

# A Prospective Randomized Controlled Trial Evaluating an Acellular Porcine Liver Tissue Scaffold in Complex Wounds



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Complex, multi-dimensional wounds remain difficult to treat and are supported by limited high-quality comparative evidence. This ongoing PRCT was initiated to evaluate healing trajectory, tissue-quality response, and clinical utility of an acellular porcine liver tissue scaffold when added to standard care.

## Background

**Complex, multi-dimensional wounds** remain a significant clinical and economic burden, with limited high-quality evidence to guide treatment.

Chronic pressure ulcerations and other advanced wounds may be especially challenging when depth, undermining, tunneling, contamination, or stalled healing complicate standard management.

Acellular porcine liver tissue scaffolds\* have emerged as a novel technology designed to support wound management through a highly porous extracellular matrix. Early observational experience has suggested favorable granulation and wound progression in selected complex wounds, supporting the need for prospective randomized evaluation.

### Why this matters in pressure injury

Pressure ulcers remain a meaningful clinical burden, and registry-based analyses\*\* suggest that tunneling and undermining are relevant features in a clinically important subset of full-thickness pressure ulcers. These findings reinforce the need to study therapies in wounds whose true complexity may extend beyond surface dimensions alone.

### Registry signals in full-thickness pressure ulcers with tunneling and undermining\*\*

- 5.2%** Pressure ulcers with tunneling
- 15.6%** Pressure ulcers with undermining
- 5%** Tunneling distance > 0.5 cm
- 25%** Undermining distance > 0.5 cm

Pressure Ulcer Registry:  
18k patients / 32k wounds



Full-thickness subset:  
10k patients / 14.7k wounds

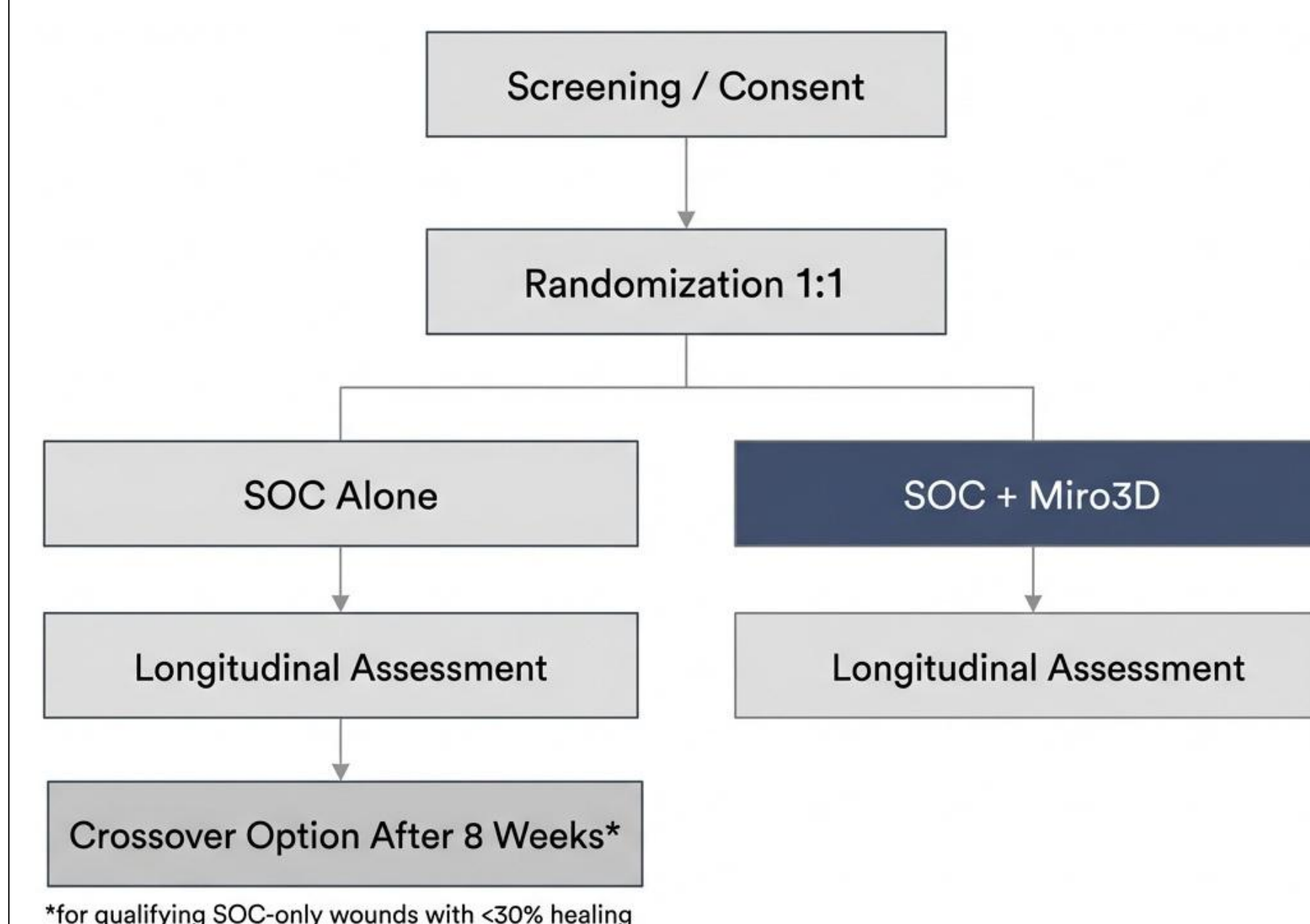
## Study Objective

To evaluate the efficacy, safety, and cost-effectiveness of an acellular porcine liver tissue scaffold\* when used alongside standard of care versus standard of care alone in two difficult-to-treat wound populations: complex soft tissue wounds and chronic pressure ulcerations.

### Study Design

This prospective, randomized, controlled trial is designed to enroll 60 subjects, with 30 subjects per wound type: complex soft tissue wounds and chronic pressure ulcerations. Within each wound type, subjects are randomized 1:1 to receive either standard of care alone or standard of care plus acellular porcine liver tissue scaffold\*.

A crossover design allows qualifying subjects in the SOC-only arm to receive acellular porcine liver tissue scaffold\* after 8 weeks if the wound demonstrates <30% healing.

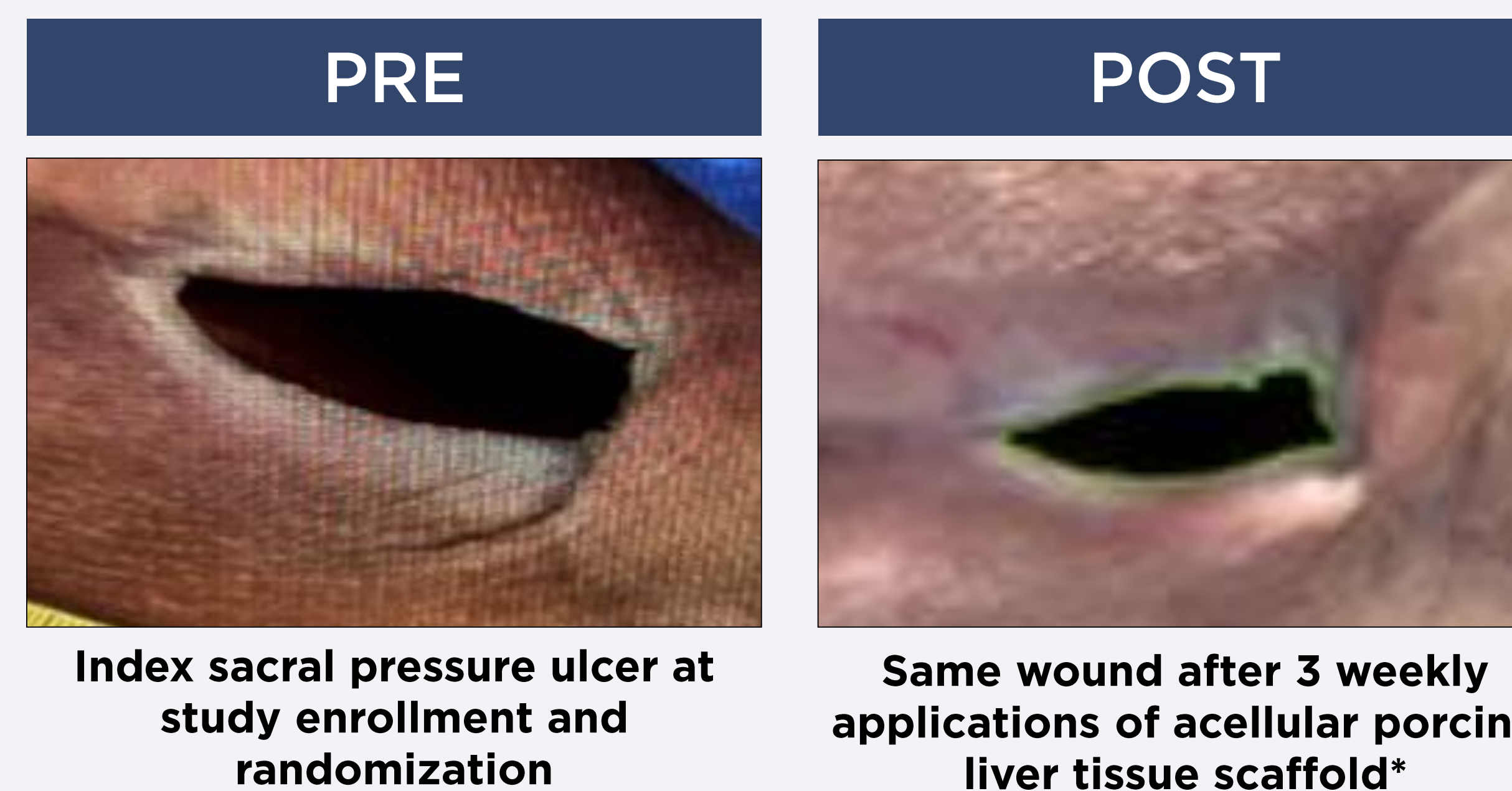


- Prospective, randomized, controlled trial
- 60 subjects total; 30 per wound type
- Two treatment arms per wound type: SOC alone and SOC + acellular scaffold\*
- Crossover permitted after 8 weeks for qualifying SOC-only wounds with <30% healing

### Primary Objective

Percent Area Reduction (PAR) and healing quality at 4 weeks as predictors of complete wound closure by 12 weeks

## Illustrative Case from Ongoing Clinical Trial



This case illustrates our research aims. An 82-year-old male with a chronic sacral pressure ulcer entered the trial after prolonged, >4 years, wound persistence and prior unsuccessful flap-based management.

During study participation, the index wound received four applications the scaffold. Over the same general period, the patient experienced falls at home such that he developed a separate nearby deep soft tissue injury on his left buttock while on chronic anticoagulation that became infected and necrotic. Despite these competing clinical events and overall physiologic fragility, the primary research index wound remained resiliently un-infected despite being in proximity and continued to demonstrate favorable local responses.

Notably, although the wounds were anatomically near one another, they remained separate rather than coalescing during the observed course. This case illustrates that this trial can take real-world data into high quality research and yet belies that would care patients by their very nature of having non-healing wounds are a fragile, complex and difficult patient population to enroll and study.

### Why this case is notable

The key observation was not simply wound improvement but continued favorable progression of the treated index wound despite serious competing events, including a separate adjacent wound process and progressive systemic decline.

## Interim Observations

- Favorable wound-area reduction trajectory in interim experience
- Improved tissue-quality signals
- Acceptable tolerability with no device-related serious adverse events observed in the reported interim dataset

The Interim analyses demonstrate that weekly application of the acellular porcine liver tissue scaffold\* is associated with accelerated wound-area reduction and improved tissue quality compared with standard care alone. Participants have reported favorable tolerability, and no device-related serious adverse events have been observed.

Early signals suggest that this scaffold may be particularly relevant in complex, multi-dimensional wounds that have stalled despite conventional therapy.

**This trial remains ongoing; conclusions are interim and directional.**

### Conclusions

- Higher-quality prospective evidence in complex wounds remains needed
- Early experience supports continued study of response patterns, cadence, and patient selection
- This PRCT is designed to clarify how this technology may fit into evidence-based management of complex multi-dimensional wounds

## Clinical Questions

Early trial experience suggests that response may not be uniform across all patients and wound types. Ongoing experience has raised three practical response-pattern questions:

### Rapid responders

Patients who appear to improve quickly and completely with limited applications.

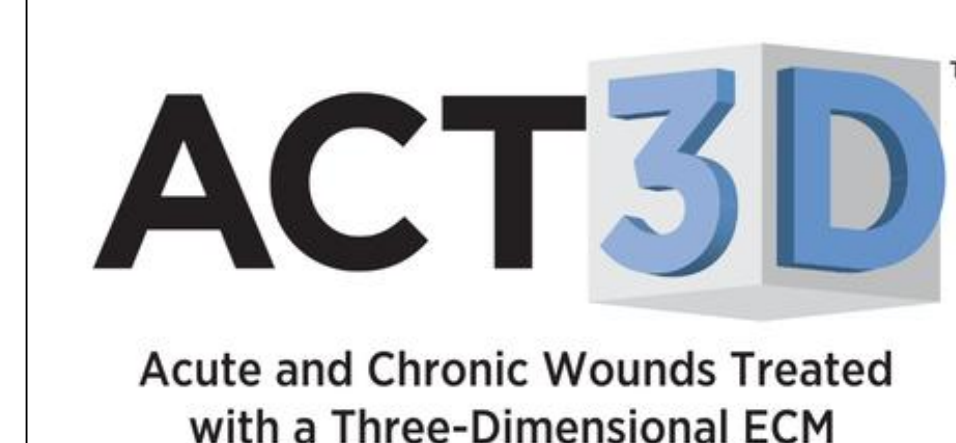
### Intermediate responders

Patients in whom the therapy appears safe, helpful, and clinically active, but in whom the ideal cadence for serial applications and duration of treatment remain uncertain and under study.

### Limited or nonresponders

Patients in whom little benefit to complete closure even with subjective improvements is observed, prompting reconsideration of wound biology, host factors, competing barriers to healing, or other diagnostic variables rather than reflexive continuation of unchanged therapy. Interestingly these patients still report subjective improvements

Accordingly, one of the practical questions this PRCT may help clarify is whether serial weekly application should be the default strategy across wound presentations, or whether a more individualized apply-and-reassess approach may provide a better therapeutic outcome in selected patients.



View trial listing

Clinicaltrials.gov

\*MIRO3D® WOUND MATRIX, REPRIS BIOMEDICAL, INC., PLYMOUTH, MINNESOTA.

\*\*LIFT OFF PRESSURE INJURY REGISTRY