Retrospective Descriptive Analysis of Extended Wear Transforming Powder Dressing in 70 Patients with Hard-to-Heal Wounds

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INTRODUCTION

Chronic wounds impose a significant clinical, financial and social burden to the individual, the healthcare system and the society at large. Atypical, hard to heal wounds comprise about 20% of all chronic wounds, are challenging to diagnose, and do not fall into a typical wound category. Atypical wounds can present with an abnormal presentation or location and fail to heal within 4-8 weeks despite standard of care (SOC) treatment plans.[1] A broad spectrum of conditions or diseases caused by inflammation, infection, malignancy, genetic disorders and chronic conditions may result in atypical wounds. Currently, high quality evidence for optimal treatment of these wounds is sparse[1], and SOC treatments are often ineffective. This case series evaluated the impact on wound healing when a group of patients with hard to heal wounds (including diverse atypical wounds) were converted from SOC to a novel transforming powder dressing (TPD*).

METHODS

Objective: To study the safety and efficacy of TPD with up to 30-day wear time

Setting: University-based and dermatology-led wound clinic in Germany that specializes in the treatment of severe recalcitrant wounds including atypical, vascular, immunological, medication-induced, metabolic, infectious, malignant, pressure related and surgical wounds

Selection Criteria | Population Sample: All patients (70) treated with TPD from June 2018 to May 2020 were selected.

Cohort patients were predominantly vulnerable with respect to wound healing with recalcitrant non-healing wounds (mean wound duration of 19.1 months) and / or significant associated comorbidities.

Specific Procedures: A retrospective analysis was performed on all patients with approval from the University's ethics committee.

- All patients were treated with Transforming Powder Dressing (TPD*)
- TPD was applied post wound cleansing (or debridement) and covered with a non-occlusive secondary dressing
- TPD was added or "topped off" as needed and outer dressings were changed when clinically necessary
- Wound assessments were analyzed 1 week post post TPD application, 4 weeks post application, and 12-14 weeks post application
- Demographics, wound history (including size), incidence of wound healing and achievement of clinician's treatment goals at 14 weeks, wound healing trajectories (reduction of wound surface area), number of wounds with 30-day wear time and incidence of unanticipated wound-related adverse events were collected

Analysis: Data was collated and final results for incidence of wound healing were compared to a matching cohort of data from the European Wound Registry (EWR) for SOC treatment. SOC was based on local European guidelines for treatment of chronic wounds.

ABOUT TPD

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

References: Isoherranen K, Jordan O'Brien J, Barker J et al EWMA document: Atypical Wounds. Best clinical practices and challenges. JWC. Vol 28, No6 EWMA Document 2019. | **Acknowledgements:** This poster is created in collaboration with Altrazeal Life Sciences Inc. (ALSI). Dr. Kirsten and Dr. Augustine serve as clinical consultants to ALSI. Please refer to Altrazeal Instructions for Use for information about its uses and benefits.

**Altrazeal® Transforming Powder Dressing*

RESULTS

Demographics

- **N=** 70 patients | **Male:** 29 (41%); **Female:** 41 (59%)
- **Patient Age:** Mean= 65.3 years (range: 23-96)
- **Wound Duration (Prior to TPD Application):** Mean =19.1 months (min: 0 months, max: 240 months)
- **Wound Area:** Mean = 16.5 cm^2 (min = 0.2, max = 240)

Extended Wear Time:

- **30-day wear without primary TPD changes was documented in 66% patients (46 wounds)**

Adverse Events: No unanticipated or adverse events related to TPD were reported

Wound Healing Outcomes:

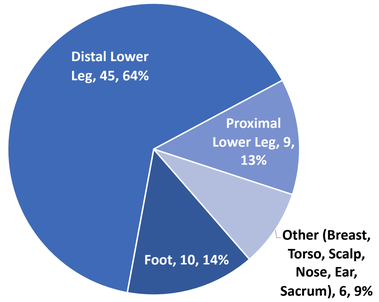
- **53% (37 of 70 patients) healed as compared to 8% for SOC** based on the EWR cohort over the 14-week study period
- **Treatment goals were achieved for 71% (50 patients)**
- Treatment was discontinued for 24 patients due to various reasons (e.g., treatment goals, stagnation, death, etc.)
- **80% healed of the group that continued TPD over the full study period (37 of 46 patients)**

Wound Surface Area Reduction: Accelerated wound surface area reduction was observed for stagnating wounds

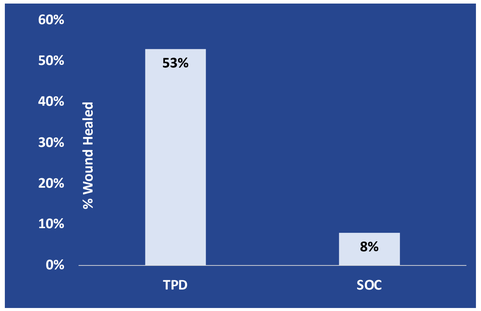
WOUND HEALING TRAJECTORY

Weekly Wound Area Reduction	% Reduction
% by Week 1	22% (n=36)
% by Week 4	45% (n=53)
% by Week 12-14	61% (n=59)

WOUND LOCATION



% WOUND HEALING ACHIEVED IN 14 WEEKS



OUTCOMES FOLLOWING CONVERSION TO TPD

		NUMBER OF WOUNDS HEALED			CLINICAL GOALS ACHIEVED		
Type of Wounds	Total Wounds	Wounds Healed	Wounds Not Healed	% Wounds Healed	Yes	No	Goal Achievement (%)
Venous Ulcer	23	13	10	57%	16	7	70%
Atypical Wound	18	7	11	39%	12	6	67%
Traumatic and Post Surgical	10	7	3	70%	8	2	80%
Diabetic Foot Ulcer	7	6	1	86%	7	0	100%
Arterial	5	1	4	20%	2	3	40%
Other	7	3	4	43%	5	2	71%
Total	**70**	**37**	**33**	**53%**	**50**	**20**	**71%**

DISCUSSION

TPD was observed to be safe and effective in the treatment of a wide range of hard-to-heal wounds and to significantly accelerate healing relative to European SOC guidelines. No unanticipated adverse events were observed during extended wear time. Extended wear time of up to 30 days TPD presents a promising new wound treatment strategy with potential to improve healing outcomes and the patient experience while reducing the burden of care associated with time required for dressing change relative to SOC.