

Real-World Use and Outcomes of Hard-to-Heal Wounds Managed with Porcine Placental Extracellular Matrix (PPECM)

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Introduction

- In 2019, 16% of Medicare beneficiaries had hard-to-heal wounds¹
- Literature supports the use of cellular acellular matrix-like products (CAMPs) for the treatment of hard-to-heal wounds²
- For over 15 years, researchers have acknowledged the non-generalizability of wound randomized controlled trials (RCTs), which exclude 50%–90% of real-world patients^{3,4,5}
- In the real world, practitioners use CAMPs on severe wounds among patients with serious comorbidities⁶
- Real-world data (RWD) allows for the inclusion of heterogenous, vulnerable patient populations, increasing the completeness of evidence-based medicine for clinical guidelines⁷
- This is the first clinical study of porcine placental extracellular matrix (PPECM)*, the only FDA-cleared placental-derived product for wound management

Aims
To retrospectively analyze the performance of PPECM*, a novel CAMP, in a challenging, real-world patient population

Methods

- This study analyzed a patient population with severe, limb/life-threatening (L/LT), hard-to-heal wounds treated with standard clinical care via data abstraction from the US Wound Registry (USWR) containing 76,278 patients with 248,278 wounds screened
- Wounds treated with at least one PPECM* application at participating clinics from 10 October 2022 – 25 March 2024 were included in the analysis
- **Primary Endpoint:** complete wound closure at any time
- In addition to **Wound Closure**, other outcome categories included:
 - **Major Improvement:** wounds with a percent area reduction (PAR) <100% and ≥85% from the initial documented size
 - Modest Improvement, Stalled, or Deteriorated (**MISD**)
 - and Lost-to-Follow-up (**LTF**)

Results

Patient and wound characteristics

- Data were provided by 11 providers at seven sites (five outpatient wound clinics and two mobile practitioners at skilled nursing facilities) in four states
- 41 patients with 60 wounds received PPECM* treatment, with a median patient age of 74 years (**Table 1**)
- 52% of wounds were designated as limb/life-threatening (L/LT)

PPECM* utilization

- At time of first PPECM* application, wounds were a median of 66 days old (IQR, 38-154)
- The median number of PPECM* applications applied per wound was 2 (IQR, 1–5)
- Wounds were treated for a median of 32 days (IQR, 20–60)

Table 1. Baseline characteristics

		Patients (n=41)
Age, median (IQR)		74 (66–80)
Female, n (%)		19 (46)
Method of arrival, n (%)	Fully ambulatory	21 (51)
	Impaired ambulatory	18 (44)
	Bedridden	2 (5)
		Wounds (n=60)
Limb/life-threatening wounds, n (%)		31 (52)
Necrotic tissue at first PPECM* application, n (%)	0%	2 (3)
	0-25%	20 (33)
	≥ 25%	26 (43)
	Not Recorded	12 (20)
Baseline wound size, median (IQR)		1.5 cm ² (0.4–4.7)
Wounds present ≥ 1 year, n (%)		9 (17)
Baseline signs of bioburden/infection, n (%)		52 (87)

Wound Outcomes

- At weeks 4, 8, and 12, median percent area reduction (PAR) was 55.8%, 96.7%, and 100%, respectively (**Figure 1**)
- 32 wounds (53%) closed (44% were L/LT). Five wounds (8%) demonstrated major improvement (60% were L/LT). 13 wounds (22%) demonstrated MISD (62% were L/LT). 10 wounds (17%) did not have outcomes reported (**Table 2**)
- 14 (45%) of L/LT and 18 (62%) of non-L/LT wounds closed (**Figure 2**)

Figure 1. Median Percent Area Reduction (PAR)

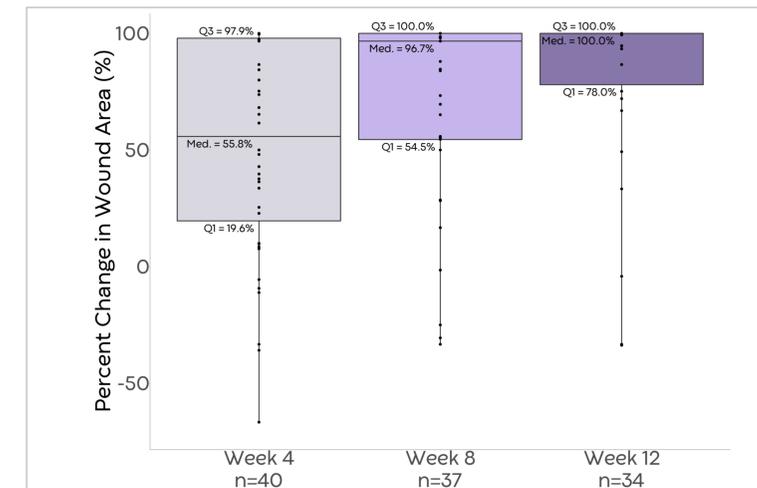


Figure 2. Outcome by Limb/Life-Threatening (L/LT) Wound

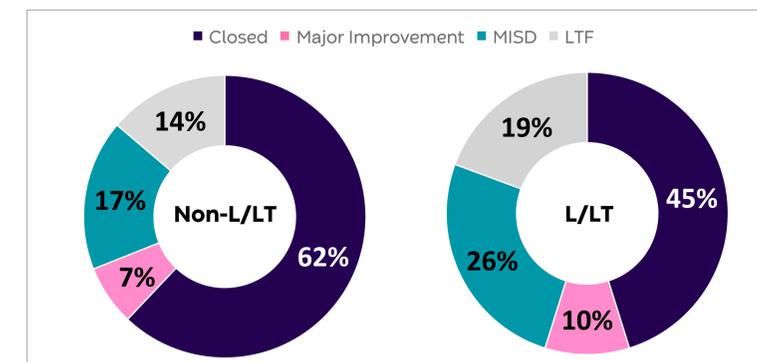


Table 2. Outcome by Wound Type

Wound type, n(%)	Closed	Major improvement	MISD	LTF
Chronic ulcer (n=18)	8 (44%)	2 (11)	7 (39%)	1 (6%)
Diabetic foot ulcer (n=10)	4 (40%)	1 (10%)	4 (40%)	1 (10%)
Surgical wound (n=7)	2 (29%)	0 (0%)	1 (14%)	4 (57%)
Venous leg ulcer (n=6)	5 (83%)	1 (17%)	0 (0%)	0 (0%)
Pressure injury (n=7)	4 (57%)	0 (0%)	0 (0%)	3 (43%)
Traumatic wound (n=5)	2 (40%)	1 (20%)	1 (20%)	1 (20%)
Other (n=7)	7 (100%)	0 (0%)	0 (0%)	0 (0%)
Total (n = 60)	32 (53%)	5 (8%)	13 (22%)	10 (17%)

Safety

- No adverse events or complications were identified

Discussion

- Despite the poor health of patients and severity of wounds, the majority (53%) closed after PPECM* treatment, including 83% of venous leg ulcers
- These outcomes are remarkable because, based on previously published USWR and RCT data, it was reported that in the real world, among complicated patients, closure incidences of >40% may not be achievable³
- PPECM* rates are comparable to wound closure incidences (57–59%) in other real-world studies that evaluated viable placental membranes^{8,9}
- 69% of all non-L/LT wounds achieved major improvement or closed, showing evidence of excellent outcomes in that cohort

Conclusion
In the real world, PPECM* may offer clinicians a safe, innovative option for the management of hard-to-heal wounds

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*PPECM: InnovaMatrix® AC, Convatec Triad Life Sciences, LLC, Memphis, TN, USA