Retrospective Analysis of Real-world Use of Porcine Placental Extracellular Matrix in Hard-to-Heal Wounds

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INTRODUCTION

- In 2019, 16% of Medicare beneficiaries had hard-to-heal wounds.[1]
- Literature supports the use of cellular acellular matrix-like products (CAMPs) for the treatment of hard-to-heal wounds.[2]
- 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 comorbidities.[6]
- Real-world data (RWD) allows for the inclusion of heterogenous, vulnerable patient populations, increasing the completeness of evidence-based medicine for clinical guidelines.[7]
- This is the first clinical study of porcine placental extracellular matrix (PPECM)* the only FDA-cleared placental-derived product for wound management.

STUDY OBJECTIVE

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 United States 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.

RESULTS

Table 1. Patient Demographics

Age, mean (SD)		71.9 (11.2)
Gender, n (%)	Male	22 (54%)
	Female	19 (46)
Method of arrival, n (%)	Fully ambulatory	27 (62%)
	Impaired ambulatory	12 (29)
	Bedridden	2 (5)
Comorbidities, n (%)	Obesity	16 (39%)
	Diabetes	11 (27)
	Autoimmune Disease	5 (12)
	Nicotine Use	5 (12)
	Peripheral arterial disease	5 (12)
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, mean (SD)		5.2 cm^2 (13.3)
Wounds present ≥ 1 year, n (%)		9 (17%)
Baseline signs of bioburden/infection, n (%)		52 (87%)

- 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.
- The IQR (Q1, Q3) number of PPECM* applications applied per wound was 4.0 (1.0, 5.0). (**Table 2**)
- At weeks 4, 8, and 12, median PAR was 55.8%, 96.7%, and 100%, respectively. (**Figure 1**)
- 32 wounds (53%) closed, 44% of which were L/LT. Five wounds (8%) improved, 60% of which were L/LT. 13 wounds (22%) did not improve, 62% of which were L/LT. 10 wounds (17%) did not have outcomes reported. (**Table 3**)
- No adverse events or complications were reported.

Table 2. Patterns of Use

Values	Min	Max	Mean	Median	SD	IQR (Q1, Q3)
Number of PPECM* applications	1.0	13.0	3.4	2.0	3.2	4.0 (5.0, 1.0)
Length of treatment (days)	6.0	104.0	36.9	32.0	26.8	40.0 (60.0, 20.0)
Wound age at first PPECM* application (days)	7.0	1,489.0	124.2	66.0	214.8	116.0 (154.0, 38.0)

Figure 1. Median Percent Area Reduction (PAR)

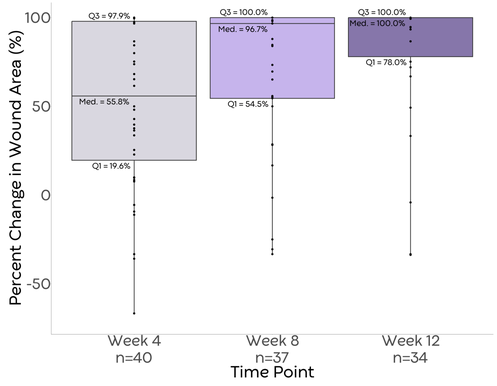

Figure 2. Outcome by Limb/Life-Threatening (L/LT) Wound

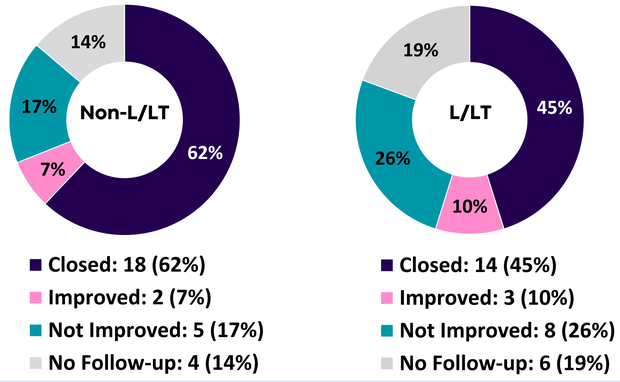

Table 3. Outcome by Wound Type

Wound type	Closed n (%)	Improved n (%)	Not improved n (%)	No follow up n (%)
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%)
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%)

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 is likely that in the real world, among complicated patients, healing rates better than 40% are not achievable.[3]
- PPECM* rates are comparable to healing rates (57–59%) in other real-world studies that evaluated viable placental membranes.[8,9]
- Different outcome measures are needed to reflect success in challenging, real-world populations relative to the standard metrics utilized in RCTs.

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

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