

Evaluation of Altrazeal transforming powder dressing on stage 2–4 pressure ulcers: a clinical case series

Objective: Pressure ulcers (PUs) are hard-to-heal, open wounds that affect millions of adults worldwide. Patients experience physical, mental, social and financial impairment. On average, <50% of stage 3 and 4 PUs heal by the sixth month. Treatment of PUs is highly variable due to a patient's comorbidities, demographics and wound characteristics. Because of this, there exists no standard dressing for PUs. Altrazeal transforming powder dressing (TPD, Uluru Inc., US) offers a promising new form of wound treatment; however, little evidence exists for TPD in the treatment of hard-to-heal PUs. This case series sought to examine the effect of TPD in hard-to-heal PUs that have previously undergone unsuccessful standard of care (SoC) wound therapy.

Methods: This case series used retrospective data from patients with stage 2–4 PUs that failed to heal after SoC therapies. Factors examined were: number of dressing changes; time between dressing changes; time to wound closure; and pain level. While data were assessed for all patients, we focused on the six particular cases that most clearly illustrated the effect of TPD on wound healing.

Results: Each of the 21 patients treated with TPD experienced successful and expedited wound closure. Stage 4 PUs took an average of 87 days with approximately six dressing changes to closure. Stage 3 PUs took an average of 41 days with approximately four dressing changes, and stage 2 PUs an average of 13 days to closure with approximately one dressing change. In the cases presented herein for which pain scores were reported, each showed a reduction in pain from an 8 or 9/10 to a 1 or 2/10 with the first dressing change.

Conclusion: In this case series, TPD effectively reduced pain and healed PUs that had previously failed SoC interventions. We suggest future prospective studies in order to more effectively measure the wound healing capability and healthcare utilisation of TPD for treatment of PUs.

Declaration of interest: None of the authors has a financial interest in any of the products, devices or drugs mentioned in this manuscript. None of the authors received compensation or has any other conflict of interest to declare.

Altrazeal transforming powder • chronic wound • dressings • hard-to-heal • pain reduction • powdered dressing • pressure injury • pressure ulcer • stage 4 pressure ulcer • ulcer • wound • wound care • wound healing

Pressure ulcers (PUs), sometimes known as decubitus ulcers, are localised damage to skin and underlying soft tissue due to sustained pressure, typically occurring over bony prominences. Prolonged pressure to the skin initiates a sequential damage cascade involving cell deformation, distortion and corresponding inflammatory responses.¹

PUs are a global problem, affecting >7 million people, annually.² In the US alone, >2.5 million people have PUs each year, causing >60,000 deaths.³ Cost of individual patient care ranges from US\$20,900–151,700 per PU, resulting in a total cost of US\$9.1–11.6 billion within the US, annually. Stage 3 and 4 PUs account for 58% of all hospital-acquired PU (HAPU) costs.⁴ Patients with PUs experience increased hospital lengths of stay, readmission rates and healthcare costs due to the

chronicity of their injuries.⁴

Several risk factors impact wound healing in patients with PUs, including medications, nutrition, alcohol use, offloading regimens, mobility, pressure, trauma, oedema and smoking.^{5,6} The Braden Scale for predicting PU risk has also been developed to promote early identification of patients at risk of developing PUs by considering six key factors:⁷

- Sensory perception
- Skin moisture
- Activity
- Mobility
- Friction and shear
- Nutritional status.

However, prevention and treatment of PUs are both time- and labour-intensive, imposing significant physical, mental, social and economic burdens on patients and/or their care providers.

Patients with PUs experience a severe reduction in quality of life (QoL) resulting from pain, malodours and wetness from wound discharges, stress, anxiety and depression.⁸ Notably, a recent study reported severe pain in >75% of individuals with PUs.⁹ Similarly, recent evidence showed that 87.5% of patients have immense pain during wound dressing changes, causing substantial challenges in the management of these injuries.¹⁰

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Fig 1. Altrazeal transforming powder dressing. Altrazeal methacrylate-based transforming powder dressing (TPD) (a); Moisture is applied to the powder (b); Upon contact with moisture, the TPD transforms into a shape-retentive hydrogel wound matrix (c)



A recent meta-analysis confirmed that patients with PUs have a 1.78-times higher risk of mortality compared with patients without PUs.¹¹ Disrupted skin barriers and tissue defects, often found within PUs, cause higher risks of localised infection, cellulitis and osteomyelitis. These adverse events can lead to serious, life-threatening complications such as sepsis or gangrene.²

The standard clinical practice for wound management as explained in the International Clinical Practice Guideline¹² includes proper wound bed preparation, cleansing and debridement, and the most appropriate wound dressing based on individual goals. Hydrocolloid dressings and negative pressure wound therapy (NPWT) have also proven effective for the treatment of PUs.^{13,14} Barrier dressings that prevent infection and maintain a moist wound environment are essential in PU management. It is important to optimise dressing changes as frequent changes may damage skin, trigger dehiscence and increase the risk of infection. PU management often requires a combination of different treatment modalities that both target underlying conditions and promote ulcer healing. While the standard of care (SoC) for PU treatment typically follows these clinical practice guidelines, treatment is largely influenced by patient-related factors, such as comorbidities and wound stage.¹⁵ Thus, the complex nature of PUs requires a multidimensional treatment approach. An ideal dressing would allow rapid healing and pain reduction at an affordable cost.

The proposed solution in this case series uses Altrazeal (ULURU Inc., US), a novel methacrylate-based transforming powder dressing (TPD). Upon contact with moisture, TPD transforms in situ to a shape-retentive wound matrix (Fig 1). It has been introduced and adopted into a number of prominent commercial and Veterans Administration facilities in the US and overseas, successfully treating both hard-to-heal and acute wounds. However, clinical evidence is still limited. The purpose of this study was to present initial clinical, patient satisfaction and healthcare utilisation data on the efficacy of TPD in the management of non-infected stage 2–4 PUs.

Methods

Dressing solution

The constituents of TPD are members of a family of hydrophilic polymers with two primary components: poly-2-hydroxyethyl methacrylate (pHEMA) and

poly-2-hydroxypropyl methacrylate (pHPMA). pHEMA and pHPMA are non-toxic, transparent biocompatible polymers that form hydrogels in water and exhibit suitable mechanical properties (Fig 1). In wounds, these hydrogels help reduce exudative fluid losses and maintain a moist wound environment.¹⁶ As hydrogels they swell but do not dissolve in water, and they can safely perform their functions without being absorbed into the host's bloodstream. Consequently, the limited number of side reactions allows the dressing to remain in place for an extended period of time, mitigating the risks associated with frequent dressing changes.

Patients

The study was a retrospective review of cases to assess the effectiveness of TPD therapies in the treatment of stage 2, 3 and 4 PUs. The study gathered patient data from 21 patients, both from general civilian health institutions and private clinics. The inclusion criteria were patients with hard-to-heal stage 2–4 PUs that had failed treatment with SoC therapies.

For the patients with recalcitrant wounds, all had been previously treated with a range of SoC therapies including moist wound care dressings, hydrocolloids or NPWT. The wounds were cleansed with saline. TPD was then applied and covered with an appropriate secondary dressing. The wounds were evaluated at weekly intervals, and TPD was reapplied as indicated. Days to healing, number of dressing changes and days between dressing changes were recorded. Pain scores determined by the Visual Analog Scale (VAS) and changes in wound size were observed before and after TPD treatment. Treatment with TPD dressing continued until the physician determined that the condition of the PU no longer warranted its use.

Ethics and permissions

The Institutional Review Board (IRB) of Northwestern University granted this project exemption on 17 November 2020, under the submission number STU00213695. The IRB granted the following special determinations: 'Waiver of HIPAA authorization; Waiver/alteration of the consent process; Waiver of consent documentation.' De-identified data from all accessible TPD-related PU cases from various clinicians were collected in collaboration with the manufacturer and subsequently analysed by the research team. The protocol granted permission to use patient images for data analysis and publication as long as the patient data and images were de-identified.

Results

The mean age of the 21 participating patients was 49.8 years. Each patient had hard-to-heal PUs of various aetiologies and stages that had failed previous wound management therapies. Of the patients, one patient had two wounds, both of which were included in the study but considered as one. With regards to the classification of the PUs, seven (33%) were severe (stage 4) PUs,

11 (53%) were stage 3, and three (14%) were moderate (stage 2) PUs. The majority of patients had comorbidities which could compromise wound healing, including: type 2 diabetes (29%); paraplegia, hemiplegia or serious immobility (48%); and blood disorders. A history of a stroke was present in four of the patients. The majority of PUs were located on the sacrum (38%), coccyx or sacrococcyx (33%) or ischium (19%). Dressings were changed on a weekly to monthly basis, based on the clinician's judgement and the needs of the individual patient. In seven patients, more frequent dressing changes were needed initially, but with consistent use of the TPD dressing, the dressing remained in situ for longer intervals. The mean number of dressing changes was 4.1 and the

mean time to heal was 52.2 days. All patients experienced complete wound healing. The end results from the study are shown in Tables 1 and 2.

We have highlighted six cases to more clearly illustrate TPD's wound healing capability. In the presented cases, for which pain scores were reported, each showed a reduction in pain from an 8 or 9/10 to a 1 or 2/10 with the first dressing change, and a visible reduction in wound size was observed by the second dressing change.

Case reports

Case 1

A 74-year-old male patient with type II diabetes and hemiplegia developed a stage 4 PU on the sacrococcygeal

Table 1. Summary of Altrazeal transforming powder dressing (TPD) treatment use and outcomes on stages 2–4 pressure ulcer cases

Stage of ulcer	Cases analysed	Average days to healing	Average number of dressing changes	Average days between dressing changes
All	21	52.2	4.1	13.9
Stage 4	7	87.4	6.3	17.7
Stage 3	11	40.6	3.5	12.3
Stage 2	3	12.7	1.3	10.8

Table 2. Deconstructed summary of patient conditions and Altrazeal transforming powder dressing (TPD) treatment outcomes on stages 2–4 pressure ulcer cases

No	Age, years	Sex	Known pre-existing conditions/diseases	Stage of ulcer	Days to healing	Total dressing changes	Average days between dressing changes
1	74	Male	DM II, post stroke, hemiplegia	4	131	9	15
2	68	Female	DM II, post stroke, hemiplegia	4	37	2	19
3	25	Male	>6-year-old PU	4	57	2	29
4	8	Female	Spina bifida	4	38	2	19
5	88	Male	Hemiparesis after stroke, Parkinson's disease	4	125	6	21
6	20	Male	Paraplegia due to car accident, hospital-acquired PU post surgery	4	104	7	15
7	68	Female	Demyelinating disease	4	120	16	8
8	56	Female	Posttraumatic, DM II, hemiplegia	3	39	3	13
9	57	Male	Wheelchair-bound, DM II, hypertension	3	42	3	14
10	71	Male	DM II, post stroke, hemiplegia	3	48	2	24
11	43	Male	>1-year-old PU	3	34	2	17
12	42	Male	>3-year-old PU	3	21	3	7
13	16	Male		3	21	3	7
14	38	Female	>1-year-old PU	3	24	2	12
15	75	Female	DM II	3	70	7	10
16	42	Male		3	85	5	17
17	68	Female	Demyelinating disease	3	21	3	7
18	18	Female	Cerebral palsy, sclerosis, wheelchair-bound and bedbound	3	42	6	7
19	52	Male	> 3-year-old PU	2	11	2	6
20	38	Female	Accident, bedbound for 7 months	2	15	1	15
21	78	Female	Paralysis	2	12	1	12

DM—diabetes mellitus; PU—pressure ulcer

Fig 2. Case 1: a 74-year-old male patient with a hard-to-heal stage 4 pressure ulcer (PU) on the sacrococcygeal area (a); there is reduced purulent exudation seen 9 days after transforming powder dressing (TPD) application (b); TPD dressing change on the improving ulcer on day 42 (c); noticeable increase in re-epithelialisation and decrease in wound size is seen on day 50 (d); after 131 days, the hard-to-heal PU is in the final stage of healing with complete granulation tissue formation, no open ulcer and there is no longer a need for TPD dressing (e)

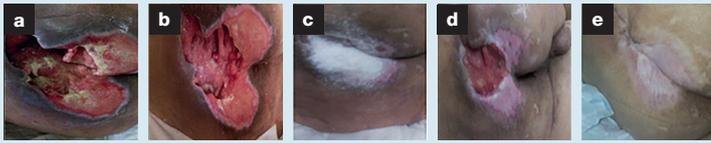


Fig 3. Case 2: a 56-year-old female patient with two stage 3 pressure ulcers (PUs) on the sacrococcygeal region with significant erythema and erosion (a); with the start of transforming powder dressing (TPD) therapy, contraction around the edges of the wounds is already seen on day 13 (b); there is a reduction in erythema and re-epithelialisation of the undermined wounds by day (c); after 39 days of TPD therapy, both ulcers are in the final stage of healing with no signs of dehiscence (d)



Fig 4. Case 3: a 68-year-old female patient with a stage 4 pressure ulcer (PU) on the sacral region with significant exudation and erythema (a); a new transforming powder dressing (TPD) is applied to the improving ulcer on day 25 (b); the TPD is covered with standard dressing (c); after 37 days of therapy, there is complete wound healing and no signs of dehiscence (d)



area two months following a stroke. The PU had previously been treated with silver sulfadiazine cream covered with foam dressings three times daily (Fig 2). Prior to TPD therapy, the patient rated his wound pain as 9.5/10. Although the TPD dressing was anticipated to be changed twice weekly, the actual time between dressing changes ranged from 7–27 days, with an average time of 15 days over the total treatment period. After three dressing changes over five weeks, the pain score reduced drastically from 9.5/10 to 1/10. Decreased exudation and re-epithelialisation were noted at the fifth, sixth and seventh dressing changes. The eighth and ninth dressing changes took place at three-week intervals. After 19 weeks (131 days), the hard-to-heal PU was in the final stage of healing and no longer needed TPD. The wound had contracted around the edges and

granulation tissue had formed. The borders were clean without any purpura and the ulceration was completely re-epithelialised (Fig 2). The patient went from having three dressing changes per day prior to TPD application, to one dressing change every 3–4 weeks with TPD. In the total treatment time to healing with TPD (18 weeks), the patient would have required 393 dressing changes with the SoC treatment.

Case 2

A 56-year-old female patient with type II diabetes and hemiplegia had two stage 3 PUs with undermining on the sacrococcygeal region for five months prior to TPD therapy (Fig 3). The wounds were previously treated using a hydrocolloid dressing. Prior to TPD application, the patient was experiencing severe pain, scoring both her PUs as 9/10 on the pain scale. With TPD therapy, the dressing was changed every 12–14 days and, after two dressing changes, the pain score reduced to 1/10. After 39 days of TPD therapy (three dressing changes), both PUs were in the final stage of healing, with no signs of dehiscence or exudate. They no longer required TPD therapy (Fig 3).

Case 3

A 68-year-old female patient with type II diabetes and hemiplegia developed a stage 4 PU on the sacral region three months following a stroke (Fig 4). The patient rated her wound pain as 9/10. Following one treatment with TPD, the patient rated her wound pain as 2/10. The wound surface was significantly reduced and re-epithelialisation was near completion. TPD was removed after 37 days and two dressing changes due to complete wound healing (Fig 4). The entire treatment duration to healing was 37 days.

Case 4

A 20-year-old male patient with paraplegia developed a stage 4 PU in the coccygeal area following surgery for his spinal cord injury (Fig 5). The wound was 14×19cm (266cm²) and had failed previous NPWT. The patient was receiving three home health visits per week for SoC wound dressings. The patient's PU had a high risk of skin graft failure and impacted his QoL as he had difficulty working at his retail position. The patient was treated with TPD, using a non-adherent secondary dressing. By the second dressing change, there was a visible reduction in wound size, and by the final dressing change, the wound had decreased to 0.5×1.5cm (Fig 5). Seven dressing changes were performed over 104 days, for an average time between dressing changes of 15 days. Therefore, the patient went from having three dressing changes per week with SoC wound dressings to one TPD application every two weeks. In the total treatment time with TPD (14 weeks), the patient would have required 42 SoC dressing changes versus a total of seven with TPD. The patient avoided readmission for skin grafting and returned to work, improving his QoL.

Case 5

An 88-year-old male patient with hemiparesis after a stroke and Parkinson's disease developed a stage 4 PU on the posterior iliac region for an unknown amount of time prior to TPD therapy (Fig 6). The wound was 12×6×4cm deep. The wound decreased to 12×4×4cm deep, by the first dressing change. The patient noticed a visible reduction in wound size by the third dressing change. Every consecutive dressing change thereafter showed further significant decreases in wound size (fourth dressing change: 9.5×5×3cm, fifth dressing change: 7×3×1.5cm, sixth dressing change: 7×3×1cm). The TPD dressing was removed after 125 days (six dressing changes in total) due to decreased exudation and re-epithelialisation. The average time between dressing changes was 21 days, and the wound size at the end of treatment was 5×1.5×0.5cm.

Case 6

A 68-year-old female patient with a prior diagnosis of demyelinating disease developed a stage 3 PU on the left gluteal region (Fig 7). The wound was present for eight months prior to application of TPD, was measured to be 2×3×0.5cm and was initially covered with a foam dressing. Prior treatment included silver hydrofibre, Vaseline gauze and hydrocolloid dressings three times per week (every other day). Initial application of TPD resulted in dressing change requirements once every 8–10 days. Following the second application of TPD, the size of the wound was reduced satisfactorily. Wound re-epithelialisation occurred in 15 days (three dressing changes in total) and the wound was fully healed in 21 days. The average time between dressing changes was seven days. Observations included less frequent dressing changes required and overall reduction in nursing time after conversion to TPD.

Discussion

The ideal dressing therapy for PUs should maintain a moist environment without causing maceration or desiccation. Additionally, it should allow gaseous and fluid exchange while providing mechanical and bacterial protection without adhering to the wound. It should also provide substantial pain relief, unrestricted movement and protection from pressure or shear.¹⁷ No single product has yet fulfilled all requisite criteria of an ideal dressing for treatment of PUs.

The pHEMA in TPD is intended to reduce continued fluid loss by providing a protective gel, and the gel's oxygen permeability and ability to retain water content while managing excess exudate through vapour transpiration helps create an ideal physiological environment to support cellular growth and tissue repair.¹⁶ This seems to translate into the relatively small number of days it took to heal the wounds for these retrospective cases, with the average days to healing for all cases being 55 days. PUs are notoriously difficult to heal, with previous research showing that only 45.2% and 30.6% of those with stage 3 and 4 PUs, respectively,

Fig 5. Case 4: a 20-year-old male patient with a stage 4 pressure ulcer (PU) in the coccygeal area measuring 14×19cm and deep erosion (a); with the start of transforming powder dressing (TPD) treatment, there is visible contraction of the wound edges and reduction in wound size by day 23 (b); the wound continues to heal with successful re-epithelialisation of the surface and closure of any undermining by day 53 (c); after 74 days, the wound shows almost complete closure and healing (d)



Fig 6. Case 5: an 88-year-old male patient with a stage 4 pressure ulcer (PU) on the posterior iliac region measuring 12×6cm, and 4cm deep, and with significant exudation (a); the wound decreases noticeably in surface area and depth of ulceration with transforming powder dressing (TPD) therapy by day 24 (b); the wound edges are less demarcated and granulation tissue formation is noticeable on day 64 (c); the ulcer is completely re-epithelialised and shows no exudation or erythema by day 125 (d)

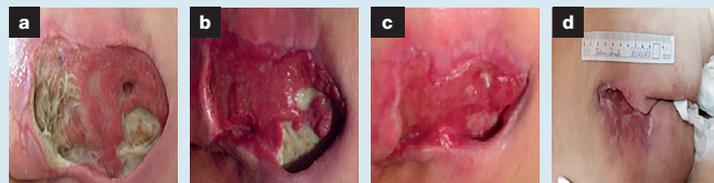


Fig 7. Case 6: a 68-year-old female patient with a stage 3 pressure ulcer (PU) on the left gluteal region measuring 2×3×0.5cm before the start of transforming powder dressing (TPD) therapy (a, b); wound re-epithelialisation and complete healing is seen in 21 days (c)



heal within six months.¹⁷ Considering the severity, chronicity and comorbidities of stage 3 and 4 wounds, this time to healing was promising.

TPD provides beneficial treatment for patients with PUs as the dressing conforms to the wound margin, covers and protects the wound, allows oxygen transport and releases excess exudate through vapour transpiration, all the while shielding the wound from bacteria. Its extended wear time and visible margins enable wound inspection without disruption of wound healing from frequent dressing changes, thereby minimising exposure to contamination.¹⁸ It is believed that TPD's biocompatible and skin-like moisture levels may deceive the brain into thinking that the injury is mitigated, thereby affecting pain signalling and inflammatory responses.¹⁹ The impact of TPD on pain relief was illustrated by the dramatic drop in pain

reported by patients experiencing it. Pain scores fell from 8–9/10 to 1–2/10 within one application of TPD. The reduction in dressing changes also enhanced patient comfort and reduced resource use, as seen in our patient sample. The average number of days between dressing changes across all cases indicated that TPD applications were required every two weeks over the treatment period, with the maximum time between dressing changes extending to 30 days, while conventional therapies, such as foams and NPWT, typically require 2–3 changes per week. Although TPD is commercially available and adopted in facilities worldwide for wound care, there is a limited amount of literature studying the effectiveness of TPD, making the results of this study important. TPD's versatility and possible combinations with various therapeutics provide the basis for development of customised and comprehensive solutions to treat complex wounds.

Limitations

The main limitations of this case series were the limited sample size and retrospective nature of the study. In addition, wound healing trajectories may be confounded by numerous local and systemic factors independent of the types of dressings used, including, but not limited to

age, body type, chronic diseases, medications, vascular insufficiency, other comorbidities, nutrition, alcohol, smoking, offloading regimens, mobility, pressure, trauma and oedema. Despite these limitations, this case series showed promising results and improvements with TPD dressing for a variety of patients.

Conclusion

This case series suggested that TPD, a biocompatible dressing with extended wear times, promoted wound healing and significantly reduced pain in patients with PUs without any major adverse effects, where previous therapies had failed. TPD also required significantly fewer dressing changes than SoC therapies, thereby dramatically reducing resource use and burden of care in the treatment of PUs. Furthermore, healing by TPD therapy avoided major surgeries (including skin grafting and amputation) for certain patients, thus markedly improving the QoL of these patients. TPD has the potential to provide a safe, simple, portable, cost-effective and customisable multi-dimensional treatment platform that may be used across various stages of wound healing. Further prospective investigation is needed to validate TPD as a potential SoC in the treatment of PUs. **JWC**

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Reflective questions

- How might transforming powder dressing (TPD) be used in an integrated approach with other wound treatments like topical steroids and antibiotics for the best results?
- How might TPD be made more easily accessible and applicable at home for patients so it can become a potential standard of care in the treatment of pressure ulcers?
- How might patients be stratified, based on their comorbidities and confounding factors, for future prospective studies?