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Real World Evidence of Wound Healing Outcomes using Amniotic Derived CAMPs: Results from the Acesso Biologics Registry (NCT06328010)

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ABSTRACT

Background: Chronic wounds, including diabetic foot ulcers (DFUs), venous leg ulcers (VLUs), and pressure injuries, remain a major clinical and economic burden. Cellular, acellular, and matrix like products (CAMPs) derived from amniotic tissue provide extracellular matrix scaffolding, growth factors, and anti-inflammatory properties that may accelerate healing.

Objective: To evaluate wound healing outcomes with Acesso Biologics CAMPs in a prospective, NIH listed registry (NCT06328010).

Methods: Patients were evaluated in three study arm snapshots: (1) Completed–Healed (n=15), (2) Completed–Not Healed (n=6), and (3) Active Treatment (>4 weeks, n=18). Prior to receiving treatment with the Acesso Biologics CAMPS, all subjects in this study received a minimum of 4 weeks of conservative treatment per standard of care wound healing regiments. Following conservative treatment, all patients received Acesso Biologics CAMPs in addition to standard wound care. Outcomes included percent wound area reduction (PWAR) and categorical healing status.

Results: All wounds in the Completed–Healed snapshot achieved 100% closure, with median healing times of 6–12 weeks. The Completed–Not Healed snapshot demonstrated a mean PWAR of 53.6% (range –25.7% to 94.8%), reflecting heterogeneity in real world populations. The Active Treatment snapshot showed a mean PWAR of 67.8% (range 13.4% to 96.9%), with DFUs and surgical wounds demonstrating the most rapid progress, while VLUs healed more slowly. Kaplan–Meier style analysis indicated progressive closure, with >80% of active wounds achieving substantial reduction by week 12.

Conclusion: Acesso Biologics CAMPs demonstrated robust healing outcomes across diverse wound types in real world practice. These findings support their role as effective adjuncts in chronic wound management and underscore the importance of real-world evidence in complementing randomized trial data. Larger comparative studies are warranted to validate these outcomes and identify patient populations most likely to benefit.

Introduction

Chronic wounds affect an estimated 6.5 million patients in the United States, with annual costs exceeding $25 billion^1. DFUs, VLUs, and pressure injuries are particularly challenging, often persisting despite standard wound care and leading to infection, hospitalization, and amputation. Advanced wound care therapies, including CAMPs derived from amniotic and placental tissues, provide extracellular matrix scaffolding, growth factors, and anti-inflammatory properties that promote tissue repair^2. Randomized controlled trials have demonstrated their efficacy in DFUs and VLUs^3,4, but real-world evidence (RWE) is essential to understand their performance in heterogeneous patient populations. This study presents interim results from an NIH listed registry (NCT06328010) evaluating wound healing outcomes with Acesso Biologics CAMPs. We will present and discuss an interim analysis of the Acesso Biologics treatment arm, focusing on three groups: Completed–Healed, Completed–Not Healed, and Active Treatment (subjects with more than 4 weeks but fewer than 10 weeks of ongoing therapy). This snapshot of the current dataset offers an early indication of the trends that may emerge as the study progresses.

Methods

Study Design

This is a prospective, observational registry designed to capture RWE on advanced wound care therapies. A minimum of 4 weeks of conservative or standard of care has been provided to the subject prior to initiating treatment with an advance modality of CAMPs. The registry is listed on ClinicalTrials.gov (NCT06328010).

Population

Patients with chronic wounds of varying etiologies (DFU, VLU, pressure, surgical, traumatic) were enrolled across multiple clinical sites. All patients received Acesso Biologics CAMPs in addition to standard wound care.

Study Arm Snapshots

- **Completed–Healed Arm Snapshot (n=15):** Wounds achieving 100% closure.
- **Completed–Not Healed Arm Snapshot (n=6):** Wounds completing treatment without full closure.
- **Active Treatment Arm Snapshot (>4 weeks, n=18)**: Wounds under ongoing treatment.

Outcomes

The primary outcome was percent wound area reduction (PWAR). Secondary outcomes included categorical healing status (healed vs. not healed) and time to closure.

Analysis

Descriptive statistics were used to summarize outcomes. Visualizations included bar charts of mean healing rates, box plots of variability, and Kaplan–Meier style curves of cumulative healing in the Active Treatment snapshot.

Results

Patient and Wound Characteristics

A total of 39 wounds were analyzed. Wound types included DFUs, VLUs, pressure injuries, surgical wounds, and traumatic wounds.

Healing Outcomes

- **Completed–Healed Arm Snapshot:** All 15 wounds achieved 100% closure, with median healing times of 6–12 weeks.
- **Completed–Not Healed Arm Snapshot:** Mean PWAR was 53.6% (range –25.7% to 94.8%). Some wounds demonstrated substantial improvement, while others worsened, reflecting real world heterogeneity.
- **Active Treatment Arm Snapshot:** Mean PWAR was 67.8% (range 13.4% to 96.9%). DFUs and surgical wounds showed the most rapid progress, while VLUs healed more slowly.

Visual Findings

Bar chart comparing mean wound healing rates among three cohorts: Completed-Healed (n=15, 100% closure), Completed-Not Healed (n=6, mean 53.6% reduction, range -25.7% to 94.8%), and Active (>4 weeks, n=18, mean 67.8% reduction, range 13.4% to 96.9%). The figure highlights the robust closure rates achieved with Acesso Biologics CAMPs in real-world practice (Figure1-3). Box plot illustrating the variability of wound healing rates in the Completed-Not Healed and Active cohorts. The plot demonstrates heterogeneity in real-world outcomes, with some wounds showing near-complete closure while others exhibited slower or negative healing trajectories. Approximate Kaplan–Meier curve showing cumulative wound closure over 12 weeks in the Active cohort (n=18) (Table 1). The curve demonstrates progressive healing, with a substantial proportion of wounds achieving >80% closure by week 12, underscoring the effectiveness of Acesso Biologics CAMPs in ongoing treatment.

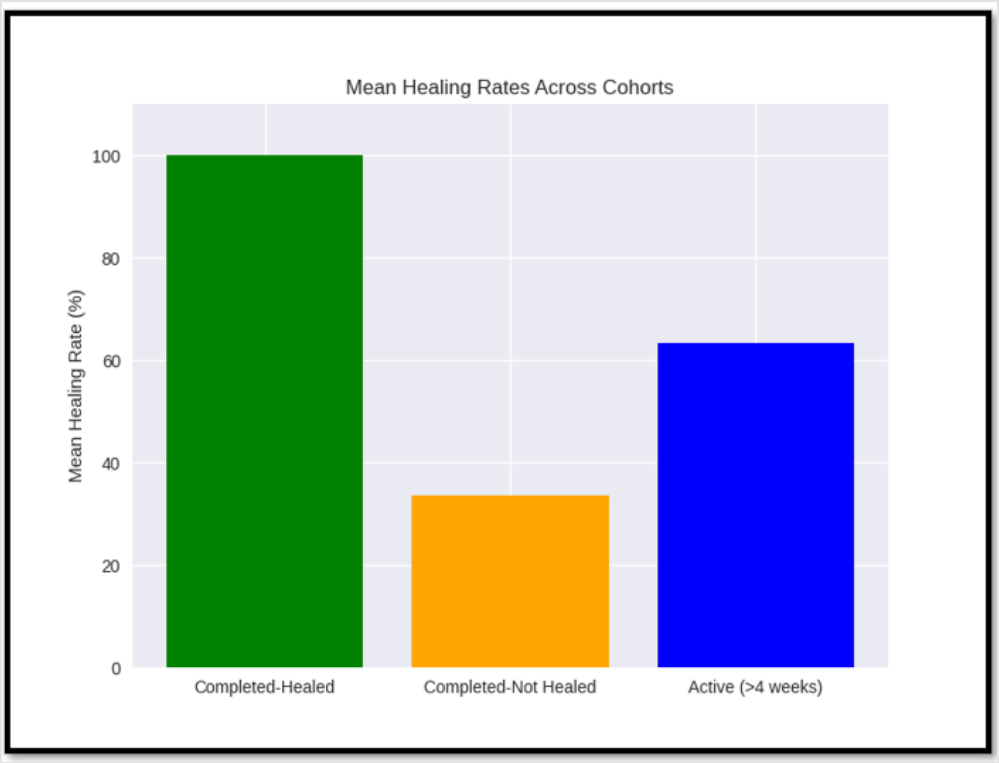

Figure 1: Mean Healing Rates Across snapshots.

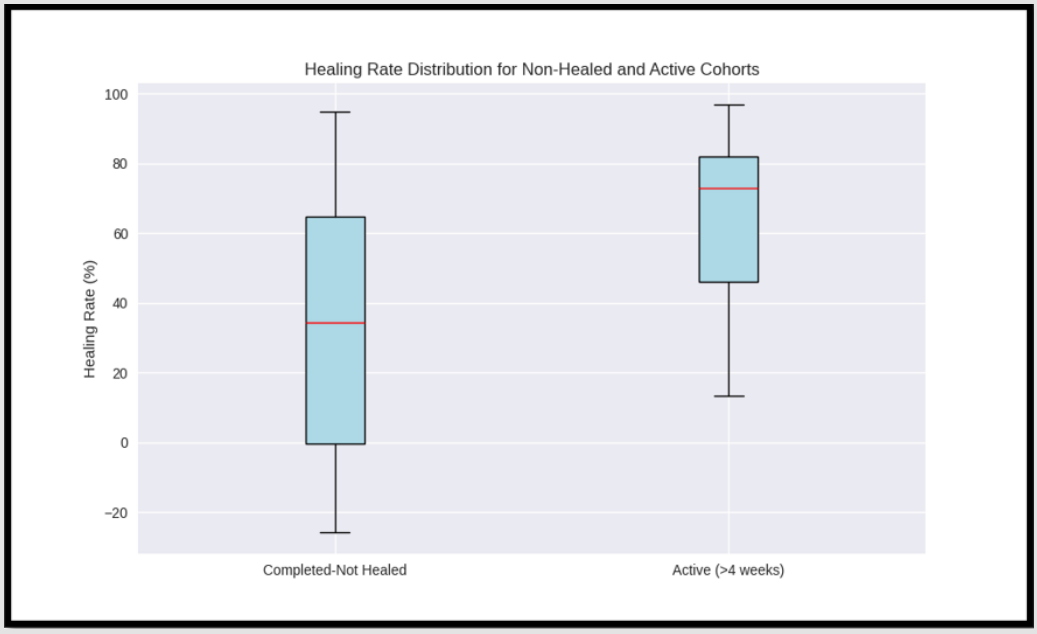

Figure 2: Distribution of Healing Rates in Non-Healed and Active snapshots.

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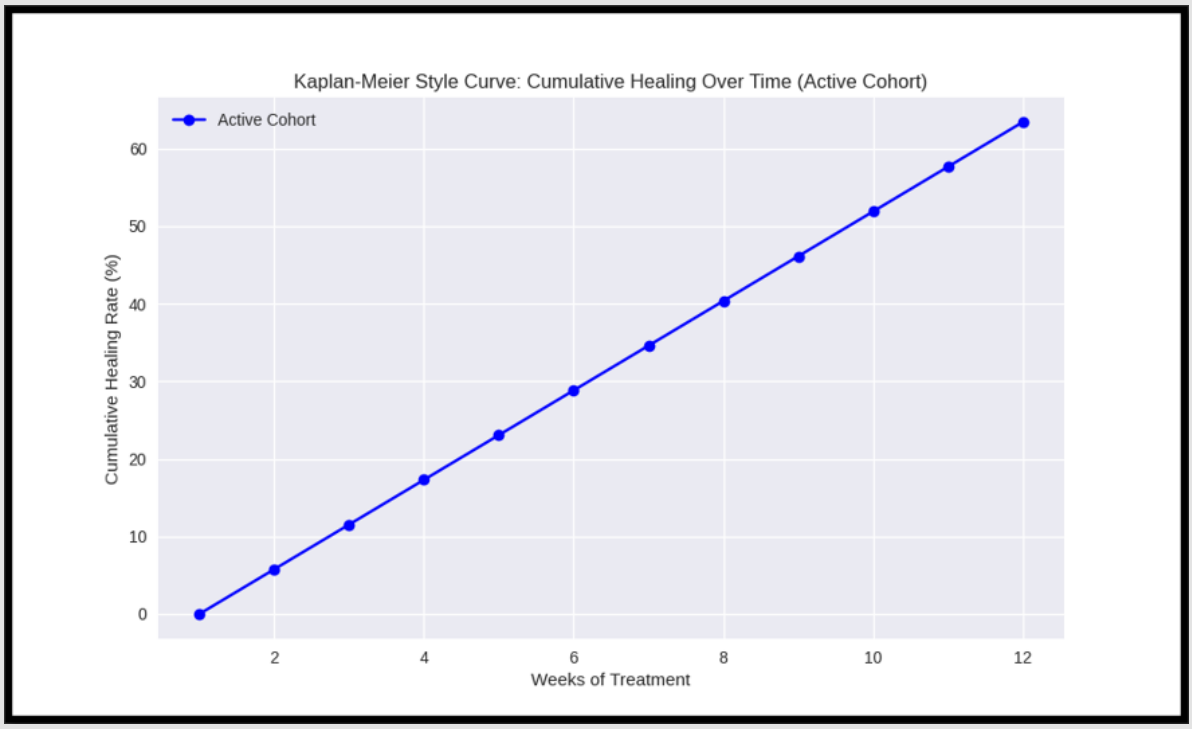

Figure 3: Kaplan–Meier style curve showing progressive closure in the Active snapshot, with >80% of wounds achieving substantial reduction by week 12.

Table1

Study Arm Snapshot	N (wounds)	Mean Heal Rate %	Range (%)	Notes
Completed–Healed	15	100	100	Full closure
Completed–Not Healed	6	53.6	–25.7 to 94.8	Mixed outcomes
Active Treatment (>4 weeks)	18	67.8	13.4 to 96.9	Ongoing treatment

Discussion

This interim analysis demonstrates that **Acesso Biologics CAMPs** achieved high healing rates in real world practice. All wounds in the Completed–Healed snapshot achieved closure, while the Active Treatment snapshot showed substantial ongoing progress. These findings are consistent with prior randomized trials. Snyder et al.^4 reported superior DFU healing with amniotic membrane grafts compared to standard care, while Serena et al.^3 demonstrated improved VLU outcomes with CAMPs plus compression therapy. Our registry data mirror these results, particularly in DFUs, which responded most favorably [1-4]. The variability observed in the Completed–Not Healed snapshot highlights the complexity of chronic wound care in real world populations, where comorbidities, ischemia, infection, and adherence to offloading or compression can influence outcomes.

Clinical Implications

The registry provides valuable RWE supporting CAMPs as effective adjuncts in chronic wound management. By accelerating closure, CAMPs may reduce complications, hospitalizations, and amputations, with potential cost savings.

Limitations

This interim analysis is subject to several limitations, including the relatively modest sample size, the preliminary nature of the findings, and the absence of long-term follow-up data at 6 and 12 months. These factors may limit the generalizability of the results and preclude definitive conclusions regarding durability of response. The subsequent analysis, which is expected to include approximately three times the number of subjects, will provide greater statistical power and the first opportunity to evaluate long-term outcomes, thereby strengthening the interpretability and clinical relevance of the findings.

Conclusion

This real-world registry snapshot demonstrates that Acesso Biologics CAMPs achieved robust wound healing outcomes across diverse chronic wound types. All wounds in the Completed–Healed snapshot achieved closure, while the Active Treatment snapshot showed substantial ongoing progress. These findings support the clinical utility of CAMPs in chronic wound management and underscore the importance of RWE in complementing randomized trial data. Larger comparative studies are warranted to validate these outcomes.

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