



# Flowable Porcine Urinary Bladder Matrix in Complex Wounds: A Multicenter Prospective Study



Malachy Asuku, Hannah Baker, Yifei Dai, Claire Witherel, Jessica Evans, Yi Arnold, Weiwei Xu, Michael Cripps, Jeffrey W. Shupp, Alysha Oropallo

Integra LifeSciences Corp., Plainsboro, NJ

## INTRODUCTION

- Chronic wounds constitute a significant burden on healthcare systems and resources
- Annual cost of care for chronic wounds occurring in approximately 15% of Medicare population (8.2M) is put at between \$28 and \$31.7 Billion
- Wound tunneling and undermining contribute to chronicity and recalcitrance
- Resolution of tunneling, sinuses and undermining are a sine-qua-non to ultimate wound closure
- Flowable configuration intimately delivers active porous bio-scaffold into wound depths
- Evidence of effectiveness and safety of porcine UBM in sheet and micronized configurations already abound

## OBJECTIVE

To evaluate the effectiveness and safety of the flowable UBM in tunneling wounds under real-world clinical settings.



Figure 1. MicroMatrix Flex preparation for use (Integra LifeSciences, Plainsboro, NJ)

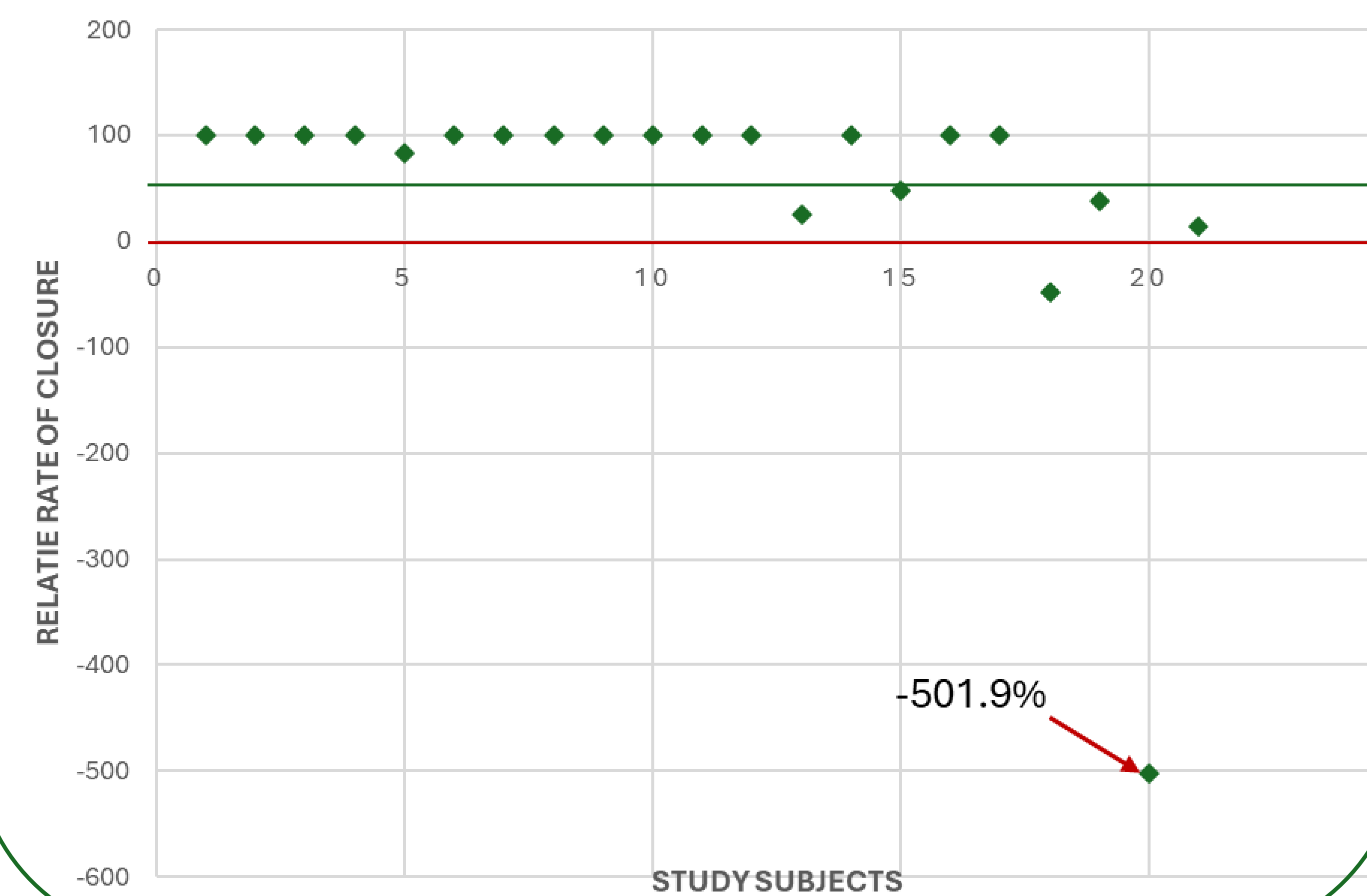
## METHODS

- IRB approved, multi-center, prospective, single-arm study in 25 consenting adult subjects
- Conducted in real-world clinical setting to enhance generalizability
- Partial & full thickness wounds for which investigational product is indicated including pressure injuries, diabetic ulcers, vascular ulcers, traumatic wounds and necrotizing soft tissue infections.
- Post-debridement inclusion criteria: tunneling  $\geq 5$ cm, undermining  $\geq 2$ cm, wound dimension  $\leq 500$ cm<sup>2</sup>

Parameter	Number, n (%)	Wound Features/ Aspect Type	FAS (25)	PPS (21)
Sites (US)	3	Undermining	18 (72%)	15 (71%)
Subjects screened	26	Tunneling	7 (28%)	6 (29%)
Subjects enrolled (FAS)	25	<b>Wound Etiology</b>	<b>FAS (25)</b>	<b>PPS (21)</b>
Study discontinuation	3 (12%)	Pressure Ulcers	11 (44%)	10 (48%)
Completed study	22 (88%)	• Sacral		
Per Protocol Set (PPS)	21 (84%)	• Ischial		
		• Inter-scapular		
		Non-Pressure Ulcers	14 (56%)	11 (52%)
		Diabetic ulcers 6 (54%)		

## Primary Endpoint

% RELATIVE RATE OF CLOSURE OF WOUND ASPECTS AT 12 WEEKS



N = 21

- Mean relative rate of closure  $50 \pm 133\%$
- Median **100%**

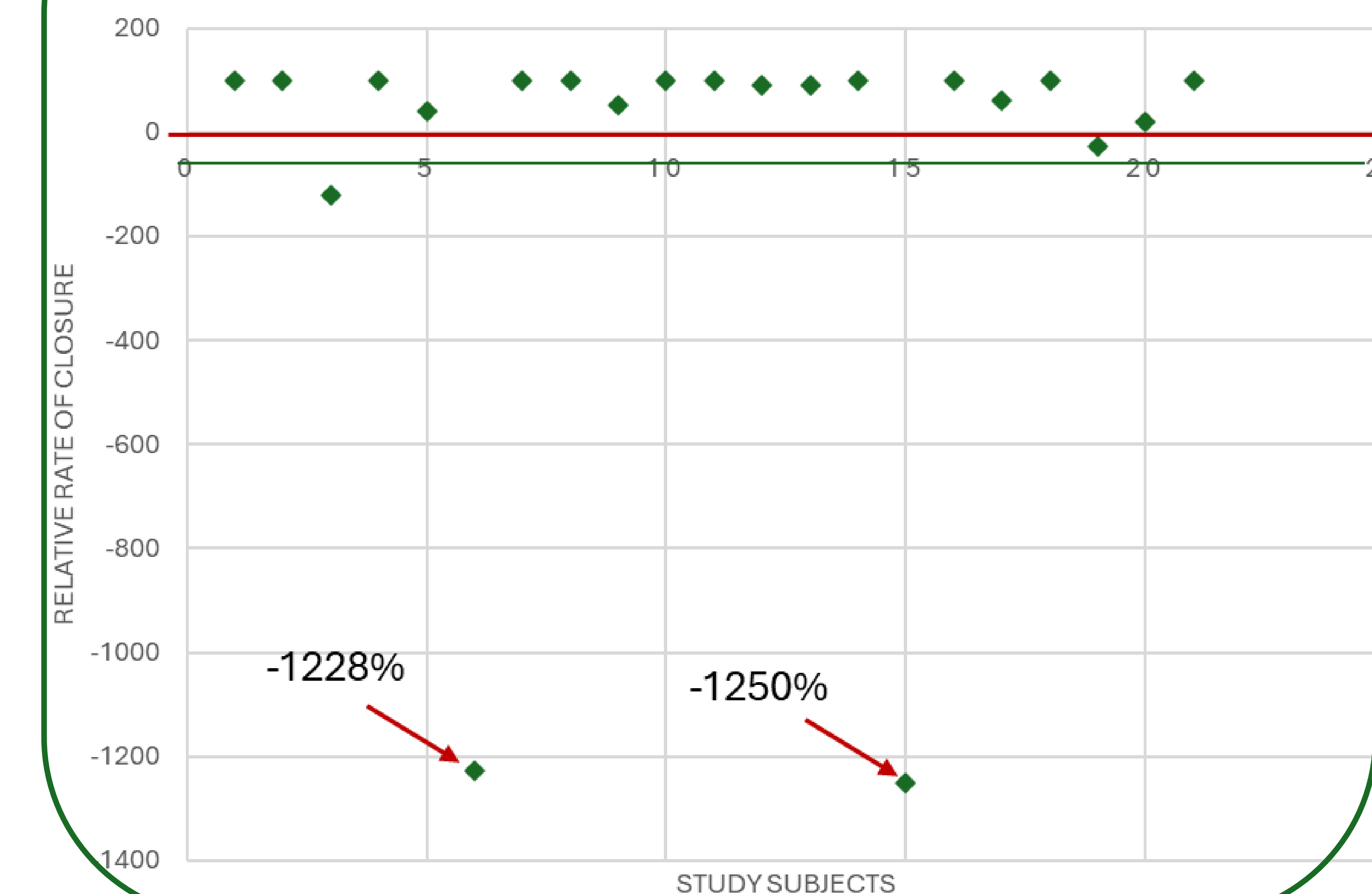
N = 20

- Mean relative rate of closure  $77 \pm 41\%$
- Median **100%**

## RESULTS

## Secondary Endpoint

RELATIVE RATE OF CLOSURE OF WOUND AT 12 WEEKS



N = 21

- Mean relative rate of closure  $-55 \pm 397\%$
- Median **99.3%**

N = 19

- Mean relative rate of closure  $69 \pm 58\%$
- Median **99.6%**

## Safety Endpoint

### Adverse Events

- A total of 20 adverse events (AEs) were reported in 10 subjects
- AEs were unrelated to study device
- Most frequently reported AEs
  - Wound infection/ cellulitis (6; 30%)
  - Osteomyelitis (3; 15%)
  - Bacteremia  $\pm$  sepsis (n = 3; 15%)

### Serious Adverse Events

- A total of 11 SAEs were reported in 4 subjects
- Consisting mainly of sepsis, osteomyelitis and wound infections
- SAEs were unrelated to study device

## DISCUSSION

- The UBM technology preserves native ECM architecture with intact epithelial basement membrane which facilitates site-appropriate organized tissue re-modelling with minimal scarring.
- Micronized and flowable configurations provide intimate contact to uneven wound surfaces enhancing onset and extent of activity.
- The study enrolled all comers accommodating subjects with comorbidities that would have excluded them from participation in routine clinical trials. This makes the study outcome even more impactful

## CONCLUSION

- Flowable UBM demonstrated clinical effectiveness in facilitating
  - Aspect closure: relative rate of  $77 \pm 41\%$  in 95% of study subjects (20/21)
  - Wound volume reduction:  $69 \pm 58\%$  in 90% of study subjects (19/21)
- Reduction in wound burden is a clinically meaningful outcome in complex wound care