Prospective, Randomized, Phase IV Clinical Trial Comparing a Novel Transforming Powder Dressing to Standard of Care in Treatment of Wagner Grade 1 and 2 Diabetic Foot Ulcers (DFU)

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INTRODUCTION AND OBJECTIVES

Challenge:

- DFU affect 19–34% of >537 mm diabetics worldwide[a]
- Despite recommended wound management strategies[b], wound care is not standardized, and no wound dressing is consistently used
- Conventional dressings require frequent changes, which can inconvenience patients and place a significant burden on caregivers

Potential Solution:

- Transforming powder dressing (TPD) is a commercially available novel wound dressing with an extended wear time (up to 30 days)
- Comprised primarily of polymers similar to those in contact lenses, TPD aggregates upon hydration to form a moist oxygen-permeable barrier that covers and protects the wound for up to 30 days

Objective:

- We aimed to compare the efficacy, safety and usability of TPD versus standard of care (SOC) in the treatment of chronic (>30 days) Wagner Grade 1 and 2 DFU

METHODS

Design: Randomized, controlled, prospective, multicenter, Phase IV study

ClinicalTrials.gov Registration: NCT05046158 | Central IRB: Advarra Office of Human Research Oversight

Treatment: Eligible subjects (Table 1) were randomized 1:1 to two groups

- Group 1: SOC as per physician's discretion
- Group 2: TPD

Study Period: Weekly subject evaluations for 12 weeks unless healed sooner

Research Sites: 11 independent sites throughout the United States, including

- 5 Veterans Administration facilities (VAMC): Maryland VAMC (MD), Dallas VAMC (TX), Hudson Valley VAMC (NY), James J. Peters VAMC (NY), Michael E. DeBakey VAMC (TX)
- 5 civilian centers: AdventHealth (FL), Baylor College of Medicine (TX), MedStar Health (MD), Northwestern University (IL), Northwell Health (NY)
- 1 private clinic: Bronx Foot Care (NY)

Study Endpoints: Primary – wound closure incidence Secondary – healing trajectory, safety (adverse events and secondary infections), usability (user surveys*), patient acceptance (satisfaction surveys, impact on pain and wound quality of life scores)
Exploratory – cost effectiveness (resource utilization)

Table 1: Inclusion and Exclusion Criteria

INCLUSION	EXCLUSION (abbreviated)
• Men or non-pregnant/non-lactating women 18-89 years of age • Diagnosed with diabetes mellitus with Hgb A1C <12% • Diabetic foot ulcer present >30 days • Diabetic Foot Ulcer (DFU) classification: Wagner Grade 1 or 2 ulcers • Wound drainage is minimal or moderate • No clinically active wound infection (clinical diagnosis) • Able and willing to provide written (not proxy) informed consent	• Unwilling or unable (due to balancing concerns) to wear offloading device, if wound is in location where offloading is recommended • Highly exudative wounds • Wounds with necrosis unable to undergo debridement • Body Mass Index (BMI) >45 kg/m^2 • Impending organ transplant • Lymphedema, scleroderma, lupus • Venous stasis disease • Ankle brachial index (ABI) <0.7 or toe pressures <30 mmHg • Glycated hemoglobin A1C >12%

DISCUSSION | CONCLUSION

- Despite similar demographics and comorbidities in both randomized groups, TPD cohort had statistically significant larger wound areas at baseline (median values 80% > SOC)
- Results indicated improved clinical outcomes without any adverse effects on subject safety, pain and quality of life
  - 51% greater rate of weekly WAR (p=0.002)
  - 89% of TPD subjects reported TPD as "much better than prior dressings" in subject satisfaction surveys
- Resource utilization was significantly improved
  - 67% fewer dressing changes per subject (p<0.001)
  - 33% fewer debridements (p=0.01)
  - 80+% of TPD subjects reported TPD as "much better than prior dressings" with respect to ease of use, convenience and time required for wound care

References: (a) McDermott K, Fang M, Boulton AJM, Selvin E, Hicks CW. Etiology, Epidemiology and Disparities in the Burden of Diabetic Foot Ulcers. Diabetes Care 2023; 46 (1); 209-221. | (b) International Working Group on the Diabetic Foot (IWGDF) Guidelines. 2023 Update (accessed on line 29DEC2024) | EDU-1120

RESULTS

Table 2: Demographics

N = 135, Sites = 11	SOC N = 63	TPD N = 72	p
Age in Years, Median (IQR)	61 (55.5-69.0)	64 (55.8-71.2)	0.408
Female, N (%)	9 (14.3)	9 (12.5)	0.960
Tobacco Users, N (%)	25 (41.0)	35 (51.4)	0.488
BMI, Median (IQR)	31 (28.0-36.0)	30 (26.8-33.0)	0.053
HbA1c, Median (IQR)	7.8 (6.8-8.8)	7.4 (6.7-8.8)	0.716
Comorbidities, N (%)	61 (96.8)	71 (98.6)	0.907
Caucasian Race, N (%)	34 (54.0)	43 (60.6)	0.548
Employed, N (%)	25 (41.0)	16 (22.2)	0.032

Table 3: Baseline Characteristics

N = 135, Sites = 11	SOC N = 63	TPD N = 72	p
Ulcer Size, Median cm^2 (IQR)	**1 (0.3-3.0)**	**1.8 (0.6-4.8)**	**0.029**
Ulcer Duration - Days, Median (IQR)	186 (61.0-395.5)	167.8 (91.5 - 365.0)	0.820
Pain Score - VAS, Median (IQR)	0 (0.0-3.0)	0 (0.0-0.5)	0.125
Wound QoL Score, Median (IQR)	16 (4.5 - 30.8)	13 (6.0 -25.0)	0.590
Wagner Grade I / II (N, %)	23 (36.5) / 40 (63.5)	26 (36.1) / 46 (63.9)	1.000
Offloading Prescribed (Yes, %)	48 (76.2)	56 (77.8)	0.836

Fig. 1: Wound Area Reduction (WAR)

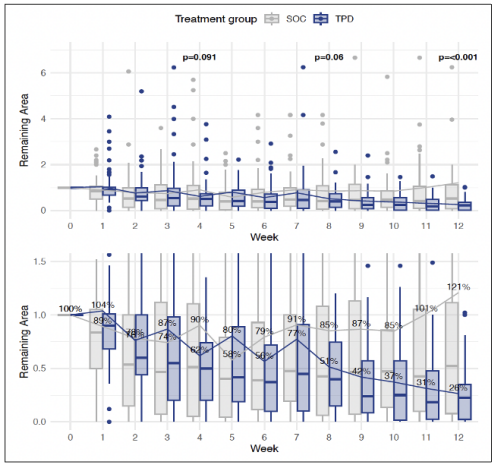

Fig. 2: Baseline Wound Area (cm²)

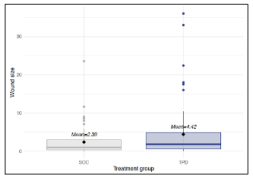

Table 4: SOC Composition

Primary Dressing Type	%
Antimicrobial	36.0
Collagen	26.0
Collagenase	16.0
Alginate	7.5
Woundgel	2.1
Honey	1.3
Hydrofiber	0.2
Other	10.8

Figure 3: Survival Analysis | Incidence of Wound Closure

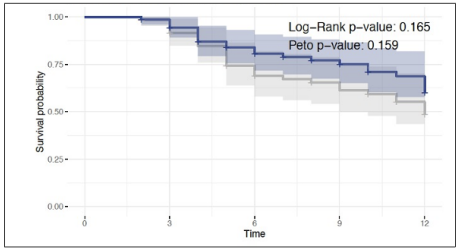

Table 5: Resource Utilization

	SOC N = 63	TPD N = 72	p
Dressing Changes / Subject, Mean (SD)	31.3 (26.3)	10.6 (15.5)	<0.001
Dressing Changes / Week / Subject, Mean (SD)	3.5 (2.4)	1.2 (2.0)	<0.001
Debridements / Patient, Mean (SD)	5.6 (3.8)	3.8 (3.2)	0.01

Table 6: Usability and Subject Satisfaction

TPD Subject Survey Summary (N=56) Subjects Reporting TPD as Much Better than SOC - N (%)			
Overall Satisfaction	42 (89.4)	Ease of Use	38 (80.9)
Convenience	39 (83.0)	Pain	23 (50.0)
Time for Wound Care	42 (89.4)	Comfort	36 (76.6)

Table 7: Adverse Events

	SOC N = 63	TPD N = 72	p
Subjects with AEs, N (%)	13 (20.6)	16 (22.2)	0.989
% Possibly Related or Related	10.5	0.0	
Infections, N (%)	8 (12.7)	10 (13.9)	1.000
% Osteomyelitis	62.5	20.0	

Table 8: Recurrence of Healed Ulcers

	SOC N = 26	TPD N = 28	p
Ulcer Recurrence 12 Weeks Post End of Study, N (%)*	5 (19.2)	1 (3.6)	0.127

*Final data analysis is pending completion of the remaining subject follow-up 12 weeks visits post-treatment