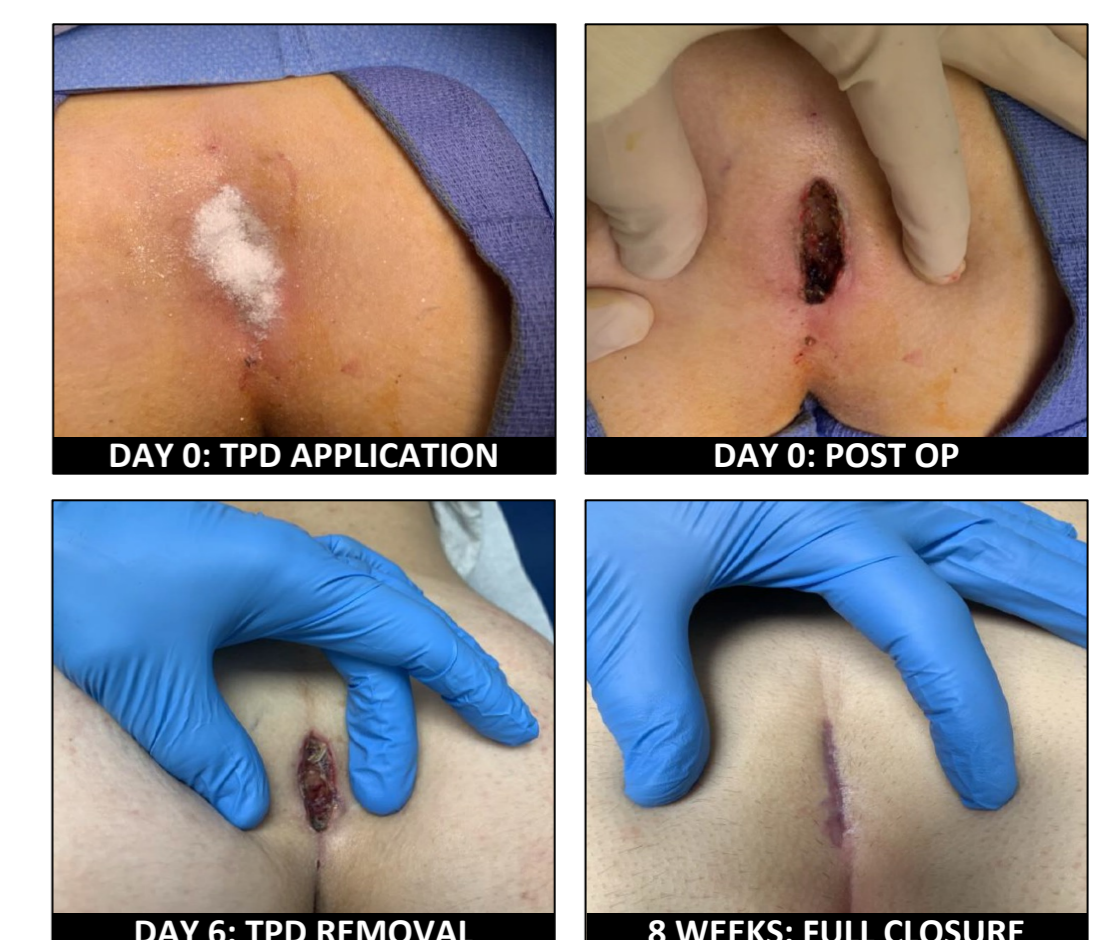
### PERIANAL FISTULA-IN-ANO

- 5-month-old male with perianal abscess
- Initial treatment: I&D ad antibiotics at eight-weeks-old; c/b recurrent infections drained spontaneously through a persistent tract over next three months
- Taken to surgery with fistula-in-ano for fistulotomy
- TPD applied post-fistulotomy and at Day 6
- Full wound closure within three weeks**
- Two primary dressing changes** versus 21-42 (1-2x daily) with conventional dressings over three-week treatment period in this clinical practice



### PILONIDAL CYST:

- 18-year-old female with three distinct sinus tracts
- 6 x 2 x 2 cm wound post surgical debridement
- Applied TPD to control pain first week post-op; contact layer and gauze; rinsed on Day 6
- Conventional dressing thereafter
- Full closure within eight weeks**
- One TPD application during week 1 versus 14 with conventional dressing changes (2x daily)** in this clinical practice
- Marked granulation tissue after week 1** after which conventional dressings used



Acknowledgements: This poster was developed and presented in collaboration with Altrazeal Life Sciences Inc. For application instructions and risks of this device please refer to Altrazeal Instructions for Use. | EDU-0059, REV 01

## 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<sup>1</sup>. 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.<sup>1,2,3</sup> 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.

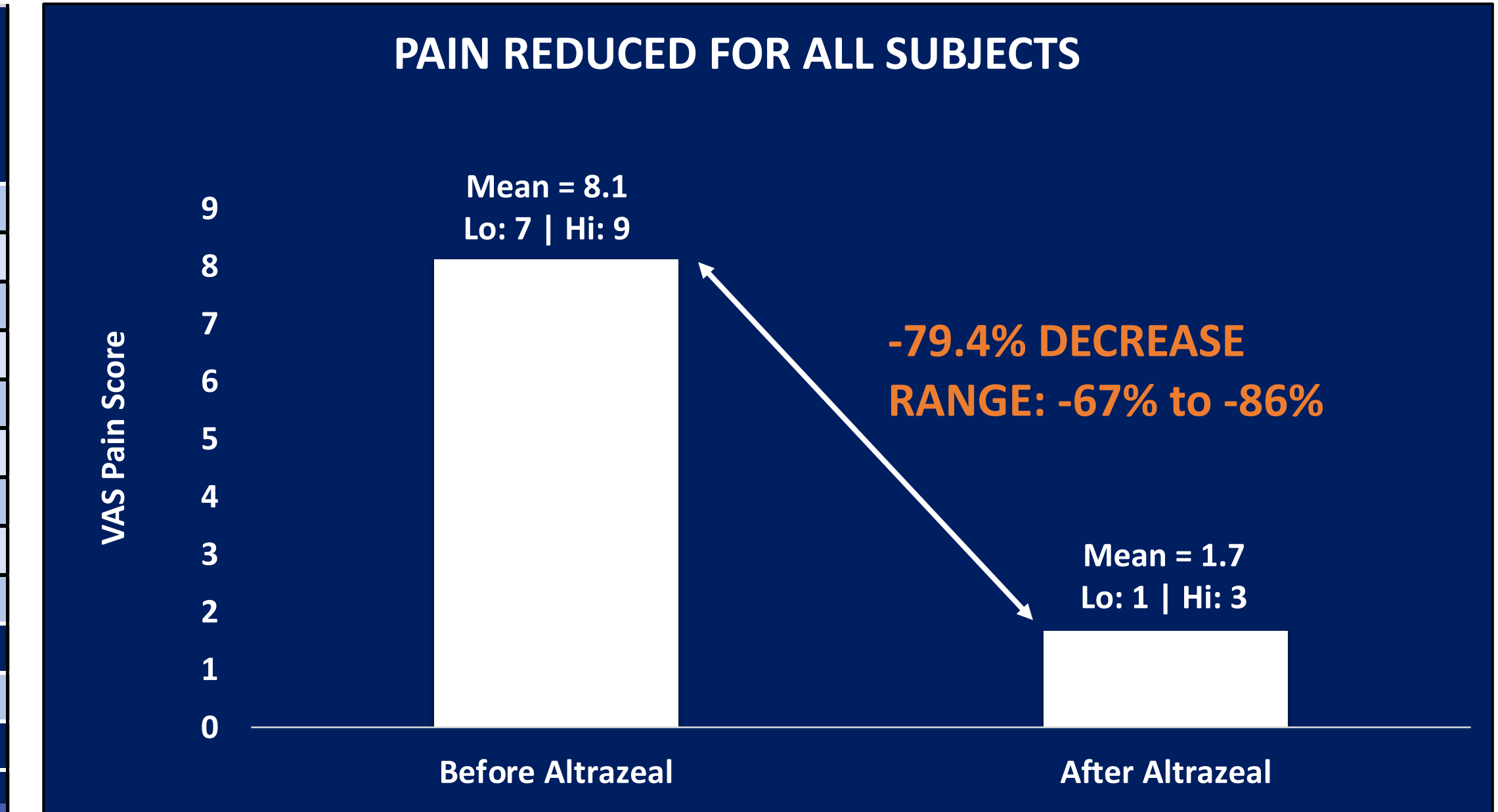
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Please see the Altrazeal Instructions for Use for a complete listing of indications for use, precautions, and warnings

## 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
	<b>Average</b>			<b>12.1</b>	<b>8.1</b>	<b>1.7</b>	<b>0.4</b>
	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 flexibility 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

Ann Marie Nie, PhD, MSN, APRN, FNP-BC, CWOCN<sup>1</sup>; Erica Eberhard, MSN, APRN, FNP-BC, CWOCN<sup>2</sup>; Dawn Jennifer Wang, MD, FACS<sup>3</sup>

1. Dayton Children's Hospital; 2. Children's Minnesota; 3. UPMC St. Margaret Hospital

## BACKGROUND

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

## PAST MANAGEMENT

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

## CURRENT CLINICAL APPROACH

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




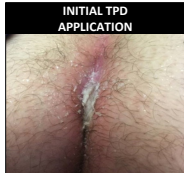






## MATERIAL

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

\*Altrazeal® Transforming Powder Dressing

## PATIENT OUTCOMES

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

18 y/o Female		20 y/o Male			17 y/o Female
					<ul style="list-style-type: none"> <li>• Nonhealing pilonidal cyst for 15 weeks refractory to SOC wound care with daily packing</li> <li>• Originally, wound volume measured 1 x 1 x 2.5 cm. After 15 weeks, when converted from SOC to TPD, wound measured 0.5 x 0.5 x 1.5 cm</li> <li>• Wound was closed in one week with a single TPD application</li> <li>• No re-opening on follow up and no complications reported</li> </ul>
					

## CONCLUSION

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

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