BIOVANCE®
Human Amniotic Membrane Allograft
A Celularity Innovation

Real-world Experience With a Decellularized Dehydrated Human Amniotic Membrane Allograft: A Prospective, Observational, Multicenter Study of a Broad Patient Population in All Wound Types.

Wounds 2015;27(6):158-169 *Janice M. Smiell, MD[a]; Terry Treadwell, MD[b]; Helen D. Hahn, RN, MBA[a]; Michel H. Hermans, MD[c]*

The aim of this observational study was to gain experience in the use and performance of BIOVANCE® versus standard of care (SOC) in a real-world wound population. **A broad range of partial and full thickness wounds were studied across a mix of patient types.**

- Eligibility for inclusion included any patient that would benefit from treatment
- Unlike other chronic wound prospective, randomized, controlled trials, there were no limits on patients' age, baseline wound size or co-existing conditions
- Key comorbidities included: arterial insufficiency, autoimmune disease, diabetes, and edema/lymphedema

BIOVANCE SUPPORTS WOUND CLOSURE ACROSS A VARIETY OF WOUND AND PATIENT TYPES

BIOVANCE: at 8 weeks

100%
Wounds < 3.12 cm

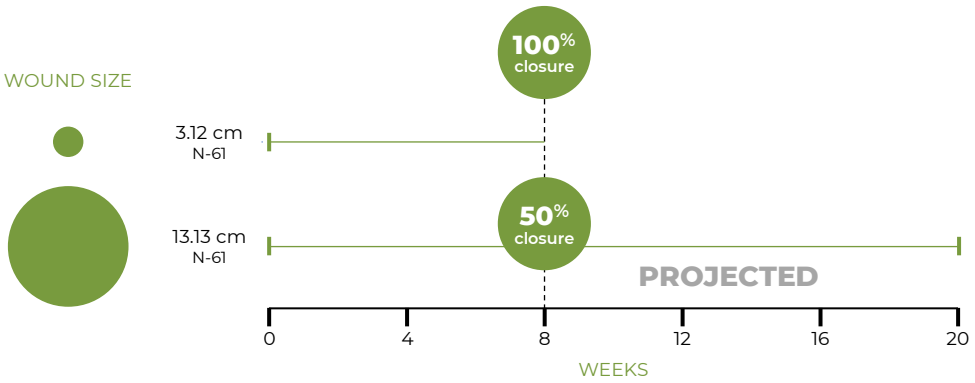
50%
Wounds > 13.13 cm

2X BIOVANCE closed nearly twice as many wounds as control

SOC: at 12 weeks

24-34%
(average baseline)

PROJECTED WOUND CLOSURE AT 12-20 WEEKS



- A longer observation time may have resulted in closure of the larger wounds
- Many chronic wound studies capture wound closure at 12–20 weeks

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[b] Institute for Advanced Wound Care, Montgomery, AL
[c] Hermans Consulting Inc, Newtown, PA

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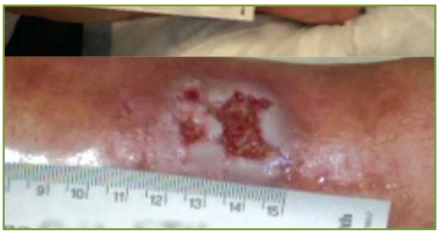
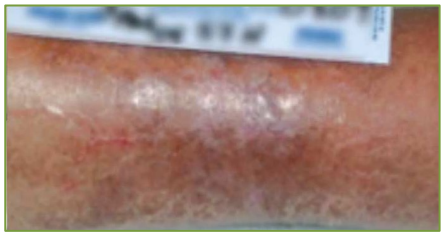
CASE STUDY 1: VENOUS STASIS ULCER

Patient	Comorbidities	Baseline Wound Size	Closure
• 61 year old female with 3 prior treatment failures	• Peripheral vascular disease • Venous insufficiency • Immuno deficiency	1.8cm x 1.2cm x 0.2cm	7 weeks with 1 application



BASELINE



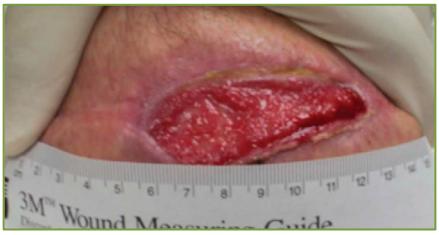
WEEK 7 CLOSED

Treatment Regimen:

- Burow's Solution was applied to the periwound area twice a day

CASE STUDY 2: ACUTE WOUND

Patient	Comorbidities	Baseline Wound Size	Closure
• 67 year old male with right BKA stump dehiscence	• Severe peripheral artery disease • Diabetes	7cm x 2.5cm x 0.1cm	6 weeks with 1 application



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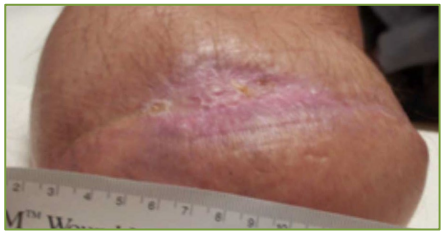


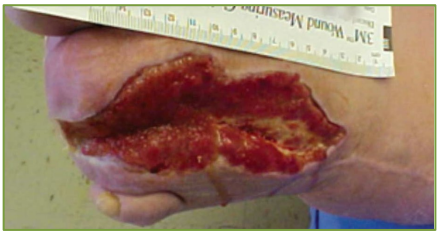
WEEK 6 CLOSED

Treatment Regimen:

- 1 application of BIOVANCE, not fenestrated
- Secondary dressing with nonadherent petroleum gauze and moist gauze

CASE STUDY 3: DIABETIC FOOT ULCER

Patient	Comorbidities	Baseline Wound Size	Closure
• 68 year old male with full thickness wound	• Type 2 DM, Chronic Renal Failure, Neuropathic, Lymphedema	12.9cm x 4.8cm x 0.1cm	25 weeks with 5 applications



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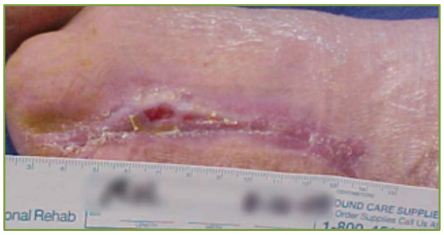

WEEK 25 CLOSED

Treatment Regimen:

- Application of BIOVANCE on Days 1, 4, 16, 38 and136
- Secondary dressing during treatment with petroleum gauze, topical gentamicin, silver hydrofiber dressing, polyurethane foam with gauze and elastic wrap
- Patient placed on gentamicin at week 3 with positive cultures for *staphyloccus aureus*

CITATION: Smiell JM, Treadwell T, Hahn HD, Hermans MH. Real-world Experience With a Decellularized Dehydrated Human Amniotic Membrane Allograft. *Wounds a Compend Clin Res Pract*. 2015;27(6):158-169. http://www.ncbi.nlm.nih.gov/pubmed/26061491.

Presentation: The Progenerative Power of Amnion: The Science and the Clinical Experience for BIOVANCE® Human Amniotic Membrane Allograft, Mohit Bhatia, PhD. This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

BIOVANCE is a registered trademark of Celularity, Inc.
Please contact Celularity Medical Affairs to obtain additional information regarding this clinical summary at medicalaffairs@celularity.com
For product information or adverse reaction reporting, telephone 1-844-963-2273.
Please refer to the BIOVANCE Package Insert for complete product information.

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