

Assessing Treatment Efficiency in Diabetic Foot Ulcers: Processing for Retention Versus Lamination: A Retrospective Analysis

1. Zwelithini Tunyiswa, BA
Chief Executive Officer
Open Wound Research
(610) 955-9563
zveli@openwoundresearch.com
2. Dr Robert Frykberg, DPM, MPH
Chief Research Officer
Open Wound Research
(855) 673-6963
rqfdpm@openwoundresearch.com
6012 Bayfield Parkway, #245
Concord, NC 28027
3. Wendy W. Weston, PhD, CTBS
VP Research and Development
BioStem Technologies
(305) 978-8527
wweston@biostemtech.com

Introduction: Diabetic foot ulcers are a severe complication in diabetic patients that significantly impact healthcare systems and patient quality of life, often leading to hospitalization and amputation. Traditional Standard of Care (SOC) treatments are inadequate for many patients, necessitating advanced wound care products like human placental membranes. These products are intended as covering for acute and chronic wounds. We conducted a retrospective analysis to compare the effectiveness of two human placental membrane products, retention-processed (RE-AC) and lamination-processed (L-AC) in managing diabetic foot ulcers.

Materials/Methods: The study collected retrospective observational data from electronic health records of patients treated at three outpatient wound care centers. Patients were categorized into two cohorts based on the treatment received. Key metrics included wound size progression and the number of product applications. The analysis employed Bayesian regression and Hurdle Gamma Analysis of Variance (ANCOVA) models.

Results:

Even with a higher starting wound area, results indicated that RE-AC achieved a higher expected Percent Area Reduction (xPAR) compared to L-AC at 12 weeks. Although L-AC was slightly more effective in complete wound closure, RE-AC required 27% fewer applications and 14% fewer treatment days, suggesting greater efficiency in general wound closure.

Discussion/Conclusions: RE-AC, as a wound covering, offers overall better treatment efficiency, especially in reducing the frequency of applications. This efficiency can lead to improved patient comfort, reduced treatment costs, and optimized resource utilization in healthcare settings.

Assessing Treatment Efficiency in Diabetic Foot Ulcers: Processing for Retention* Versus Lamination: A Retrospective Analysis

Zwelithini Tunyiswa, BA¹, Robert Frykberg, DPM¹, Wendy W Weston, PhD²

¹ Open Wound Research, Puyallup, WA, ² BioStem Technologies, Pompano Beach, FL

Abstract

Diabetic foot ulcers are a severe complication in diabetic patients that significantly impact healthcare systems and patient quality of life, often leading to hospitalization and amputation. Traditional Standard of Care (SOC) treatments are inadequate for many patients, necessitating advanced wound care products like human placental membranes. These products are intended as covering for acute and chronic wounds. We conducted a retrospective analysis to compare the effectiveness of two human placental membrane products, retention-processed (RE-AC) and lamination-processed (L-AC) in managing diabetic foot ulcers.

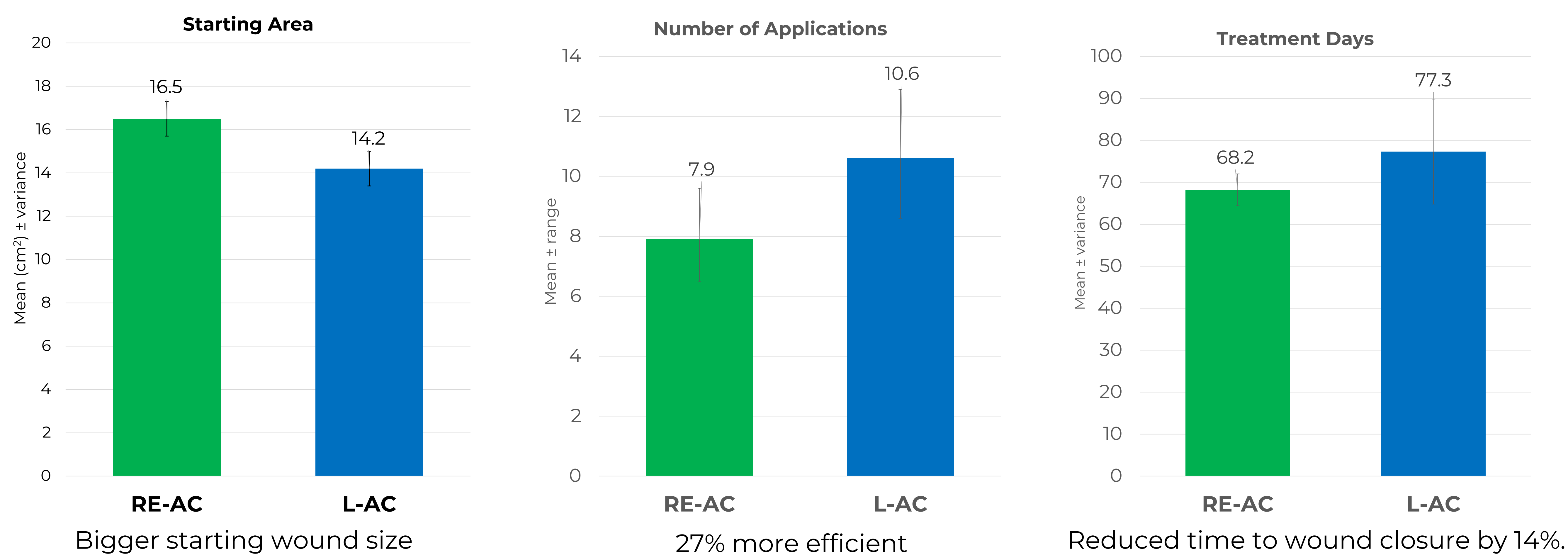
Methods

The study collected retrospective observational data from electronic health records of patients treated at three outpatient wound care centers. Patients were categorized into two cohorts based on the treatment received. Amnion/chorion (AC) was isolated from the placenta and processed with a proprietary BioREtain® procedure (RE-AC)*. The comparator AC was processed by separation of the amnion from the chorion, cleaning of the layers individually and re-lamination of layers before dehydration. The analysis employed Bayesian regression and Hurdle Gamma Analysis of Variance (ANCOVA) models.

Results

Even with a higher starting wound area, results indicated that RE-AC achieved a higher expected Percent Area Reduction (xPAR) compared to L-AC at 12 weeks. Although L-AC was slightly more effective in complete wound closure, RE-AC required 27% fewer applications and 14% fewer treatment days, suggesting greater efficiency in general wound closure. RE-AC, as a wound covering, offers overall better treatment efficiency, especially in reducing the frequency of applications. This efficiency can lead to improved patient comfort, reduced treatment costs, and optimized resource utilization in healthcare settings.

RE-AC versus L-AC



Demographic Overview

	RE-AC	L-AC
Subjects	23	18
Age	71.0 (11.7%)	58.6 (8.1%)
Sex	Female 5 (22%)	3 (17%)
	Male 18 (78%)	15 (83%)
Race	Asian 2 (9%)	0 (0%)
	Black 1 (4%)	1 (6%)
	Hispanic 8 (35%)	7 (39%)
	Native Hawaiian or Other Pacific Islander 1 (4%)	0 (0%)
	White 3 (13%)	2 (11%)
	Unknown 8 (35%)	8 (44%)

Wound and Treatment Summary

		RE-AC	L-AC
Starting Area (in cm ²) (Gamma Likelihood)	Mean	16.5	14.2
	Variance	(10.9 - 26.1)	(8.4 - 24.9)
		0.8 (0.5 - 1.3)	0.8 (0.4 - 1.3)
Product Applications (Negative Binomial Likelihood)	Mean	7.9	10.6
	Variance	(6.5 - 9.6)	(8.6 - 12.9)
		8.3 (3.3 - 23.0)	10.9 (3.8 - 35)
Treatment Days (Negative Binomial Likelihood)	Mean	68.2	77.3
	Variance	(55.7 - 84.9)	(66.8 - 89.1)
		3.8 (2.0 - 6.7)	12.5 (4.9 - 28.5)

Bayesian analysis was performed - estimates and 95% credible intervals (not confidence intervals) are reported

Conclusions

RE-AC demonstrated a marginally higher expected Percent Area Reduction (xPAR) over 12 weeks, underscoring its effectiveness as a wound covering. Moreover, RE-AC required fewer applications than L-AC to achieve the same efficacy. RE-AC's reduced application frequency not only enhances patient comfort by lessening the need for repeated treatments but also signifies a more cost-effective and resource-efficient approach in clinical settings which positions it as a more advantageous option in many clinical cases. This study underscores the importance of evaluating both clinical outcomes and practical aspects of treatment in selecting the most suitable intervention for diabetic foot ulcers.

Our membranes are intended for homologous use as a barrier membrane or protection over acute and/or chronic wounds.

* Patent pending

Frykberg RG, Tunyiswa Z. Assessing placental membrane treatment efficiency in diabetic foot ulcers: Processing for retention versus lamination. Health Sci Rep. 2024 Jun 17;7(6):e2196. doi: 10.1002/hsr.2.2196. PMID: 38895546; PMCID: PMC1183911.

