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Successful Use of Amniotic Graft in Healing a Chronic Ulcer Aggravated by Peripheral Vascular Disease (PVD)

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ABSTRACT

Chronic wounds in patients with peripheral vascular disease (PVD) present significant challenges due to impaired perfusion, delayed healing, and increased risk of infection. This case study documents the successful use of XCELL AmnioMatrix™ (XAM), a lyophilized amniotic allograft, in closing a hard-to-heal ulcer that had plateaued under standard of care (SOC). The patient was enrolled in an independent open-label clinical registry (NCT06328010) benchmarking healing and closure rates of cellular, acellular, and matrix-like amniotic grafts. Transitioning from SOC to XAM therapy resulted in accelerated wound closure and complete epithelialization within 15 weeks, demonstrating the clinical utility of amniotic grafts in complex vascular-related wounds.

Abbreviations: PVD: Peripheral Vascular Disease; XAM: XCELL Amnio Matrix; SOC: Standard of Care; VLUs: Venous Leg Ulcers; CAMPS: Cellular, Acellular, and Matrix-Like Products

Introduction

Chronic wounds, particularly venous leg ulcers (VLUs) and ulcers complicated by PVD, are notoriously resistant to healing. Standard of care—including debridement, infection control, and compression—often yields limited progress in patients with vascular compromise. Amniotic membrane grafts, classified under cellular, acellular, and matrix-like products (CAMPS), have emerged as advanced biologic therapies. Their unique properties include:

- Reservoir of bioactive molecules: growth factors, cytokines, and amino acids that promote repair.
- Biologic scaffold: supports cell migration and tissue regeneration.
- Barrier and moisture retention: protects against infection while maintaining an optimal wound environment.
- Product versatility: XCELL AmnioMatrix[™] is a terminally

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sterilized, lyophilized single-layer amniotic membrane that is easy to handle, requires no rehydration, and provides a natural extracellular matrix scaffold.

This case highlights the clinical success of XAM in a patient with PVD, where SOC alone was insufficient to achieve wound closure.

Case Presentation Registry cited NCT06328010 (ClinicalTrials.gov)

Patient Profile

- 81-year-old male
- History: PVD, hypertension, chronic anticoagulation (Eliquis 5 mg BID)
- Injury: Traumatic degloving wound of the right lateral leg following a fall

Complication: Wound dehiscence within one week, evolving into a chronic ulcer

Initial Management

- · Serial sharp debridements
- MSSA infection treated with doxycycline followed by Augmentin
- · Adequate vascular status confirmed
- After 4 weeks of SOC, <50% improvement was observed → wound reclassified as venous ulcer secondary to PVD

Advanced Therapy

- XAM grafting initiated at week 7
- Patient demonstrated excellent compliance with dressing care, elevation, and follow-up Figures (1,2,3,4 & 5).



Figure 1

Day 1 on SOC (Week 0)



Figure 2
Start of XAM Application (Week 7)





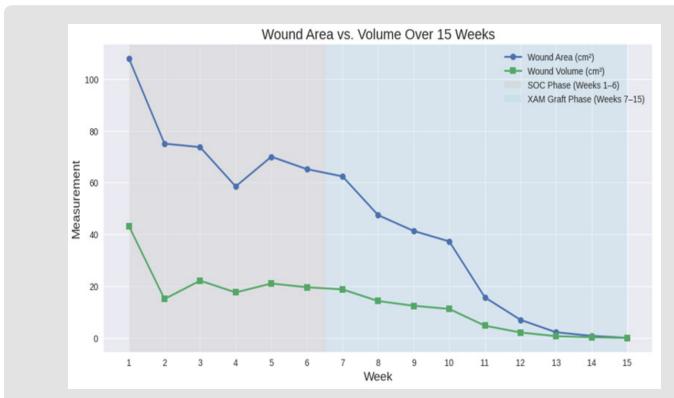


Figure 4: wound area vs. wound volume over the 15 week course. The shaded regions highlight the SOC phase (weeks 1-6) and the XAM graft phase (weeks 7-15) so you can clearly see where the healing trajectory accelerated.

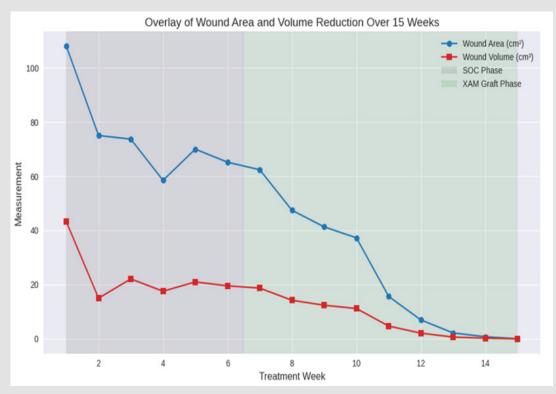


Figure 5: This visualization makes the clinical impact of switching to XAM therapy very clear: the plateau during SOC is followed by a sharp, consistent decline in both area and volume once grafting began. showing both wound area (blue) and wound volume (red) reductions over the 15 week treatment course. The shaded regions highlight the SOC phase (weeks 1–6) and the XAM graft phase (weeks 7–15), making the transition point and acceleration in healing very clear.

Results

(Table 1)

Table1

Treatment week	L (Cm)	W (cm)	D (cm)	Wound Area (sq cm)	Wound Volume (cubic cm)	Therapy
1	18	6	0.4	108	43.2	SOC
2	11.2	6.7	0.2	75.04	15.008	SOC
3	11	6.7	0.3	73.7	22.11	SOC
4	9	6.5	0.3	58.5	17.55	SOC
5	10	7	0.3	70	21	SOC
6	12.3	5.3	0.3	65.19	19.557	SOC
7	10.4	6	0.3	62.4	18.72	XAM Graft
8	9.3	5.1	0.3	47.43	14.229	XAM Graft
9	8.1	5.1	0.3	41.31	12.393	XAM Graft
10	8.1	4.6	0.3	37.26	11.178	XAM Graft
11	3.4	4.6	0.3	15.64	4.692	XAM Graft
12	2.4	2.9	0.3	6.96	2.088	XAM Graft
13	2.4	0.9	0.3	2.16	0.648	XAM Graft
14	0.7	1.1	0.3	0.77	0.231	XAM Graft
15	Healed	Healed	Healed			

Key Observations

- SOC (weeks 1-6): modest reduction in wound size, plateau in healing
- XAM therapy (weeks 7–15): rapid and consistent reduction in wound area and volume
- Complete epithelialization achieved by week 15

Discussion

This case underscores the clinical value of amniotic grafts in managing chronic wounds complicated by vascular disease. The biologic activity of XAM likely contributed to:

- · Enhanced cellular migration and angiogenesis
- Reduction in wound depth and volume
- Accelerated closure compared to SOC alone

The patient's enrollment in the open-label registry (NCT06328010) provided structured data capture, reinforcing the reproducibility of these results in real-world settings [1-5].

Conclusion

The transition from SOC to XCELL AmnioMatrix™ was pivotal in achieving wound closure in this PVD-complicated ulcer. This case demonstrates that amniotic grafts can convert stalled healing trajectories into successful outcomes. As registry data accumulates, XAM and similar amniotic products may establish themselves as standard adjunctive therapies for chronic wounds resistant to conventional care.

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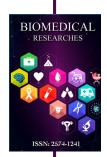
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