The Clinical Performance of Decellularized Porcine Placental Extracellular Matrix (PPECM) in Hard-to-Heal Wounds at a Single-Center: A Retrospective Study

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Introduction

- Hard-to-heal wounds do not transition through the typical phases of healing in a reasonable time despite appropriate standard of care[1]
- Randomized controlled trials and meta-analyses suggest that the addition of cellular, acellular, matrix-like products (CAMPs) to standard care can improve outcomes versus standard care alone in hard-to-heal wounds[2–4]
- Porcine placental extracellular matrix (PPECM; InnovaMatrix® AC, Convatec, Memphis, TN, USA) is a CAMP developed for the management of several wound types
  - Terminally sterilized medical device produced from decellularized amnion and chorion tissue[5,6]
  - Primarily composed of the placenta's major structural components, such as collagen, along with smaller amounts of fibronectin, laminin, elastin, hyaluronic acid, and sulfated glycosaminoglycans[5,6]

Aims

This retrospective, single-center study aimed to collect and evaluate real-world performance data on PPECM* in the management of hard-to-heal wounds

Methods

- Electronic medical records at a single wound clinic were screened for patients with hard-to-heal wounds, whose care included the use of PPECM between May 2022 – March 2024
- In this study, hard-to-heal wounds must have demonstrated a lack of clinically significant progression, defined as <50% reduction in wound area over 4 weeks of standard wound care treatment
- The primary endpoint was percent wound area reduction (PAR) at 4-weeks from initiation of PPECM*
- Additional endpoints included percent area reduction (PAR) at 12 and 20 weeks, time to complete wound closure, PPECM* utilization, concomitant management, and safety

Results

Patients

- A total of 89 patients with a median age of 79 years were included in the analysis (**Table 1**)
- Median wound age at first presentation and at first application of PPECM* was 8 weeks and 11.4 weeks, respectively
- Trauma wounds (30.3%), venous ulcers (25.8%), surgical wounds (21.3%), and diabetic ulcers (10.1%) were the most common wound types

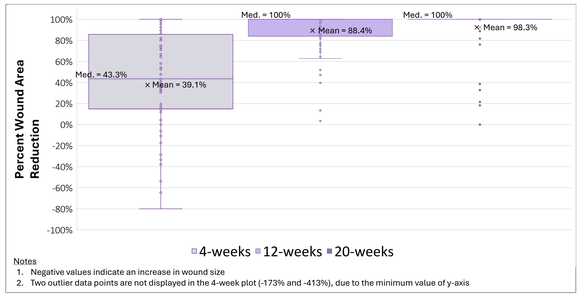
Table 1. Baseline Characteristics

	Patients (n=89)
Median age (range)	79 (48 – ≥80)
Female, n (%)	41 (46.1)
Wound age at presentation, weeks	
Mean (SD)	22.1 (58.6)
Median (range)	8 (0.3–482.9)
Wound age at first application of PPECM, weeks	
Mean (SD)	26.3 (58.6)
Median (range)	11.4 (4.0 – 484.9)
Wound etiology or type, n (%)	
Arterial ulcer	2 (2.2)
Burn	2 (2.2)
Cellulitis	1 (1.1)
Diabetic ulcer	9 (10.1)
Neuropathic	2 (2.2)
Pressure ulcer	1 (1.1)
Radiation wound	3 (3.4)
Surgical wound	19 (21.3)
Trauma wound	27 (30.3)
Venous ulcer	23 (25.8)

Wound Closure Outcomes

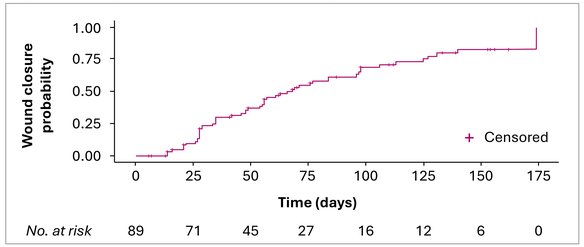
- The median percent area reduction at 4 weeks was 43.3% (95% CI, 32.92–64.29, n=75)
  - Median percent area reduction at both 12 weeks (n=65) and 20 weeks was 100% (95% CI, 100–100; n=58) (**Figure 1**)
- Complete closure was observed in 63% of patients (n=56)
- Kaplan-Meier estimate for median time to closure of 66 days (95% CI, 55–96, n=56) (**Figure 2**)
  - Estimated probabilities for complete wound closure at 4-, 12-, and 20-weeks were 0.21 (95% CI, 0.05–0.35), 0.62 (95% CI, 0.40–0.76), and 0.83 (95% CI, 0.31–0.96), respectively

Figure 1. Percent Area Reduction at 4-, 12-, and 20-weeks



Notes
1. Negative values indicate an increase in wound size
2. Two outlier data points are not displayed in the 4-week plot (-173% and -413%), due to the minimum value of y-axis

Figure 2. Kaplan-Meier Plot for Complete Wound Closure



PPECM Utilization and Concomitant Management

- Patients received a median of 5 (range, 2–13) PPECM* applications
- Wounds were debrided at a median of 7 visits (range, 2–13)
- No patients requiring antibiotics were identified during the study period
- There were no incidences of limb amputation identified during the study period
- PPECM* was discontinued in 22 (24.7%) patients: reasons included loss to follow-up (n=12), death (n=1, unrelated to wound), and other (n=9)

Safety

- No serious adverse device events were reported during the study period

Discussion

- This study provides real-world evidence for the use of PPECM* in hard-to-heal wounds of various etiologies, which had failed to show clinically significant progression under standard care
- At 4-weeks, nearly half of the population had a PAR ≥50% (n=36), and more than half had a PAR ≥40% (n=46), suggestive of a clinically meaningful return to normal wound progression
- Additionally, there was a high estimated probability of wound closure at 12- and 20-weeks
- These results across a diverse patient population suggest PPECM* offers an optimal healing environment for hard-to-heal wounds

Conclusion

Management of hard-to-heal wounds with PPECM was associated with a clinically relevant reduction in wound area at 4 weeks, with a high probability of wound closure at weeks 12 and 20

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