Phase IV Randomized Controlled Study of an Extended-Wear Transforming Powder Dressing in Partial-Thickness Burns: Interim Results

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Carolyn Yanavich, PhD[1]; Susan Rolniak St. John, MSN, APRN-NP[1]; Marcel de Souza Borges Quintana, PhD[2]; Carl Schulman, MD, PhD, MSPH[1,3]; Victor Joe, MD, FACS[4]; Mathew Bozeman, MD[5]; Caroline Park, MD[6]; Jonathan Saxe, MD, FACS, MBA, MAR[1,7]

[1] Altrazeal Life Sciences Inc. | [2] Institute of National Infectiology, Oswaldo Cruz Foundation | [3] University of Miami / Jackson Memorial Hospital | [4] University of California, Irvine | [5] University of Louisville | [6] UT Southwestern Medical Center | [7] Kettering Health

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INTRODUCTION

Challenges:

- Partial-thickness burns (PTB) are challenging to manage, particularly in combat and low-resource settings
- Standard-of-care (SOC) burn dressings require frequent changes, increasing pain and wound exposure to infection[1,2]

Potential Solution:

- Altrazeal® Transforming powder dressing (TPD) is an extended wear dressing that can remain on the wound for up to 30 days. Upon hydration, it transforms into a moist, oxygen-permeable matrix that shields the wound from contamination. Powder may be added as needed without requiring primary dressing changes. The matrix dries and flakes off as the wound heals
- TPD has demonstrated reduction in dressing change frequency, associated pain, and favorable healing outcomes across acute and chronic wounds[3,4,5,6,7,8]

This ongoing randomized, controlled trial (RCT) compares TPD to SOC dressings for dressing change frequency, related pain, and healing in PTB.

METHODS

Design: Randomized, multicenter, Phase IV controlled study (n=50)

Inclusion Criteria: Deep and superficial PTB
Duration <72 hours | TBSA ≤ 20% | Age: 18-65 years
Treatment Period: up to 28 days | **Randomization:** 1:1

Research Sites: Jackson Memorial Hospital, MedStar Washington Hospital Center, Parkland Memorial Hospital, University of California, Irvine Medical Center, University of Louisville Hospital

Study Endpoints: Primary: Pain (Visual Analogue Scale) | Secondary: Healing trajectories (wound area reduction), safety (adverse events), and patient acceptability and clinical usability (questionnaires)

BASELINE CHARACTERISTICS (N=27/50)

BASELINE MEDIAN & RANGE STATISTICS	SOC (n=14)	TPD (n=13)
Age (years)	31.5 (18-64)	34 (18-61)
Wound Area (cm^2)	94.9 (9.8-2912)	193.9 (28-1293)
TBSA (%)	2 (0.5-6)	4 (0.4-8)
Initial Pain Score (VAS)	5 (0-8)	6 (2-10)

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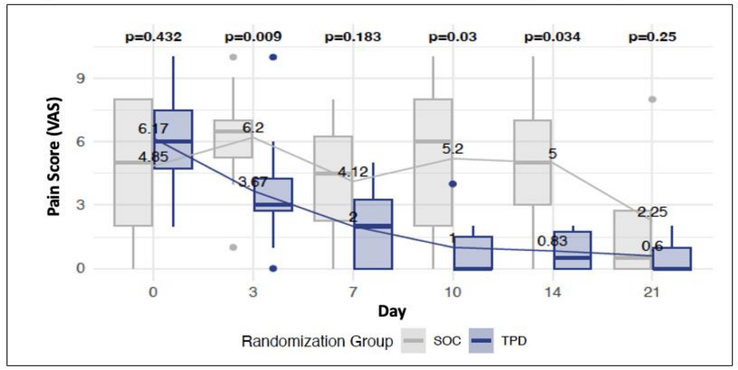
EDU-4011, Rev 01

INTERIM RESULTS (N=27/50)

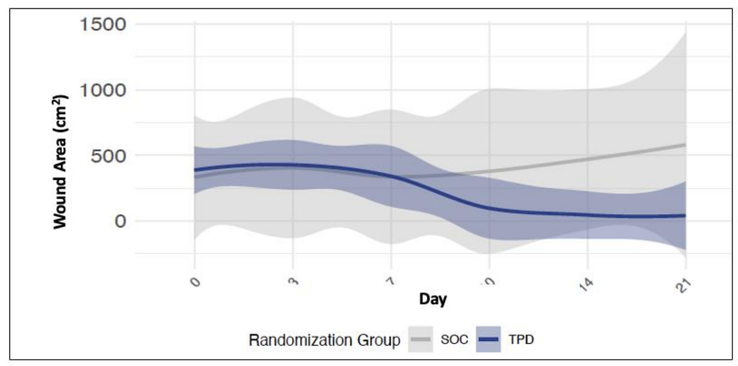
PAIN SCORES (VAS):

Daily reduction rate = 12.3% for TPD vs 2.2% for SOC (p<0.0001)



WOUND AREA REDUCTION (WAR):

Daily Area Reduction Rate = 10.2% for TPD vs. 4.5% for SOC (p=0.019)



DRESSING CHANGE FREQUENCY

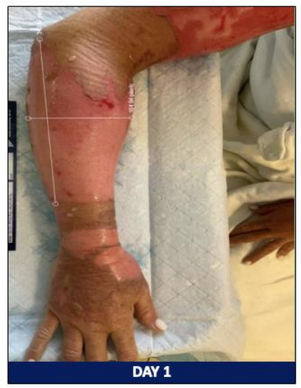
Total dressing changes were 74% lower for TPD vs SOC (p<0.001)

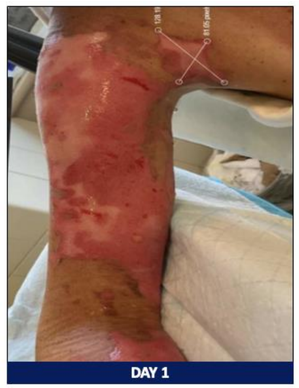
WEEKLY DRESSING CHANGES	SOC	TPD	% Reduction	p-value
Mean (SD)	3.2 (2.7)	1.6 (1.5)	50%	<0.001
Median	3 (1, 4.8)	1 (0.7, 2.1)	67%	--

TOTAL DRESSING CHANGES (28-Days)	SOC	TPD	% Reduction	p-value
Mean (SD)	8.4 (8.4)	2.2 (0.9)	74%	<0.001
Median	7 (1.5, 10)	2 (2, 3)	71%	--

ILLUSTRATIVE CASES

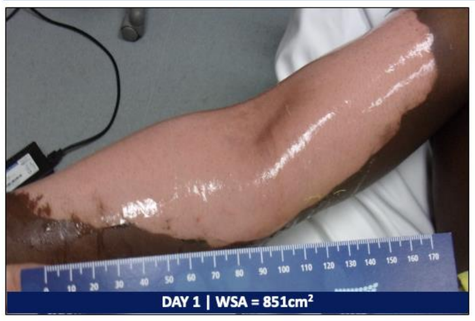
44 y/o Female with Thermal Burns | 6.1% TBSA

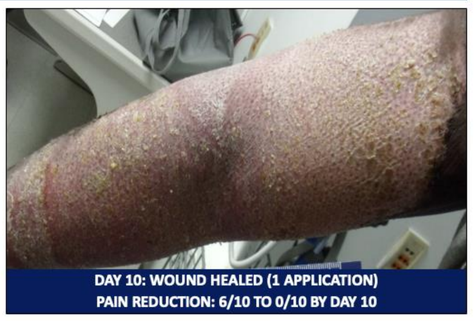

DAY 1

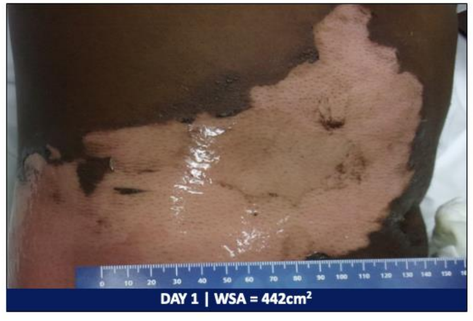

DAY 1


DAY 21: WOUND HEALED (2 APPLICATIONS)
PAIN REDUCTION: 4/10 TO 0/10 BY DAY 3

32 y/o Male with HIV with Chemical Burns | 5% TBSA


DAY 1 | WSA = 851cm^2


DAY 10: WOUND HEALED (1 APPLICATION)
PAIN REDUCTION: 6/10 TO 0/10 BY DAY 10


DAY 1 | WSA = 442cm^2


DAY 10: WOUND HEALED (1 APPLICATION)
PAIN REDUCTION: 6/10 TO 0/10 BY DAY 10

CONCLUSION

Interim results demonstrated statistically significant reductions in dressing-change frequency and pain scores, along with faster wound area reduction, in TPD-treated patients compared with SOC. No TPD-related adverse events were reported. These findings are consistent with RCTs in other wound etiologies and further support the use of TPD in the management of partial-thickness burns.