

# 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 wounds<sup>1</sup>
- Literature supports the use of cellular acellular matrix-like products (CAMPs) for the treatment of hard-to-heal wounds<sup>2</sup>
- For over 15 years, researchers have acknowledged the non-generalizability of wound randomized controlled trials (RCTs), which exclude 50%–90% of real-world patients<sup>3,4,5</sup>
- In the real world, practitioners use CAMPs on severe wounds among patients with serious comorbidities<sup>6</sup>
- Real-world data (RWD) allows for the inclusion of heterogenous, vulnerable patient populations, increasing the completeness of evidence-based medicine for clinical guidelines<sup>7</sup>
- 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)

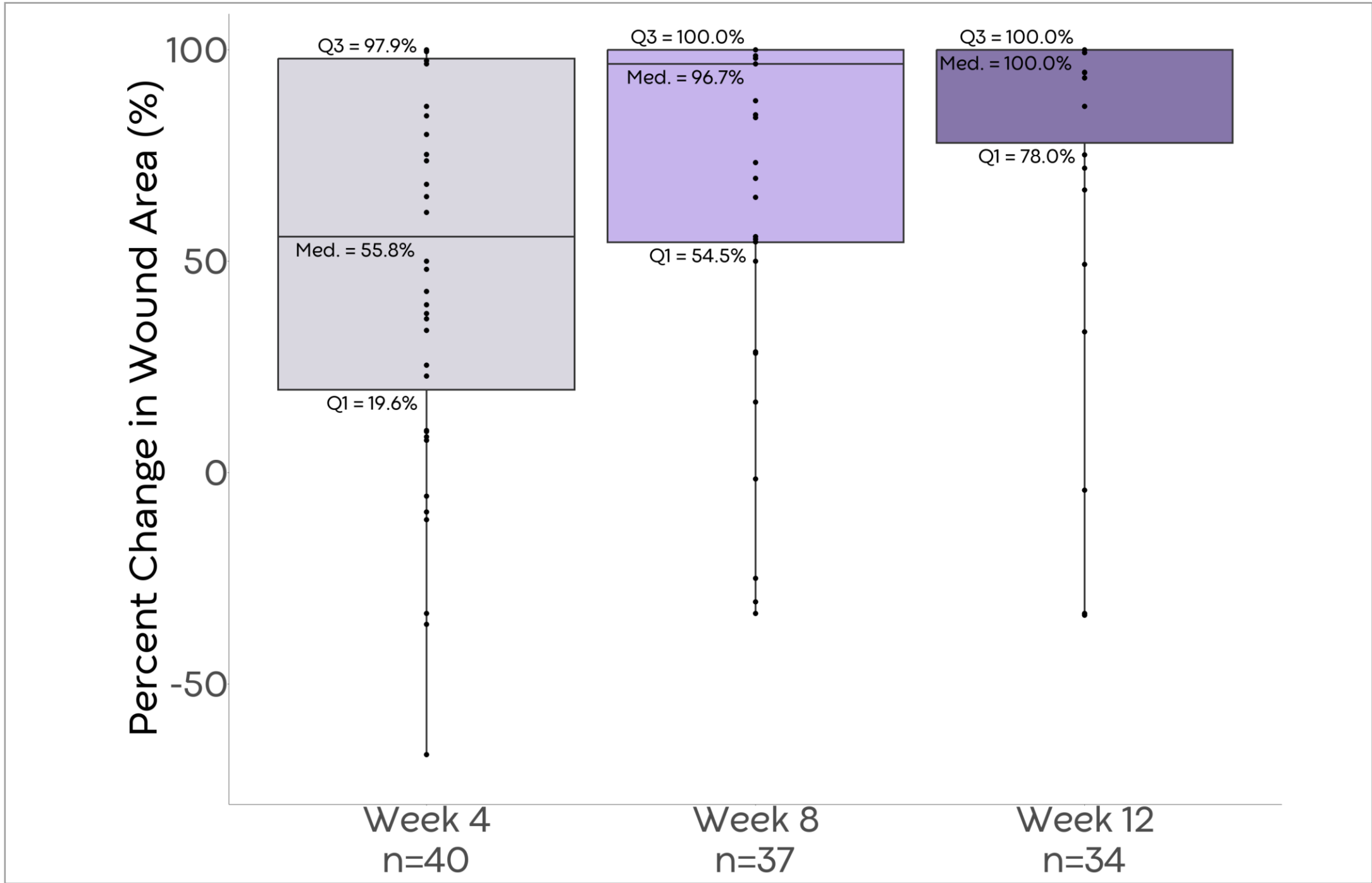
**Table 1. Baseline characteristics**

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

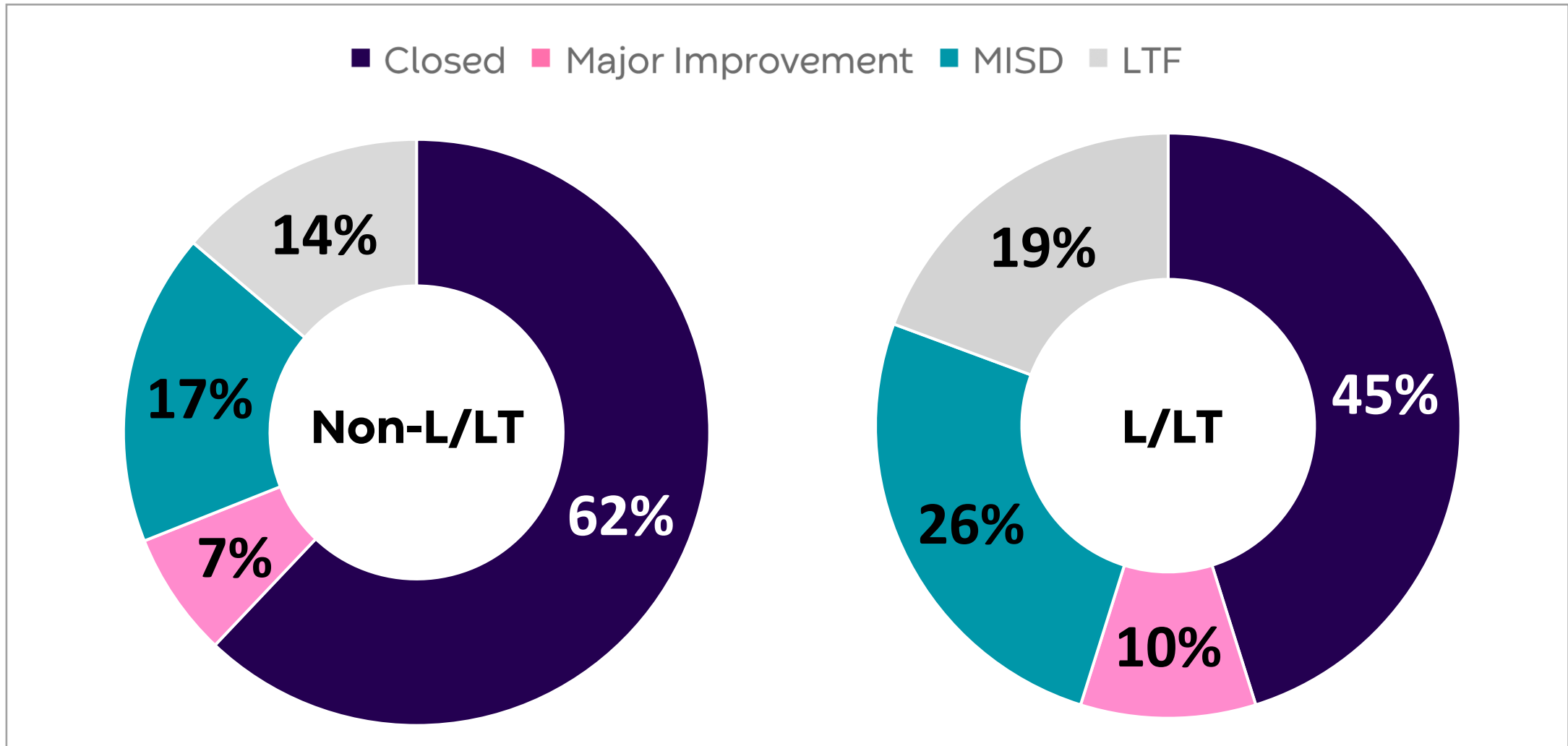
### Wound Outcomes

- 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
<b>Chronic ulcer (n=18)</b>	8 (44%)	2 (11)	7 (39%)	1 (6%)
<b>Diabetic foot ulcer (n=10)</b>	4 (40%)	1 (10%)	4 (40%)	1 (10%)
<b>Surgical wound (n=7)</b>	2 (29%)	0 (0%)	1 (14%)	4 (57%)
<b>Venous leg ulcer (n=6)</b>	5 (83%)	1 (17%)	0 (0%)	0 (0%)
<b>Pressure injury (n=7)</b>	4 (57%)	0 (0%)	0 (0%)	3 (43%)
<b>Traumatic wound (n=5)</b>	2 (40%)	1 (20%)	1 (20%)	1 (20%)
<b>Other (n=7)</b>	7 (100%)	0 (0%)	0 (0%)	0 (0%)
<b>Total (n = 60)</b>	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 achievable<sup>3</sup>
- PPECM\* rates are comparable to wound closure incidences (57–59%) in other real-world studies that evaluated viable placental membranes<sup>8,9</sup>
- 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