

Utilization of Transforming Powder Dressing to Treat Wagner Grade 1 and 2 Diabetic Foot Ulcers Refractory to Standard of Care: Case Series Review

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INTRODUCTION

Wound care has become an increased focus as the prevalence of chronic wounds continues to rise. Numerous guidelines and wound care treatments for chronic wounds have been implemented, but current wound management practices lack standardization and randomized clinical trials to guide best practices. There is a critical need for multidisciplinary collaboration and research trials to effectively establish evidenced based wound care protocols to optimally treat chronic wounds, including diabetic foot ulcers (DFUs).^{1,2}

We present 3 subjects who participated in an ongoing clinical trial entitled “Randomized Clinical Trial to Compare Transforming Powder Dressing (TPD*) and Standard of Care (SOC) Dressing Therapies to Heal Diabetic Foot Ulcers”.

TPD is a commercially available wound dressing with an extended wear time of up to 30-days. In the presence of moisture, the powder aggregates to form a moist, non-occlusive barrier to help prevent contamination. We present 3 subjects who have completed the trial at one site.

METHODOLOGY

Randomized, controlled, prospective, multi-center, open-label, post-marketing study comparing the effectiveness of TPD treatment to SOC dressings in subjects with Wagner Grade 1 and 2 DFUs. The primary objective is to evaluate the incidence of wound closure in subjects in up to 12-weeks of treatment. Secondary objectives include evaluation of wound healing trajectories, infections, subject and clinician satisfaction, pain and quality of life, comparing both groups.

This case series presents results of 3 subjects with diabetes type 2, refractory Wagner Grade 1 and 2, who were randomized to TPD and have completed the study at 1 site.

References:

1. Wound Care Awareness Week Highlights of the Chronic Wound Epidemic in U.S. Businesswire.com/news/home/20160607006326/en/Wound-Care-Awareness-Week-Highlights-Chronic-Wound. Accessed 11/5/2020.
2. Becker’s Hospital Review. “Wound care by the numbers: Medicare cost and utilization of patients with chronic wounds” Healogics. White paper - 090717. Accessed 11/4/2020.

*Altrazeal® Transforming Powder Dressing, USA

CASE SERIES

Patient 1: 45-year-old female suffering from Diabetes Type 2, HTN and neuropathy
Wound Location: Great toe
Wound Size: 0.5 x 0.3 x 0.1 cm
Wound Duration: 92 days
TPD Outcomes: Wound healed in 4 weeks with 2 applications and no subsequent debridements

Patient 2: 62-year-old male with Diabetes Type 2, neuropathy and history of a non-healing wound
Wound Location: Plantar forefoot
Wound Size: 2 x 2 x 0.2 cm | **Duration:** 90 days
TPD Outcomes: Wound got wet and macerated due to patient noncompliance in week 3 causing enlargement, but healed at 9 weeks with 3 total debridements and 8 applications (3 top offs)

Patient 3: 52-year-old insulin dependent male suffering from Diabetes Type 2 and neuropathy
Wound Location: Toe #5
Wound Size: 2 x 2 x 0.2 cm
Wound Duration: 38 days
TPD Outcomes: Wound healed in 6 weeks with 2 applications and no subsequent debridements



RESULTS

All study DFUs treated with TPD healed fully within the 12-week protocol specified treatment period (12, 6 and 4 weeks, respectively) with fewer debridements and dressing changes relative to SOC. All subjects indicated they were “Extremely Satisfied” (2) or “Satisfied” (1) with the results of the TPD treatment of their study wound.

DISCUSSION

The initial observations of our patient population involved in this study indicate that implementation of TPD treatment in subjects with Wagner Grade 1 and 2 DFUs refractory to SOC result in overall wound healing and subject satisfaction with reduced wound care resources. Additional analysis will be performed upon study close-out.