Case Series Leads to Randomized Controlled Trial: Building Evidence-Based Medicine in Contemporary Tissue Scaffold Research

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INTRODUCTION

Managing complex three-dimensional tissue defects—particularly in the pelvis and lower extremities—remains a significant challenge in modern wound care. Traditional reconstructive methods, such as serial debridement followed by flap coverage, are considered the gold standard. However, they are often limited by patient comorbidities, perioperative risks, restricted access to specialized surgical teams, and postoperative activity limitations. Even in high-volume centers, free tissue transfer procedures carry failure rates ranging from 5% to 10%, with risks of dehiscence, infection, and donor site complications[1].

In light of these challenges, regenerative tissue scaffolds have gained traction as less invasive alternatives. Cellular, acellular, and matrix-like products (CAMPs) provide structural support for host cell infiltration, neovascularization, and tissue remodeling. Among them, an acellular porcine liver-derived scaffold* has shown promise due to its native collagen architecture and three-dimensional configuration, which may support volumetric tissue regeneration more effectively than traditional flat matrices.

To explore its clinical utility, we conducted an IRB-approved case series evaluating the scaffold's* use in real-world settings. Early findings suggest that this scaffold* offers a cost-effective, outpatient-friendly alternative to complex surgical reconstruction. These results provided the rationale for a forthcoming randomized controlled trial (RCT) designed to rigorously assess clinical efficacy, healing trajectories, and economic value. This poster presents preliminary findings from the case series and introduces the structure of the planned RCT.

METHODS

An IRB-approved, de-identified case series was conducted at an academic medical center. Adult patients with complex soft tissue defects or chronic Stage III–IV pressure ulcers were selected for treatment with the acellular porcine liver-derived scaffold*. Informed consent was obtained before enrollment.

Wound characteristics were documented using advanced digital imaging platforms (Kent and eKare) to track surface area, depth, and granulation tissue development. Scaffold* applications were performed in outpatient settings once wound beds were adequately debrided and free of infection. Treatments were spaced at intervals of one to four weeks, depending on clinical response, until maximal improvement was achieved.

Standard dressings were applied after scaffold* placement, and the scaffold was secured using butterfly bandages. Primary outcomes included percent area reduction (PAR), granulation tissue development, and time to full re-epithelialization. Secondary outcomes included patient comfort, dressing durability, infection control, and satisfaction among patients and providers.

RESULTS

Preliminary data from more than 20 cases indicate that the acellular porcine liver-derived scaffold* supports meaningful wound healing and tissue regeneration across various wound types. The majority of applications were performed on an outpatient basis, without the need for surgical intervention or inpatient care, reinforcing the scaffold's* suitability for ambulatory settings.

A particularly illustrative case involved a young, otherwise healthy male with a chronic Stage IV ischial pressure ulcer (Figure 1). A long-term paraplegic, the patient was highly functional, self-transferring and independently offloading using upper body strength and a custom padded wheelchair. Despite compliance with offloading protocols and a history of prior flap surgery, he experienced recurrent ulceration. The wound bed was clean and exhibited signs of low-grade chronic osteomyelitis or osteitis that did not require antibiotics, as there were no systemic symptoms such as fever or malaise.

Given his strong healing potential (non-diabetic, non-smoker, no nutritional deficits), the patient underwent three serial scaffold* applications over several weeks. Each placement contributed to progressive wound improvement (Figure 2). By the final application, the ulcer had fully re-epithelialized, with the wound remaining closed and stable for over six months (Figure 3). Follow-up showed mature, intact epithelial tissue with no signs of recurrence or inflammation.

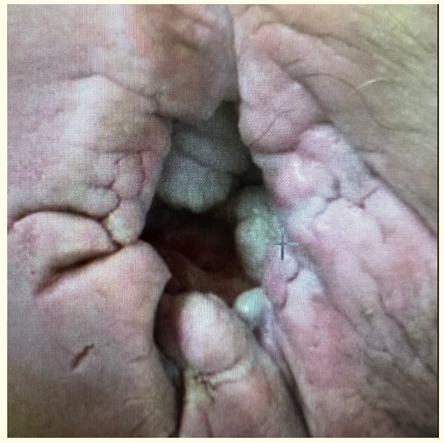

FIGURE 1

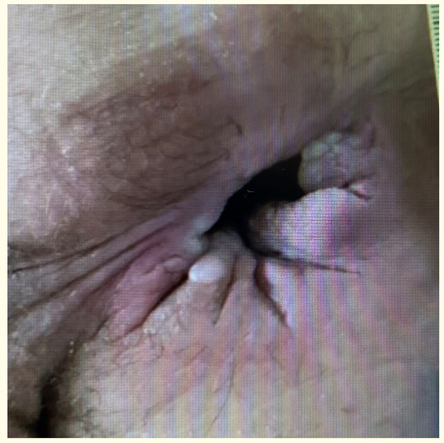

FIGURE 2

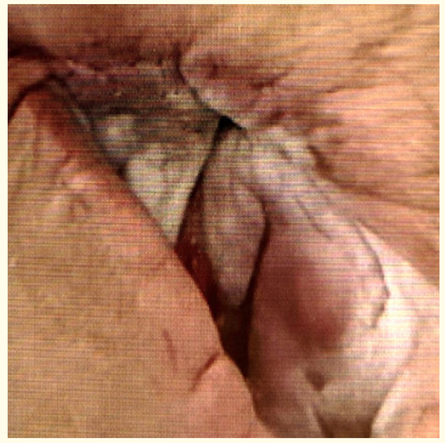

FIGURE 3

DISCUSSION

This case series highlights the real-world potential of acellular porcine liver-derived scaffolds* as a treatment option for complex wounds, particularly when conventional surgical approaches are contraindicated or unavailable. The ability to apply the scaffold* in outpatient settings, combined with favorable healing outcomes and high patient satisfaction, positions it as a valuable tool in modern wound care.

Effective patient selection and wound bed preparation are critical to success. Ideal candidates include those with well-vascularized wound beds, controlled infection, and the capacity to adhere to offloading or compression protocols. While individual response varied—particularly among immunocompromised or ischemic patients—the scaffold* was well tolerated across all cases.

To translate these findings into evidence-based practice, we have developed a 60-subject prospective RCT. The study includes two cohorts: one with complex soft tissue wounds (e.g., post-fasciotomy or necrotizing infections), and another with chronic Stage III+ pressure ulcers. Patients will be randomized to either standard of care (SOC) alone or SOC plus scaffold* treatment. A crossover design will allow patients in the SOC group to receive scaffold* treatment at eight weeks if insufficient healing is observed. Primary endpoints will include PAR and quality of healing at four weeks as predictors of complete closure by week twelve.

CONCLUSIONS

The acellular porcine liver-derived scaffold* shows significant potential as a minimally invasive solution for managing complex wounds. Our case series provides early evidence of its safety, effectiveness, and practicality in outpatient care. These findings support the initiation of a robust, controlled trial to further investigate outcomes and cost-effectiveness.

The upcoming RCT will incorporate both objective measures (e.g., digital wound imaging, granulation analysis) and patient-reported outcomes (e.g., pain levels, return to self-care). As regenerative scaffold technologies evolve, studies like this will be critical for establishing clinical best practices and expanding access to effective wound treatments beyond the surgical paradigm.

1. Horch, R.E. et al. (2024). Management of the Patient After Flap Failure. In: Téot, L., Meaume, S., Akita, S., Del Marmol, V., Probst, S. (eds) Skin Necrosis. Springer, Cham. https://doi.org/10.1007/978-3-031-60954-1_57.

**Miro3D® wound matrix, Reprise Biomedical, Inc., Plymouth, Minnesota.

Miro3D wound matrix is indicated for the management of wounds, including: partial and full-thickness wounds; pressure ulcers; venous ulcers; chronic vascular ulcers; diabetic ulcers; tunneled, undermined wounds; trauma wounds (abrasion, lacerations, partial thickness burns, skin tears); drainage wounds; and surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence).