A New Era in Diabetic Foot Management

The Science, Evidence, and Clinical Application of OFM-Hyaluronic Acid Technology

Supported by an educational grant from Aroa Biosurgery

Faculty

David G. Armstrong, DPM, MD, PhD
Distinguished Professor of Surgery and Neurological Surgery
University of Southern California School of Medicine
Los Angeles, CA

Michael N. Desvigne, MD, FACS, CWS, FACCWS, MAPWCA (Moderator)
Plastic Surgeon, Abrazo Arrowhead Hospital and Wound Center
Glendale, AZ

Ira M. Herman, PhD
Professor, Tufts University School of Medicine
Boston, MA

George J. Koullias, MD, PhD, FSVS, RPVI
Chief, Division of Vascular & Endovascular Surgery, Hospital of St Catherines

.System Chief, for Limb Preservation, Catholic Health System, NY

Faculty Disclosures

- **David G. Armstrong, DPM, MD,PhD**
  Nothing to disclose in relation to this activity
- **Michael N. Desvigne, MD, FACS, CWS, FACCWS, MAPWCA (Moderator)**
  Advisory Board: Solventum, Medical Surgical Business; Advisory Board, Consultant, Speakers Bureau: Acera Surgical; Aroa Biosurgery; Integra LifeSciences; MolecuLight, Inc.; MTF Biologics; Sanara MedTech; Smith+Nephew; Tides Medical; Urgo Medical NA
- **Ira M. Herman, PhD**
  Nothing to disclose in relation to this activity
- **George J. Koullias, MD, PhD, FSVS, RPVI**
  Nothing to disclose in relation to this activity

Disclosures

- The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational use(s) of drugs, products, and/or devices (any use not approved by the US Food and Drug Administration)
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Learning Objectives

- Review current evidence-based management strategies for complex diabetic foot ulcers (DFUs), and discuss evolving challenges and opportunities to improve patient outcomes
- Explain complementary mechanisms of action of ovine forestomach matrix (OFM) and hyaluronic acid (HA), including their roles in modulating inflammation, supporting tissue regeneration, and promoting healing in DFUs
- Evaluate current clinical evidence supporting OFM-HA technology for lower extremity (LE) reconstruction and DFU management, including findings from randomized controlled trials (RCTs)
- Apply evidence-based strategies for incorporating OFM-HA technology into individualized treatment plans for patients with DFUs through case-based discussion
- Integrate clinical, operational, and reimbursement considerations into the adoption of OFM-HA technology

DFU = diabetic foot ulcer; OFM = ovine forestomach matrix; HA = hyaluronic acid; LE = lower extremity; RCT = randomized controlled trial.

A Composite Tissue-Derived Extracellular Matrix Aiding Wound Repair and Regeneration

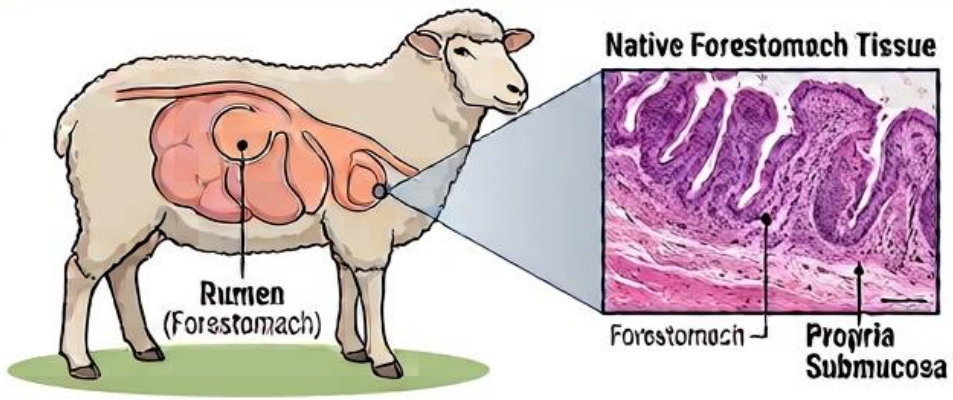
Ira Herman, PhD
Professor, Tufts University School of Medicine
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A Few Key Points to Consider…

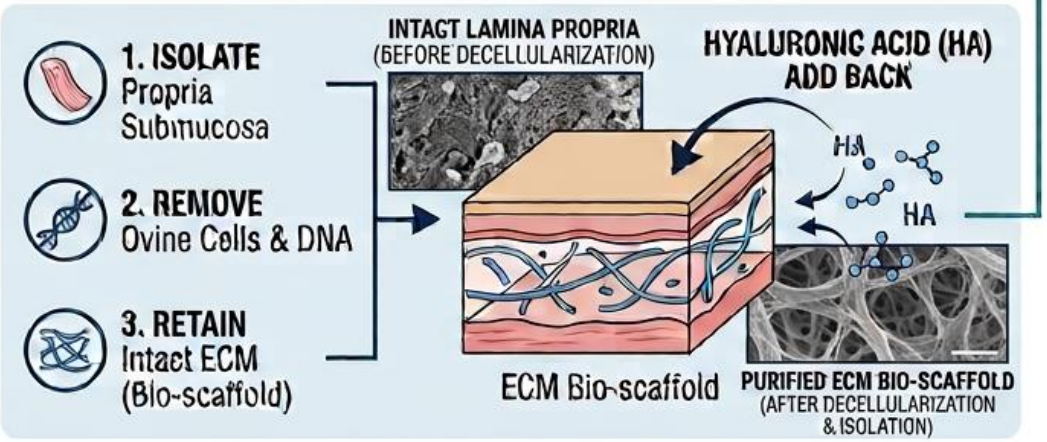
- What is OFM and how does it help healing?
- What is/are the role/s of HA in normal tissue?
- What is/are the role/s of HA in the chronic wound environment?
- A look at the composite features and functionality of a OFM-HA bioscaffold

OFM-HA BIO-MATRIX: SOURCE, DECELLULARIZATION, COMPOSITION, AND CLINICAL OUTCOMES

STEP 1: OVINE FORESTOMACH



STEP 2: PROCESSING (DECELLULARIZATION & ISOLATION)



OFM-HA CLINICAL OUTCOMES & EVIDENCE TABLE

CLINICAL ENTITY/ENTITY	BIOLOGICAL ACTIVITY PRESENT	CLINICAL OUTCOME & MECHANISM ILLUSTRATION	PEER-REVIEWED REFERENCE
STRUCTURAL COLLAGEN TEMPLATE	Collagen	Provides 3D structural template; guides cellular alignment	Negron L, Lun S, May BC. International Wound Journal. 2012; 11(4): 392-397.
VEGF, FGF2 (GROWTH FACTORS)	GF GF	Promotes fast revascularization & angiogenesis	Bohn GA, Chaffin AE, et al. Journal of Wound Care. 2019; 28(Sup2): S4-S16.
MMP SACRIFICIAL SUBSTRATE	OFM	Binds excessive proteases, downregulates depreasates inflammation	Barnett MT, Chaffin AE, et al. Wounds. 2019; 31(11): 267-273.
HYALURONIC ACID (HA) ADD BACK	HA HA (High/low MW)	Enhances hydration & moisture retention; facilitatss early granulation tissue formation	Neuman MG, Nanau RM, Oruna-Sanchez L, Coto G. Journal of Pharmacy & Pharmaceutical Sciences. 2015; 18(1): 53-60.
BIO-MATRIX INTEGRATION		Promotes native tissue infill, reduced scarring	Negron L, May BC. Journal of Wound Care. 2017; 26(Sup1): S4-S13.

Lun S, et al. *Biomaterials*. 2010;31(16):4517-4529. Dempsey SG, et al. *J Proteome Res.* 2019;18(4):1657-1668.

OFM-HA Isolation and Characterization

- OFM is isolated from the propria submucosa layer of the sheep rumen (forestomach); this layer is rich in distinct extracellular matrix (ECM) and low in native cellular content compared to other tissues
- Tissue is manually dissected, and the propria submucosa is isolated; a proprietary processing method using mild chemicals removes cells and cellular debris (DNA, proteins)
- The isolated ECM is purified of residual components while retaining the complex collagenous architecture, structure-bound growth factors, and non-collagenous proteins

ECM = extracellular matrix.

Lun S, et al. *Biomaterials*. 2010;31(16):4517-4529.

OFM Components

Matrix Entities Present	Description & Key Activities
Collagen Types I, III, IV, VI and others	Provide mechanical stability while providing key scaffolding for cell attachment and proliferation
Fibronectin & Laminin	Matrix and basement membrane mediators for cell adhesion, migration, and signaling
Elastin	Provides tissue resilience and flexibility for healing
Growth Factors (VEGF, FGF2, PDGF)	Provide molecular cues for reparative responses (eg, proliferation, migration, angiogenesis)
Hyaluronic Acid	Retains moisture, modulates inflammation, promotes early granulation tissue formation

Lun S, et al. *Biomaterials*. 2010;31(16):4517-4529. Dempsey SG, et al. *J Proteome Res.* 2019;18(4):1657-1668.

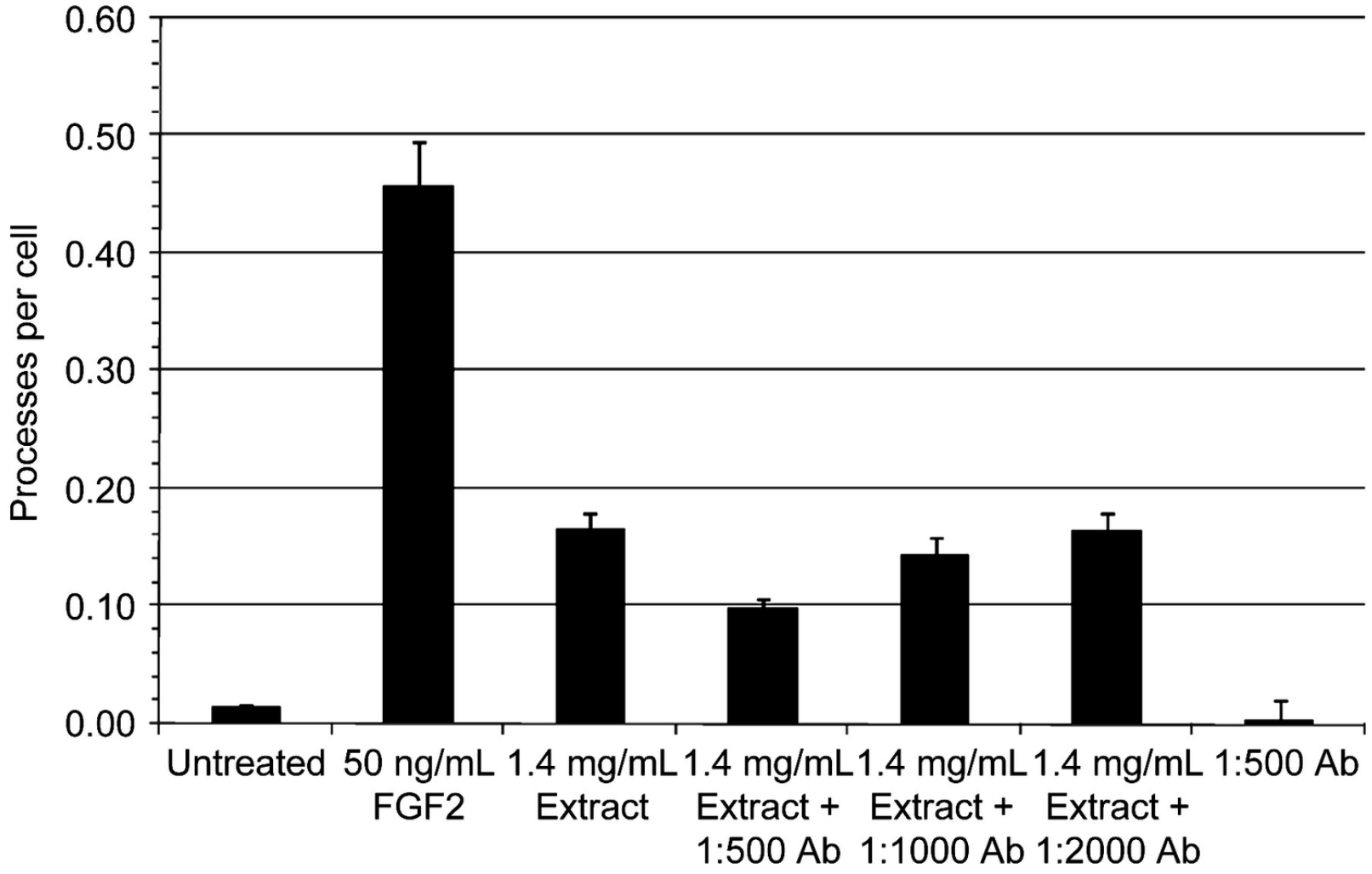
OFM Biochemical Characterization

Table 1A. Major biochemical components of the ovine forestomach and OFM.

	Ovine forestomach (mg/g±SE)	**OFM (mg/g±SE)**
Total collagen	142.7±9.7	821.0±9.0
Collagen I	81.2±6.6	738.8±63.3
Collagen III	61.3±0.7	196.8±6.9
Collagen IV	5.4±1.1	9.7±2.1
Elastin	30.9±6.4	27.5±4.5
Total GAGs	3.9±0.1	0.74±0.01
Heparan sulfate	N.D.	0.31±0.01
Hyaluronic acid	1.95±0.02	0.4±0.1
DNA	9.0±0.5	1.7±0.5
Lipid	50.2±2.9	59.0±5.2

Lun S, et al. *Biomaterials*. 2010;31(16):4517-4529.

OFM Contains Bioactive FGF2



Lun S, et al. *Biomaterials*. 2010;31(16):4517-4529.

OFM Extracts and MMP Activity

- OFM extract is ≈10-fold more potent than an oxidized regenerated cellulose and collagen (ORC/C) 'pseudo-substrate' or neutrophil elastase (NE) inhibitor

- The broad spectrum 'neutralizing' activity of OFM against a range of wound proteases suggests this material may be more effective at reducing the hyper-proteolytic environment of chronic wounds by targeting multiple enzymes in the proteolytic cascade that leads to ECM degradation and inflammation

Table 1 Inhibitory activity of OFM and ORC/C extracts against tissue proteases*

Protease	OFM IC_{50} (μg/ml)	ORC/C IC_{50} (μg/ml)
MMP1 (Collagenase 1) (0·153 U/μl)	115 ± 14	~600
MMP8 (Collagenase 2) (0·018 U/μl)	86 ± 2	~600
MMP13 (Collagenase 3) (0·014 U/μl)	38 ± 2	~600
MMP3 (Stromelysin-1) (0·029 U/μl)	96 ± 8	>600
MMP10 (Stromelysin-2) (0·01 U/μl)	45 ± 1	355 ± 51
MMP2 (Gelatinase-A) (0·009 U/μl)	23 ± 5	31 ± 6
MMP9 (Gelatinase-B) (0·009 U/μl)	50 ± 14	55 ± 7
MMP12 (Macrophage metalloelastase) (0·007 U/μl)	24 ± 1	~600
MMP14 (Membrane type 1 MMP) (0·024 U/μl)	45 ± 3	~600
Neutrophil elastase (0·002 mU/μl)†	157 ± 37	~1740

MMP, matrix metalloproteinase; OFM, ovine forestomach matrix; ORC/C, oxidised regenerated cellulose/collagen.

*Errors represent standard errors from triplicate experiments. Concentration in brackets indicates the enzyme concentration used in the respective assay.

†Errors represent standard errors from duplicate experiments.

MMP = matrix metalloproteinase; ORC/C = oxidized regenerated cellulose and collagen; NE = neutrophil elastase.

Negron L, et al. *Int Wound J*. 2014;11(4):392-397.

Composite OFM-HA Bioscaffold

- Layers of OFM
- Single layer of high molecular weight hyaluronic acid (HMWHA)

- **No chemical crosslinking required to create the composite**

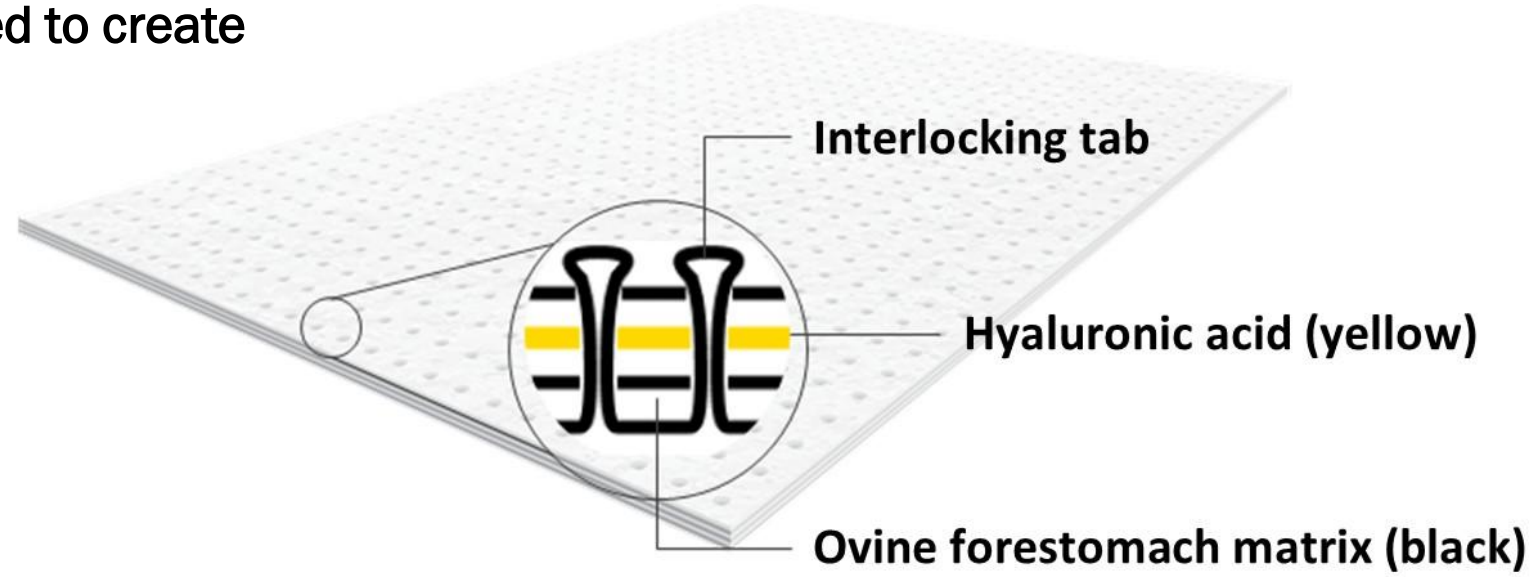
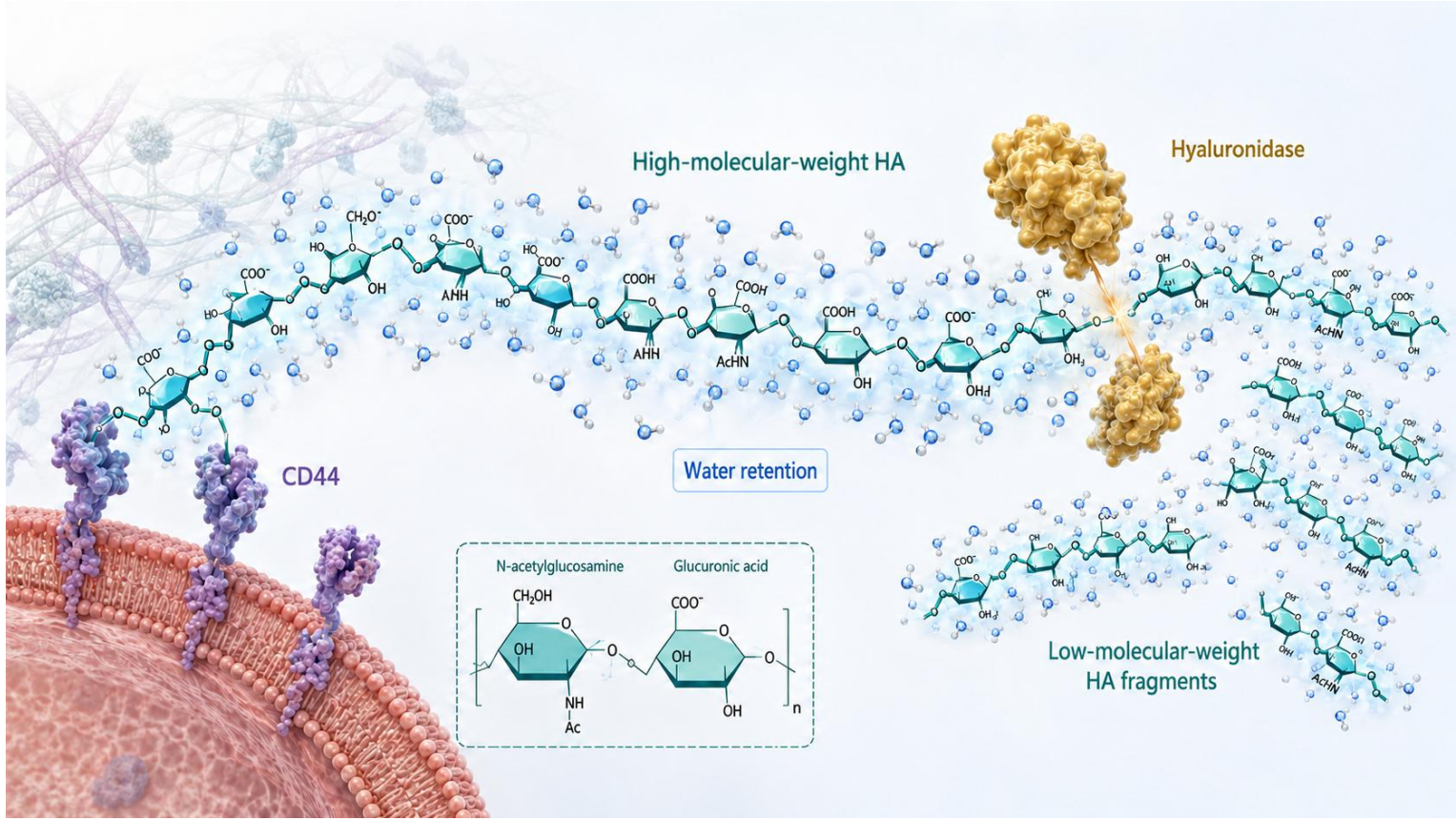


Figure adapted from Smith MJ, et al. *J Biomater Appl.* 2022 Jan;36(6):996-1010.

Hyaluronic Acid: A Primer

- Naturally occurring complex carbohydrate occurring in all tissues
- Safe and biocompatible – widely used in medical devices and cosmetics
- Retains moisture securing nearly 100x its weight in water
- Binds cell surface receptor (CD44)
- Exists in tissues at different molecular weights (MW)
  - High: HMWHA
  - Medium: MMWHA
  - Low: LMWHA



MW = molecular weight; HMWHA = high molecular weight hyaluronic acid; MMWHA = medium molecular weight hyaluronic acid; LMWHA= low molecular weight hyaluronic acid.

OFM-HA: Improved Hydration

- Moisture critical to all cellular processes → *moist wound healing*
- HMWHA known to bind/sequester water
- Inclusion of HA into OFM-HA devices increases water retention

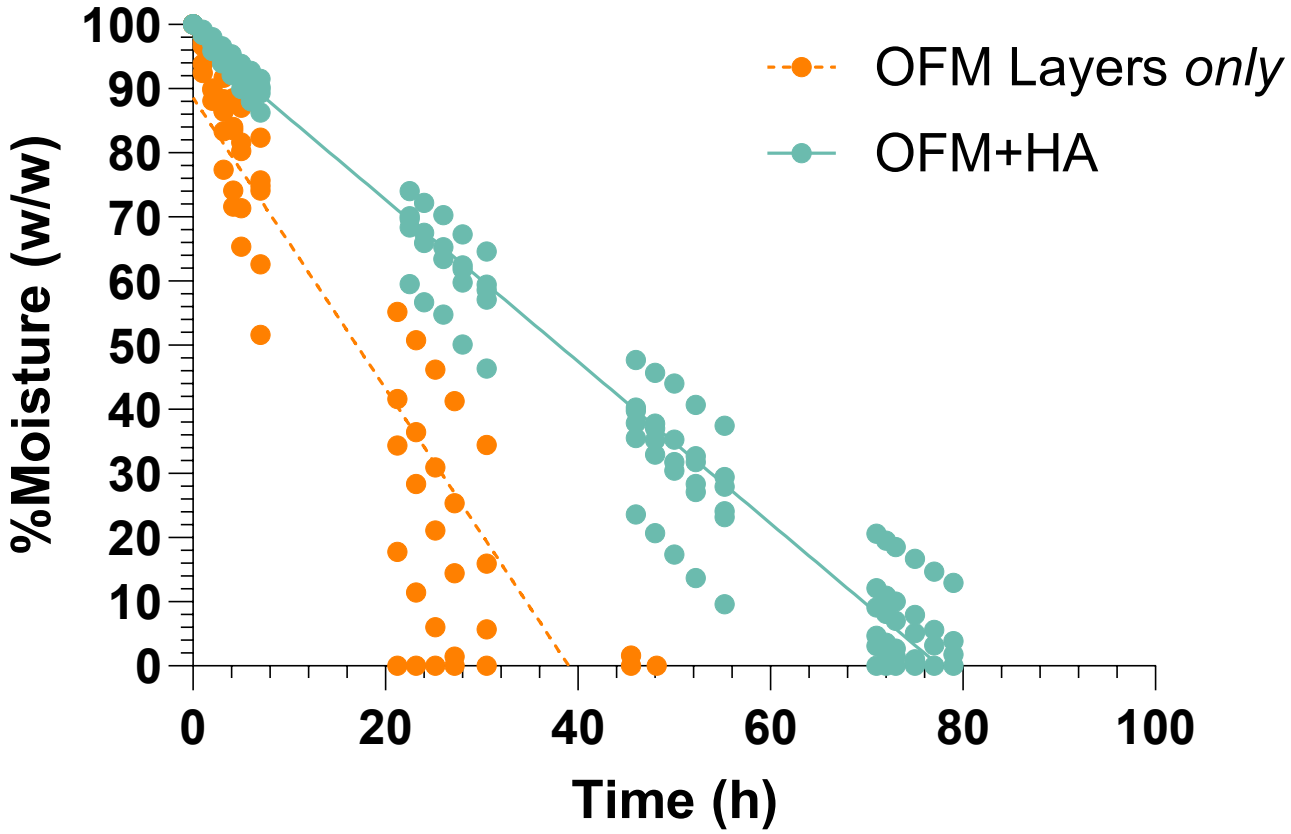
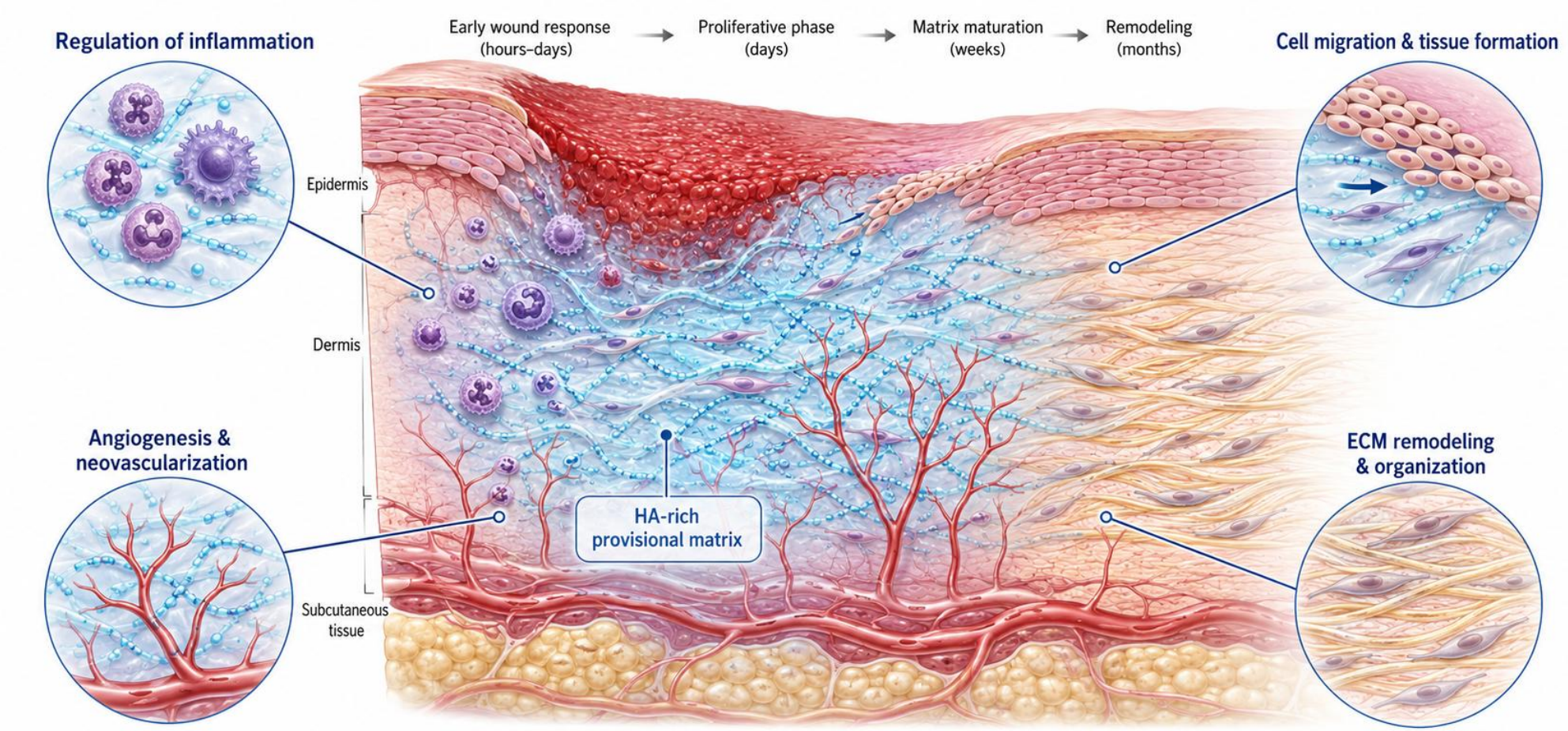


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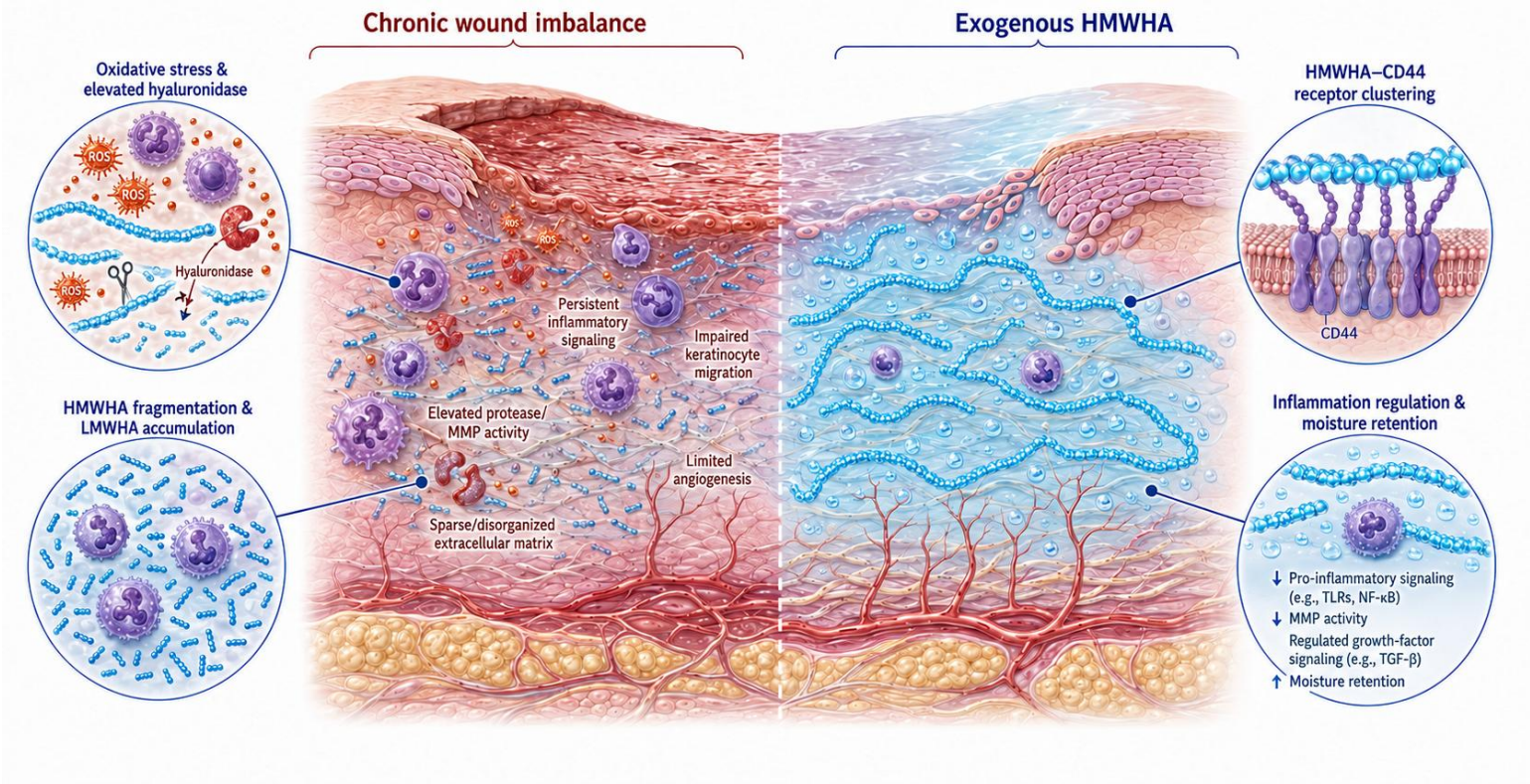
Hyaluronic Acid: In Normal Wound Healing



Aya KL, Stern R. *Wound Repair Regen*. 2014;22(5):579-93. Litwiniuk M, et al. *Wounds*. 2016;28(3):78-88. Voigt J, Driver VR. *Wound Repair Regen*. 2012;20(3):317-331. Kawano Y, et al. *Pharmaceuticals*. 2021;14(4):301.

Hyaluronic Acid: In the Chronic Wound Environment

- Chronic wounds, such as DFUs, are characterized by persistent inflammation, impaired cellular migration, and dysfunctional tissue repair[1]
- Restoration of an HA-rich wound environment may help support progression from a chronic inflammatory state toward active healing[1,2]



1. Litwiniuk M, et al. *Wounds*. 2016;28(3):78-88. **2.** Aya KL, Stern R. *Wound Repair Regen*. 2014;22(5):579-593.

OFM-HA: Improved Migration

Does the addition of HMWHA improve the cell migration response of OFM?

- The addition of HMWHA to OFM increases keratinocyte migration

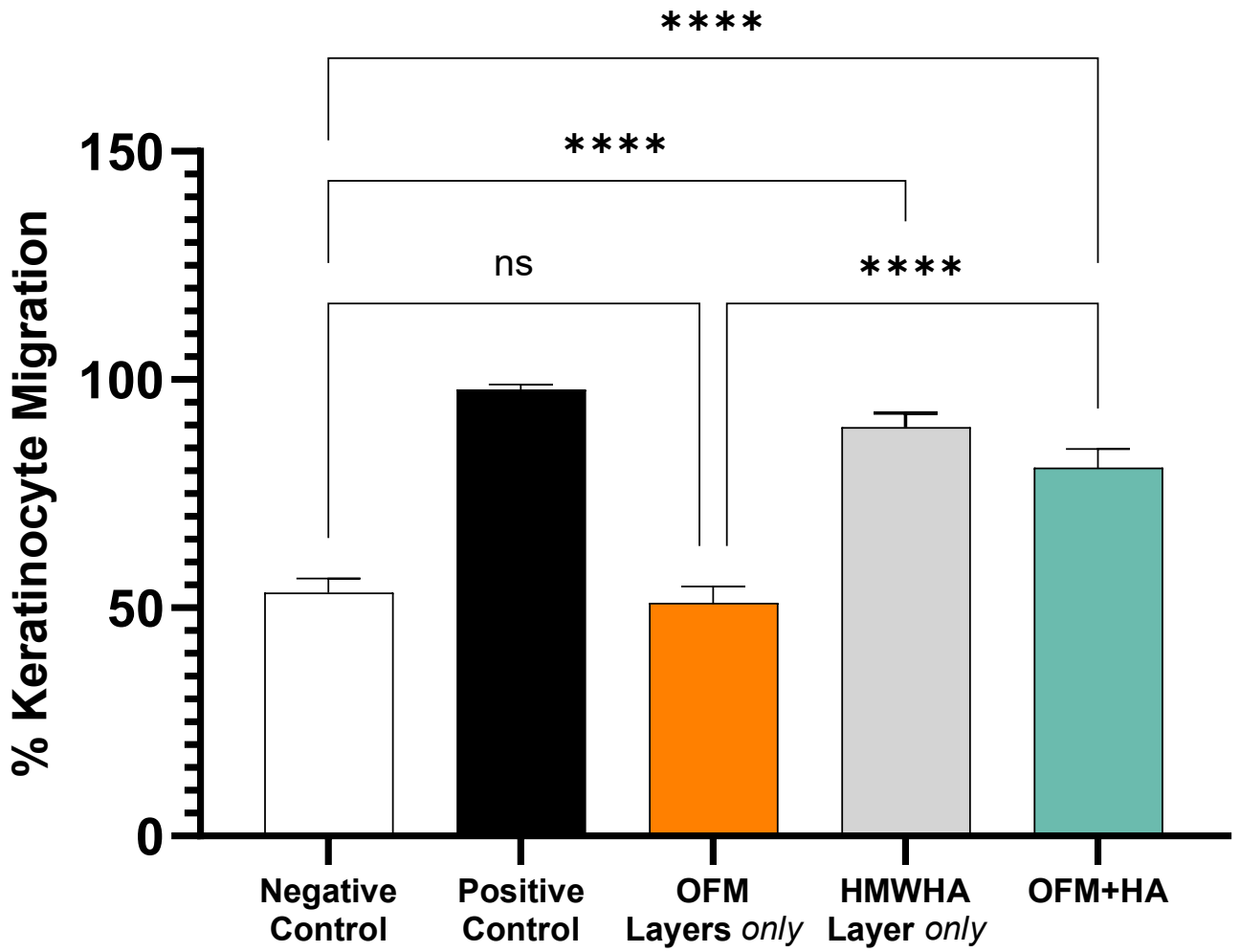


Figure adapted from Smith MJ, et al. *J Biomater Appl*. 2022;36(6):996-1010.

OFM-HA: Improved Proliferation

Does the addition of HMWHA improve the cell proliferation response of OFM?

- OFM will stimulate keratinocyte proliferation
- The addition of HMWHA to OFM further increases the biological response

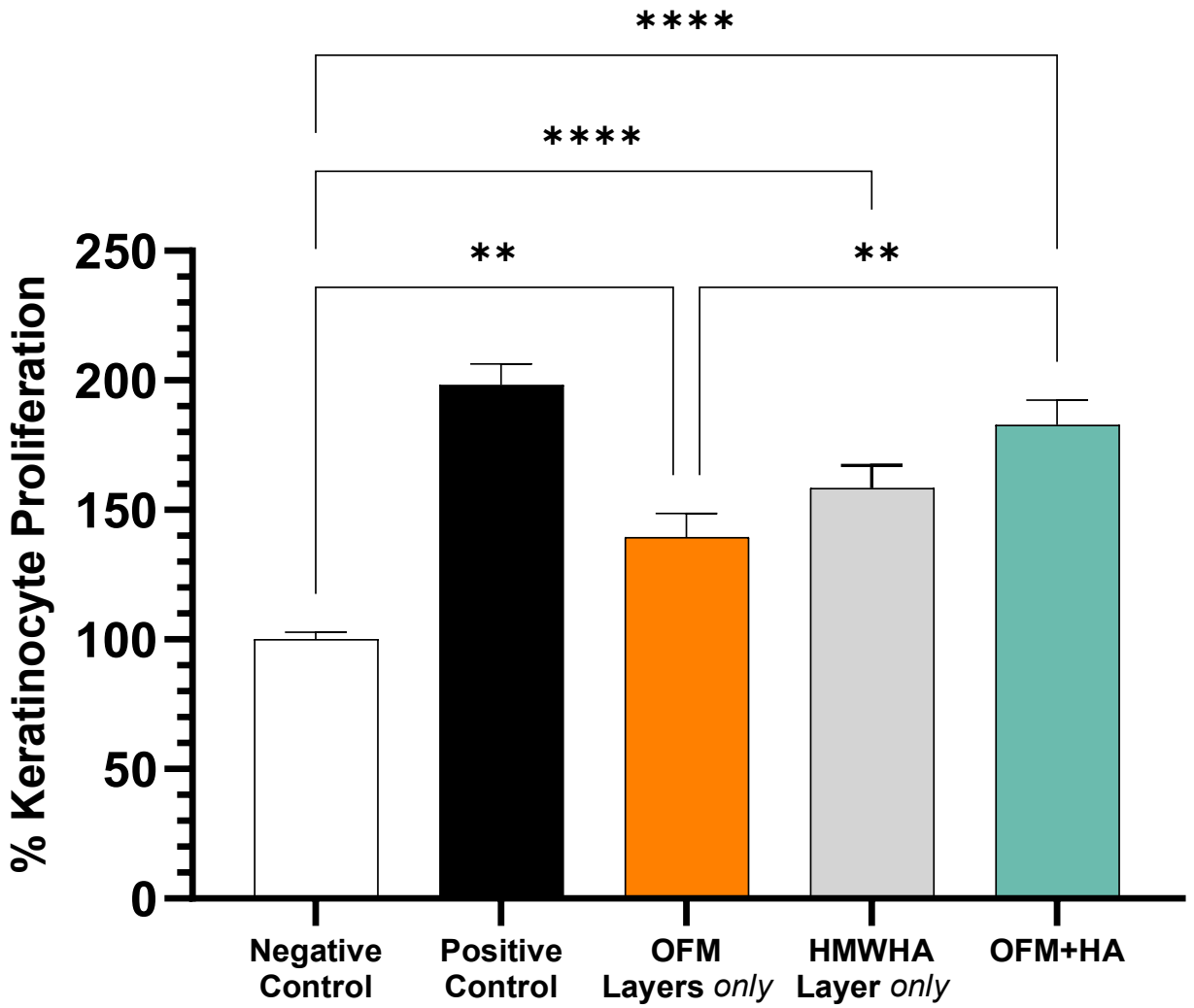
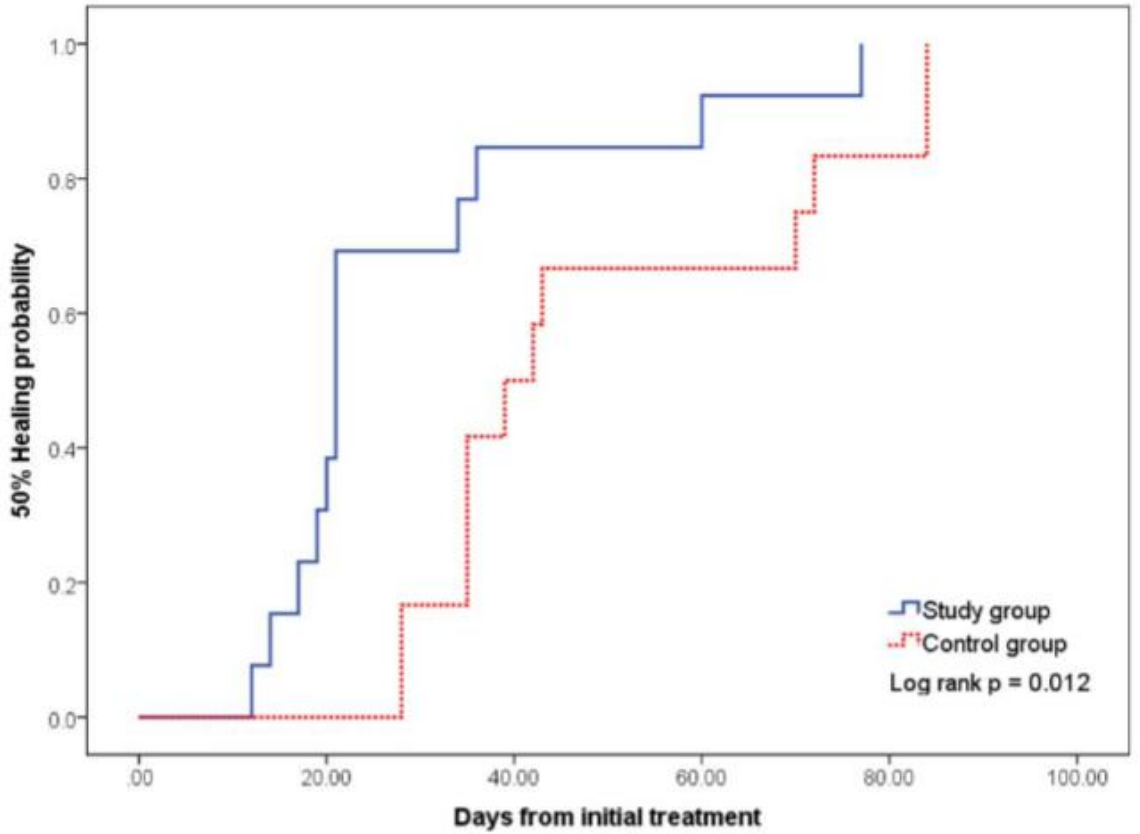


Figure adapted from Smith MJ, et al. *J Biomater Appl*. 2022;36(6):996-1010.

Exogenous HA Improves DFU Healing

- Use HA treatment to correct the micro-environment of DFU and aid healing
- Published clinical studies have shown that topically applied HA-based bioscaffolds improve healing outcomes in DFUs

Can HMWHA be added to OFM to create a new bioscaffold with properties of both OFM and HA?



Taken from: Lee M, et al. *Wound Repair Regen*. 2016;24(3):581-8.

Chen CP, et al. *Dermatol Ther*. 2014;27(6):331-6. Yao L, et al. *Front Endocrinol* (Lausanne). 2025;26(16):1627558.

OFM Bioscaffold Technology and Lower Extremity Outcomes

George J. Koullias, MD, PhD, FSVS, RPVI
Associate Professor of Surgery, Division of Vascular & Endovascular Surgery
Stony Brook University Hospital & Stony Brook Southampton Hospital
Stony Brook, NY

- Clinical applications of OFM
- Clinical outcomes with OFM-based devices in DFU and lower extremity reconstruction

OFM Bioscaffold: A Primer

- Intact ECM[1]
- Isolated from New Zealand sheep forestomach tissue[1]
- Functions as a bioscaffold for wound healing and soft tissue repair[1]

Structure

- Porous matrix structure to enable cell infiltration, migration[1]
- Relatively persistent, even in the chronic wound environment[2,3]

Biology

- Retains naturally occurring ECM components to aid healing[1,4]
- Proteins including 24 types of collagen, growth factors, and components of basement membrane[4]

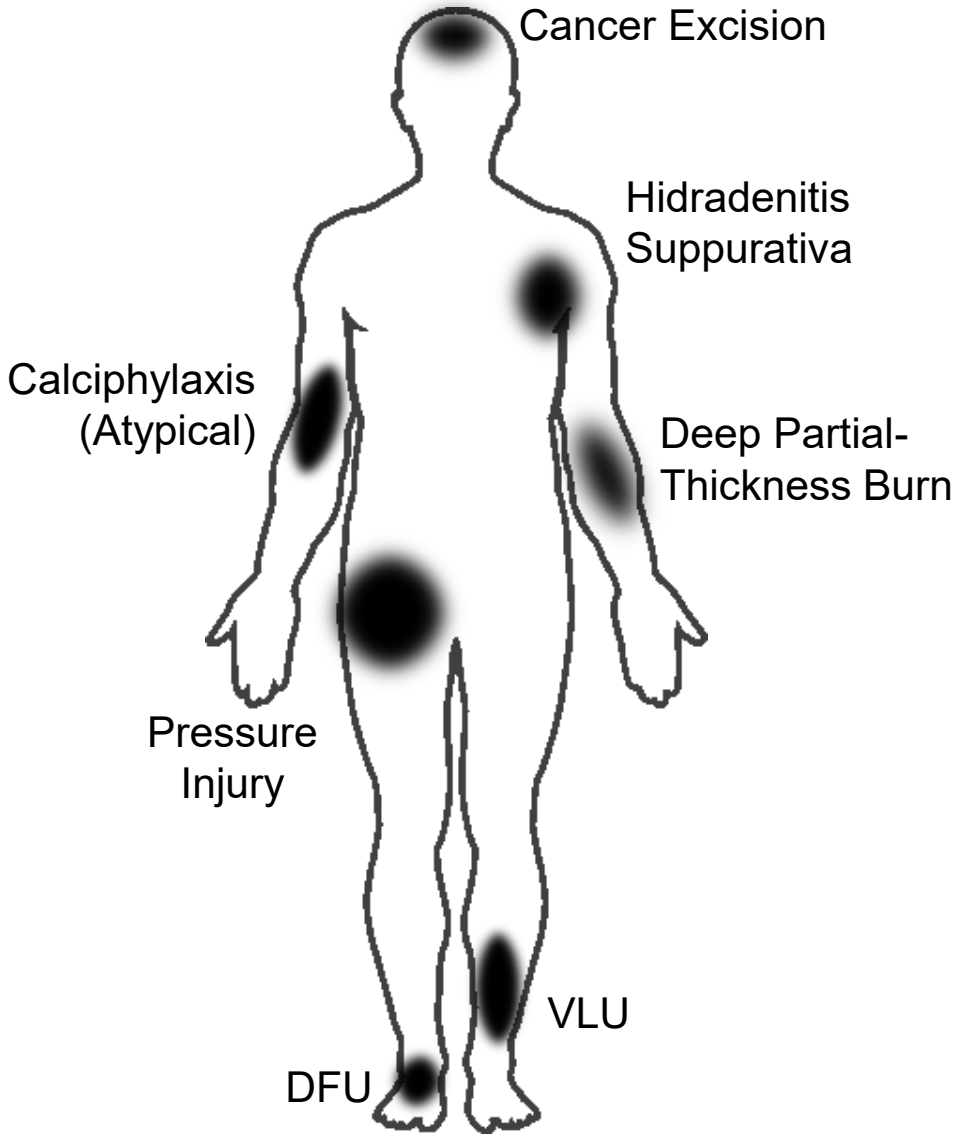
Compatibility

- Elicits pro-healing response[2,3,5]
- Supports rapid vascular ingrowth[5]
- Inhibitory to matrix metalloproteinases[6]
- Non-crosslinked[1]

1. Lun S, et al. *Biomaterials*. 2010;31(16):4517-29. **2**. Bosque BA, et al. *J Am Podiatr Med Assoc*. 2023;113(3)22. **3.** Lawlor JC, et al. *PRS Global Open*. 2024;12(12):e6406. **4.** Dempsey SG, et al. *J Proteome Res*. 2019;18(4):1657-1668. **5.** Irvine SM, et al. *Biomaterials*. 2011;32(27):6351-6361. **6.** Negron L, et al. *Int Wound J*. 2014;11(4):392-397.

Clinical Applications of OFM-Based Devices

- First commercial introduction 2012
- Over 7.5 million product applications globally
- Over 130 peer-reviewed publications
- Strong safety profile[1] – only 0.7% deep infection rate in a 400+patient prospective study



1. Short T, et al. *Adv Ther.* 2026. DOI:10.1007/s12325-026-03768-0.

OFM: DFU and Lower Extremity Reconstruction

- **Validated bioscaffold technology for healing chronic lower extremity wounds and complex limb salvage**

Reference	Study type	Sample Size	Wound Types	Key reported outcome
Ferreras, et al (2017)[1]	Out-patient retrospective comparative	N=257	Lower extremity chronic wounds	73% 12-week closure
Lullove, E. J. (2017)[2]	Out-patient retrospective case series	N=53	Lower extremity chronic wounds	59% 12-week closure
Bosque et al (2021)[3]	Out-patient RWE	N=1150	DFUs	Median closure time 14.6±0.5 w
Bosque et al. (2021)[4]	In-patient retrospective case series	N=50	Limb salvage	Mean time to tissue coverage/fill, 3.7±3.2 w
Lawlor et al. (2023)[5]	In-patient prospective	N=130	Limb salvage	Mean time to tissue coverage/fill, 5.5±0.4 w
Aburn et al. (2025)[6]	Out-patient RWE	N=551	VLUs	Median closure time 11.1 ± 0.6 w

1. Ferreras DT, et al. *Surg Technol Int.* 2017;30:61-69. 2. Lullove EJ. *Wounds*. 2017;29(4):107-114. 3. Bosque BA, et al. *Int Wound J.* 2022;19(4):741-753. Bosque BA, et al. *J Am Podiatr Med Assoc*. 2023;113(3)22. 5. Lawlor JC, et al. *PRS Global Open*. 2024;12(12):e6406. 6. Aburn R, et al. *Int Wound J*. 2025;22(4):e70368.

OFM-HA Case Example 1: NSTI/Gangrene of Foot

- **Full-thickness defect with exposed tendon and bone of the right lateral foot**

Initial presentation	Before revasc	Angiogram	4 applications of OFM-HA
			 

NSTI = necrotizing soft tissue infection.

OFM-HA Case Example 2: NSTI/Gangrene of Foot

- **Full-thickness defect with exposed tendon and bone of the right lateral foot**

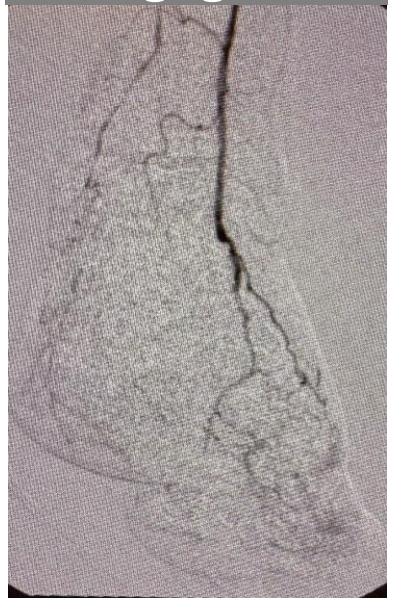
Initial presentation



Before revasc



Initial pedal angiogram



s/p ATA and PTA intervention



After revasc



4 applications of OFM-HA



Initial pedal angiogram



Completed pedal angiogram,
s/p ATA and PTA intervention



A Composite OFM-HA CAMP for the Treatment of Wagner Grade 1 and 2 DFU: A Randomized Controlled Trial

David G. Armstrong, DPM, MD, PhD
Distinguished Professor of Surgery and Neurological Surgery,
University of Southern California School of Medicine
Los Angeles, CA

- RCT design
- Study outcomes
- Initial health economics analysis

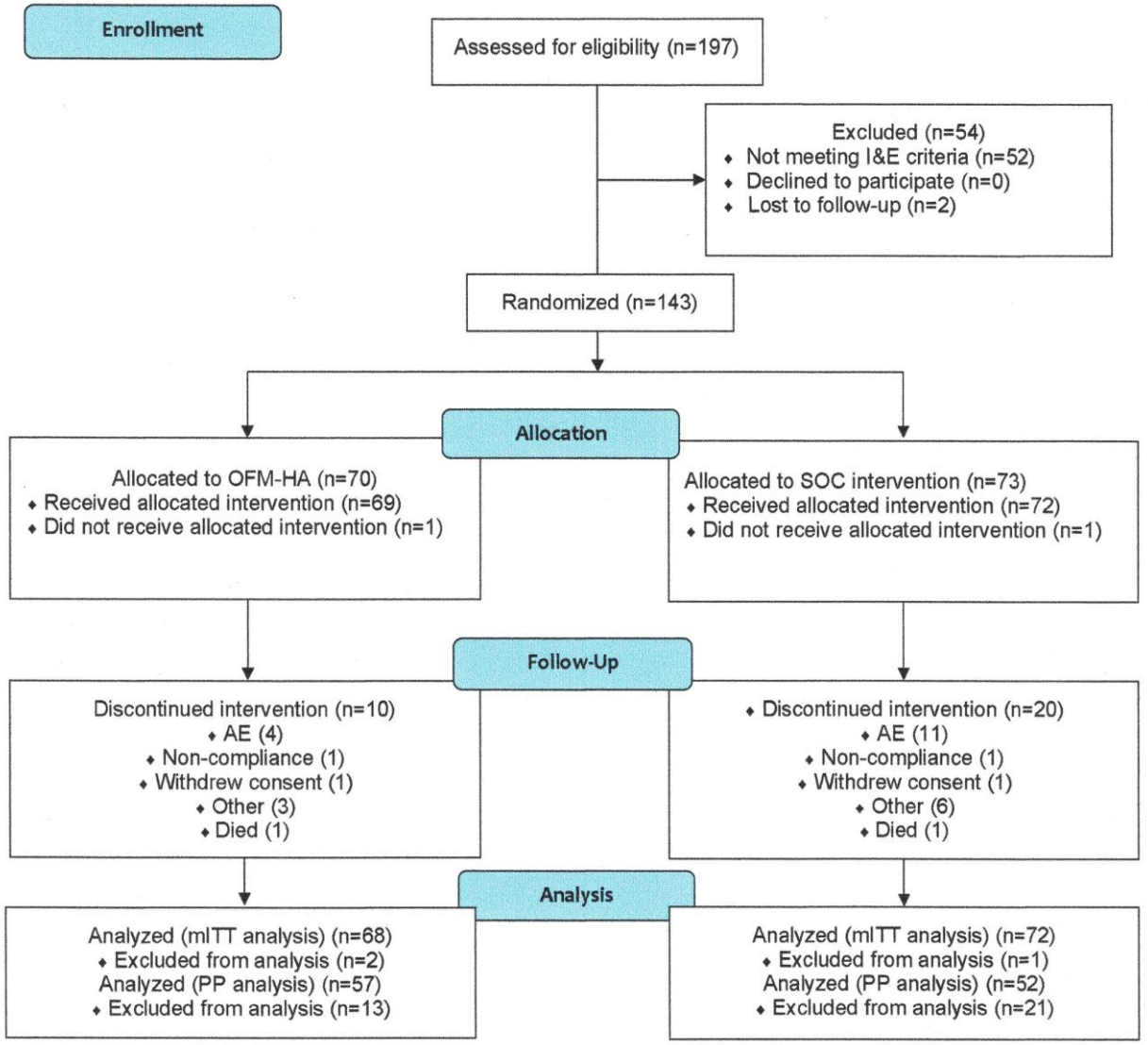
Study Snapshot

Design	Population	Control	Intervention	Endpoints
Prospective, multicenter, parallel-group RCT	Adults with chronic Wagner Grade 1 and 2 DFUs	Standard of care (SOC) alone	OFM-HA + SOC	Proportion of patients healed after 12 wks Time to heal, PAR, AEs, QoL

SOC = standard of care; PAR = percentage area reduction; AE = adverse event; QoL = quality of life.

Population and Treatment Protocol

- 197 subjects assessed for eligibility
- 143 randomized:
  - 70 to OFM-HA plus SOC
  - 73 to SOC alone
- Modified Intent-to-Treat (mITT) analysis:
  - 68 OFM-HA plus SOC
  - 72 SOC alone
- Per Protocol (PP) analysis
  - 57 OFM-HA plus SOC
  - 52 SOC alone



Subject Variables of Population

Reasonably well balanced between the cohorts, except

- Diabetes duration, higher in the OFM-HA cohort
- History of DFU recurrence, higher in the SOC cohort
- HbA1c, higher in the OFM-HA cohort at randomization and EOS

Variable	OFM-HA plus SOC	SOC	p
Age (years)	59.5 (9.87)	61.0 (10.25)	0.40
Race			
White	48 (71)	58 (81)	0.38
Black/African American	5 (7)	3 (4)	
Latino	15 (22)	11 (15)	
Ethnicity			
Hispanic/Latino	44 (65)	35 (49)	0.062
Sex			
Male	60 (88)	54 (75)	0.052
Female	8 (12)	18 (25)	
BMI	29.9 (6.04)	31.0 (7.21)	0.49
Tobacco use			
Current	6 (9)	9 (12)	
Former	21 (31)	25 (35)	0.62
Never used tobacco	41 (60)	38 (53)	
Diabetes duration (years)[1]	18.4 (10.45)	15.2 (10.21)	0.048
Subject age when first DFU appeared (years)	56.4 (9.55)	56.6 (10.58)	0.74
Prior DFU count	2.6 (3.22) Median: 2; IQR: 3	3.1 (2.98) Median: 2; IQR: 4	0.19
Other concurrent DFUs at screening:			
0	58 (85)	62 (86)	1.0
1	10 (15)	10 (14)	
History of DFU recurrence	35 (52)	50 (69)	0.038
Major amputation	5 (7)	3 (4)	0.49
Minor amputations:			
0	40 (59)	33 (46)	
1	17 (25)	17 (24)	0.078
2	6 (9)	14 (19)	
≥3	5 (7)	8 (11)	
Major foot deformities:[2]			
Charcot	3 (4)	4 (6)	1.0
Hammertoe	3 (4)	2 (3)	0.67
Equinus	1 (2)	0 (0)	0.49
Hallux valgus	2 (3)	0 (0)	0.23
Creatinine (mg/dL)[3]	1.2 (0.43)	1.2 (0.42)	0.77
HbA1c			
At randomization	8.4 (1.76)	7.5 (1.57)	0.004
At EOS[4]	7.7 (1.71)	7.3 (2.07)	0.033
Blood sugar (mg/dL) Mean (all visits)[5]	193 (80.01)	188 (70.64)	0.96

Primary Endpoint: 12-Week Wound Closure

- Complete wound closure at 12 wks

mITT

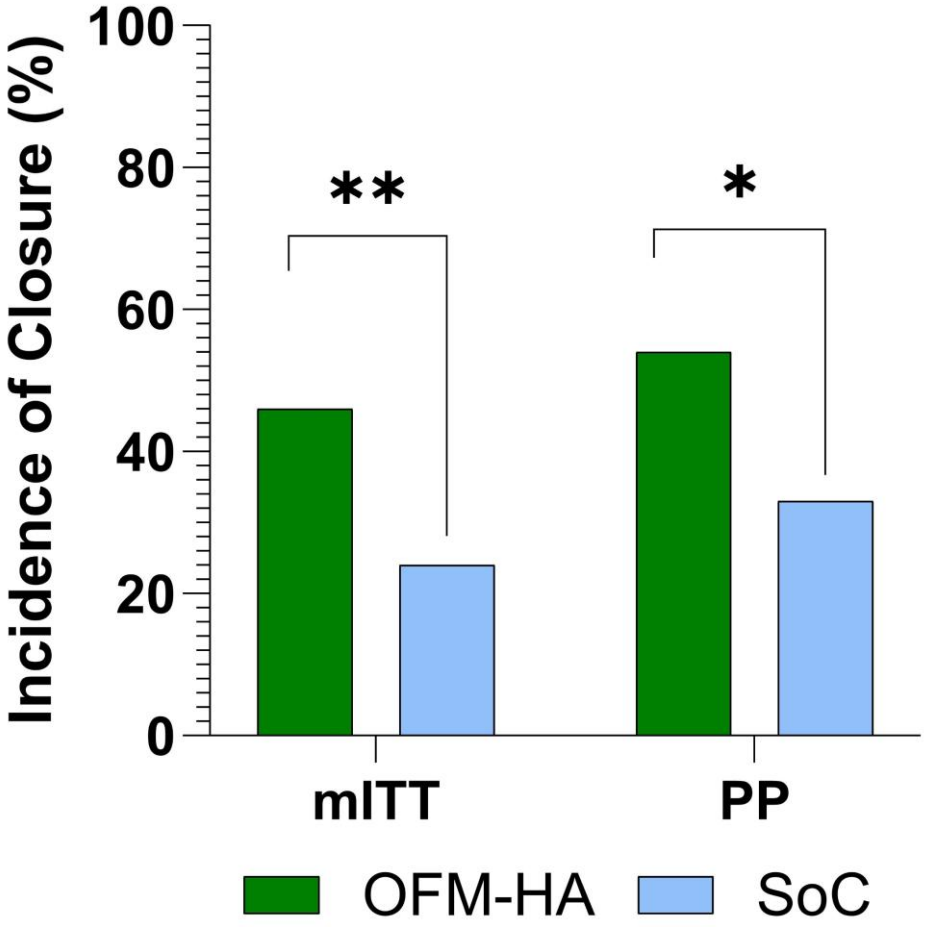
46%	24%
OFM-HA+SOC	SOC alone
31/68	17/72

mITT p=0.008

PP

54%	33%
OFM-HA+SOC	SOC alone
31/57	17/52

PP p=0.033



Secondary Endpoint: Time to Complete Closure

- Mean time to wound closure

mITT

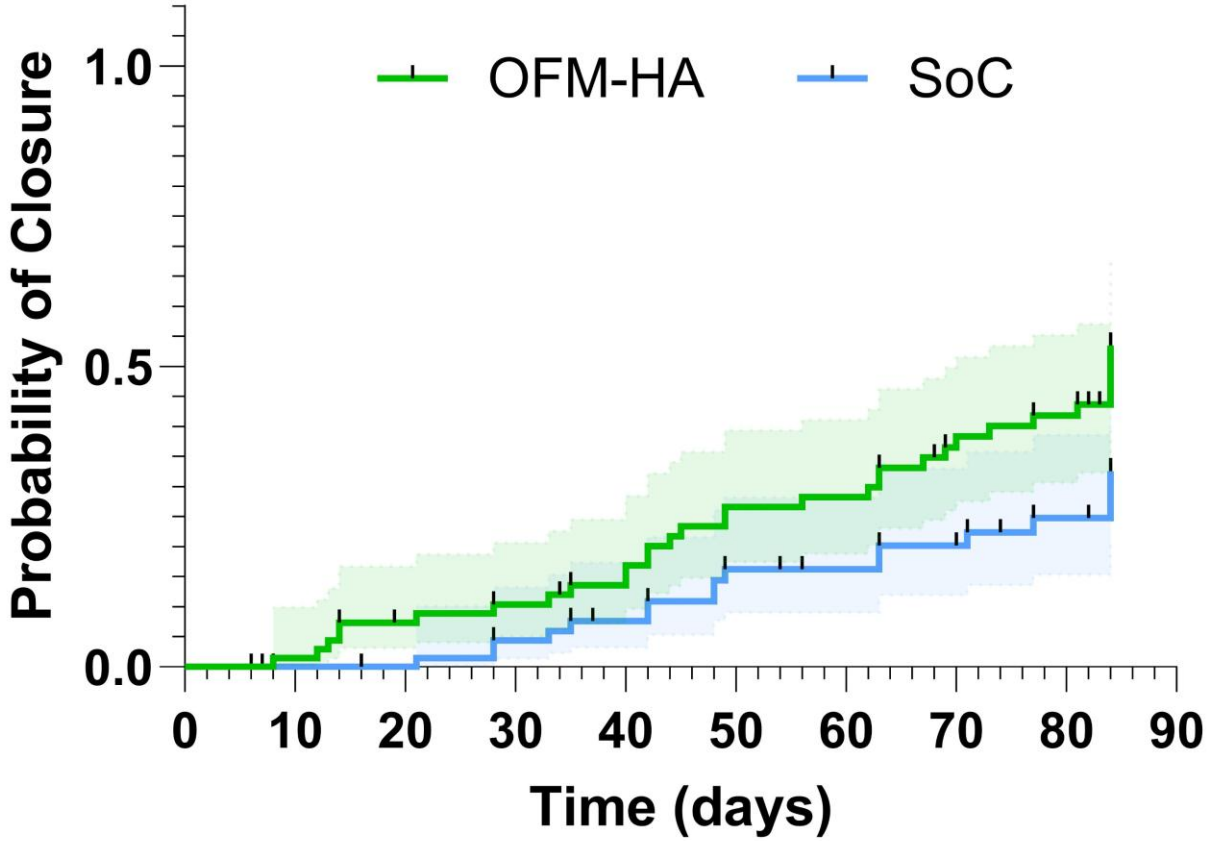
67.4 d	75.2 d
OFM-HA+SOC	SOC alone

mITT p=0.023

PP

65.4 d	73.2 d
OFM-HA+SOC	SOC alone

PP p=0.041



Shown Kaplan-Meir survival curve for mITT population

Secondary Endpoint: Safety Outcomes

- 119 AEs occurred across the study
  - 56 in OFM-HA+SOC
  - 63 in SOC
- AE rates per subject were similar
  - 50% in OFM-HA+SOC
  - 51% in SOC
- No unexpected safety-related occurrences noted
- 39 SAEs reported with 2 deaths

AE Category	OFM-HA + SOC	SOC
Severity		
Mild	22 (39)	35 (56)
Moderate	28 (50)	23 (36)
Severe	4 (7)	4 (6)
Life-threatening	1 (2)	0 (0)
Death	1 (2)	1 (2)
Relatedness		
Not related	44 (79)	54 (86)
Unlikely (to be related)	5 (9)	4 (6)
Possibly related	7 (12)	5 (8)

Index Ulcer Infection Signals

- What happened at the treated ulcer?

OFM-HA mITT

13%	1
index ulcer-related infections	osteo/gangrene

SOC mITT

17%	7
index ulcer-related infections	osteo/gangrene

As an exploratory safety outcome result, observed differences of individual adverse events between the two cohorts should be interpreted as directional signals only

Health Economics of a New CAMP: An Interim Analysis

Does OFM-HA represent value to patients and providers?

- Simplified cost-utility analysis conducted using RCT outcomes (mITT) and modeled to 1-yr time horizon
- OFM-HA improved healing for only an additional $1,405 per patient
- Infection complication costs were double for SOC group vs OFM-HA
- QALY gains increased by 0.02
- Cost per QALY gained with OFM-HA = $71,494

Category	Cost (US $) for Entire Cohort	
	OFM-HA	SOC
OFM-HA	694,539	0
Debridement (wks 0-12)	1,897	292,575
E/M (wks 0-12)	28,384	34,823
Infection complications (wks 0-12)	138,453	278,380
E/M & debridement (wks 13-52)	186,697	405,989
TOTAL	**$ 1,049,970**	**$ 1,011,767**
Per patient	$ 15,441	$ 14,052

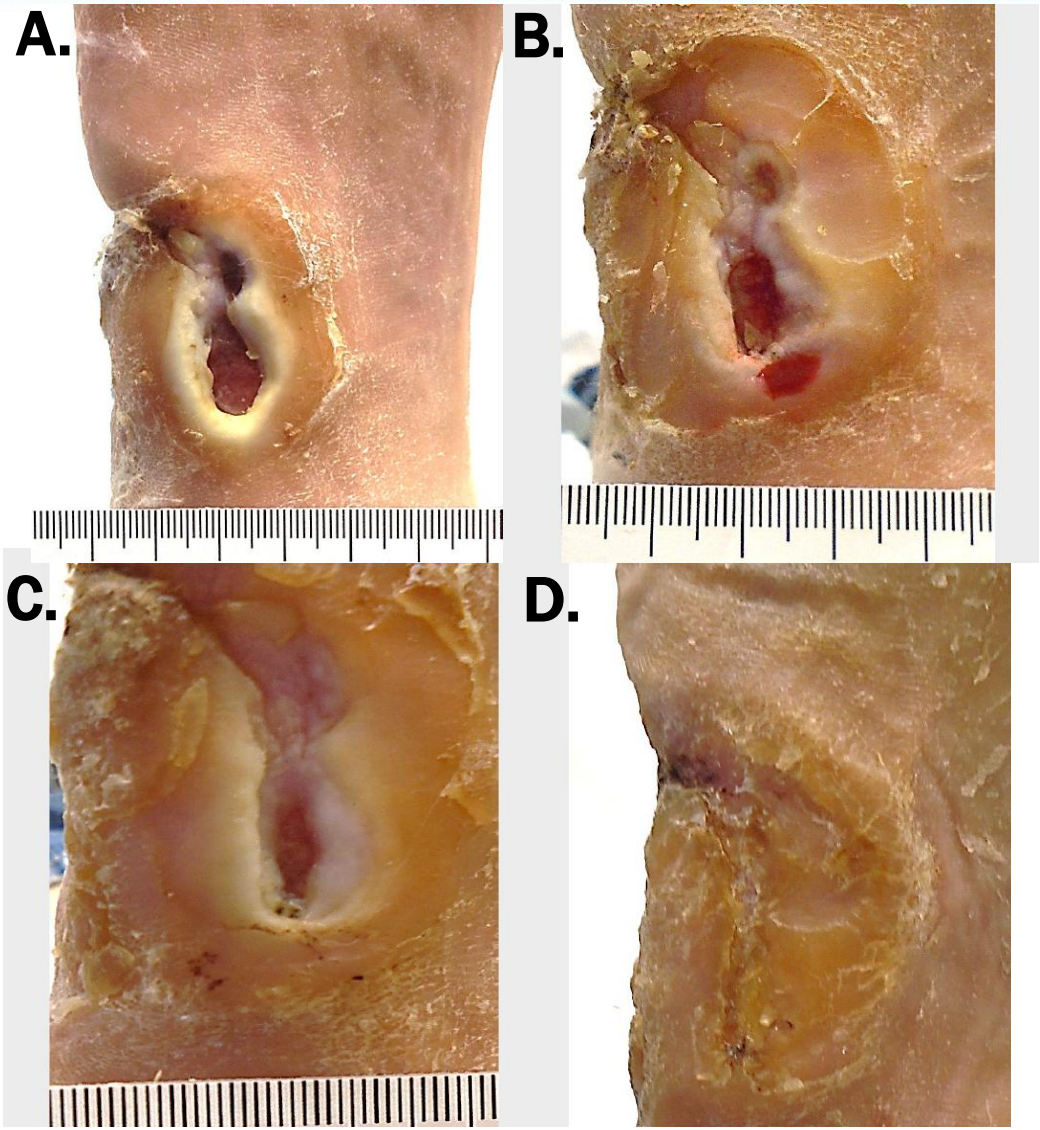
CAMP = cellular, acellular, and matrix-like product; QALY = quality-adjusted life-years.

Case Example: Right Plantar Midfoot DFU

58y Male, Wagner 2 DFU right plantar foot

A. Day 0: 2.6 x 1.2 x 0.1 cm
B. Week 1, 84% area reduction
C. Week 3, 90% area reduction
D. Week 4, 100% epithelialized

No complications nor recurrences, healing confirmed at visit 2 wks



Summary RCT Outcomes

- OFM-HA+SOC was effective in a mixed Wagner 1 and 2 population
- Significantly increased incidence of closure at 12 wks – 57% more DFUs closed with OFM-HA+SOC vs SOC alone
- Significantly reduced time to wound closure – closure reduced by 7.8 days
- Lower incidences of infection in DFU treated with OFM-HA+SOC – scope for future studies or analysis
- Improved healing time and reduced complications offset graft expense, with modeled 1-yr health outcomes improving healing at only 10% higher per-patient cost and improved QALY gains

Using OFM-HA Extracellular Matrix in Clinical Practice

Michael N. Desvigne, MD, FACS, CWS, FACCWS, MAPWCA
Plastic & Reconstructive Surgery, Wound Care & Hyperbaric Medicine
Abrazo Arrowhead Hospital & Wound Clinic
Glendale, AZ

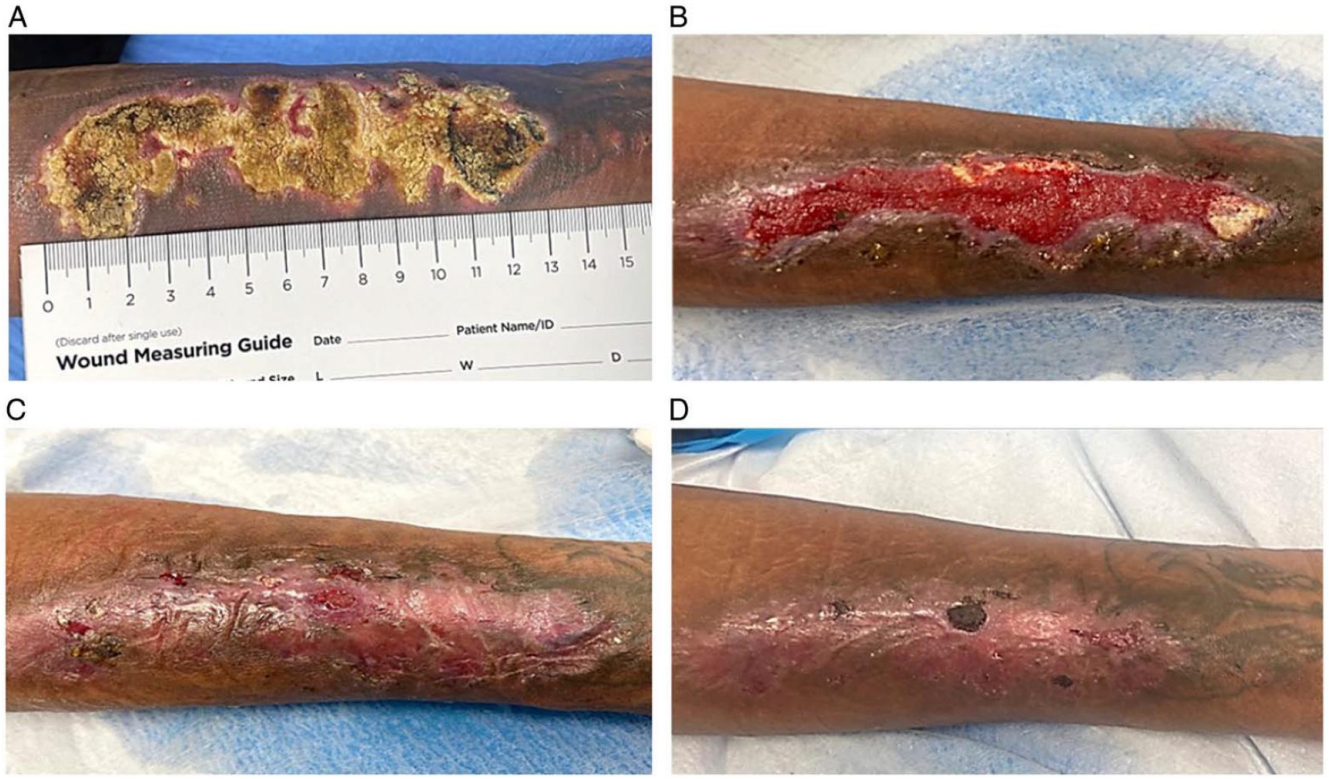
OFM-HA: Improved Cellular Response

Does the addition of HMWHA improve the cellular response of OFM? — YES

- The addition of HMWHA to OFM increases keratinocyte migration
- OFM will stimulate keratinocyte proliferation
- The addition of HMWHA to OFM further increases the biological response

Case Example: Calciphylaxis of the Arm

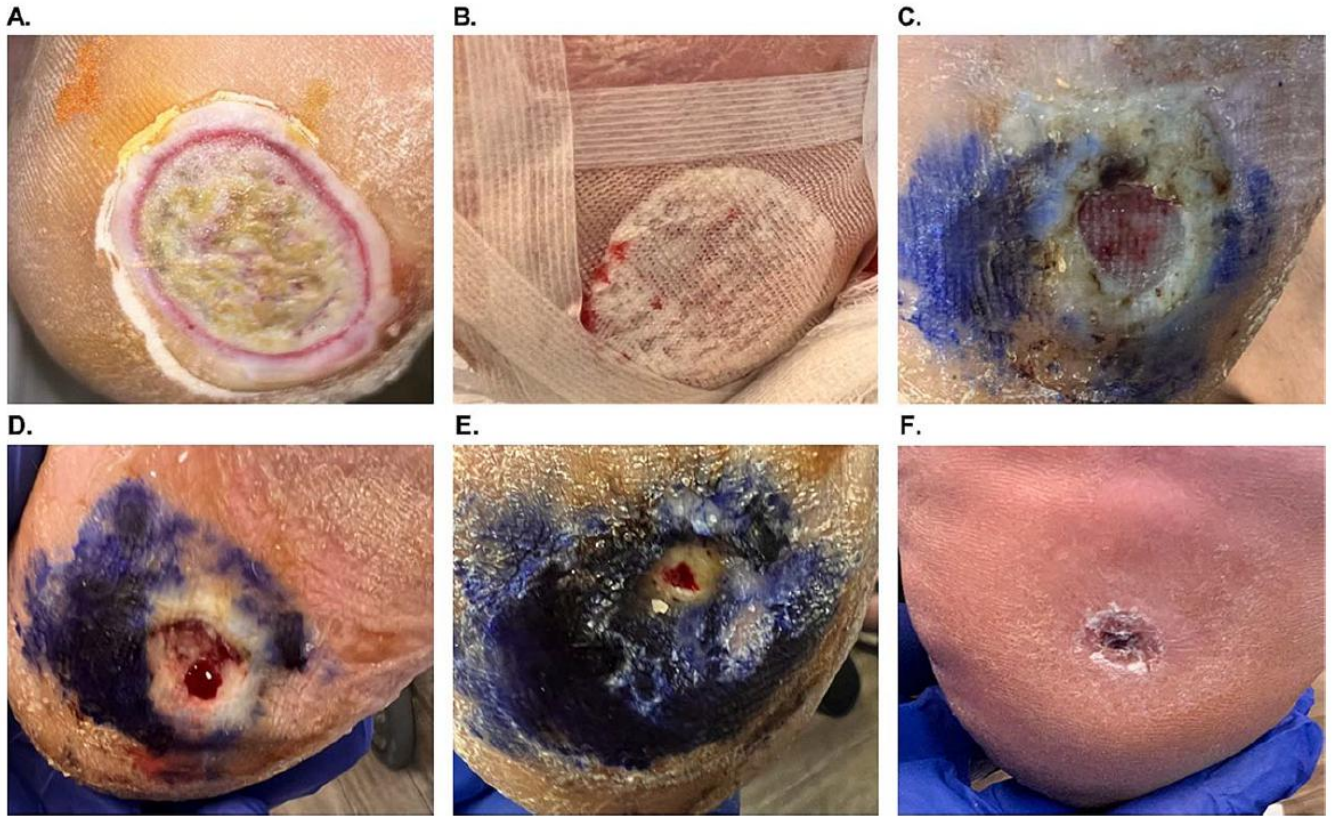
- **42y Male**
- Hx: ESRD, arterial disease, HTN
  - Initial presentation: 13x5cm, preceding ultrasonic debridement and OFM-HA application, pain 7/10
  - Wk 2: Improved wound bed and evidence of wound PAR, improved pain
  - Wk 4: 98% epithelialized, pain resolved (0/10)
  - Wk 5: 100% epithelialized, pain remains resolved, no recurrence at 1 month healing confirmation visit, 1 application of OFM-HA



Courtesy of Basil Z. Khalaf, MD
Medical Director, MEDiKAL VIP Medical Concierge Services, Houston, TX

Case Example: Wagner 2 DFU of the Plantar Heel

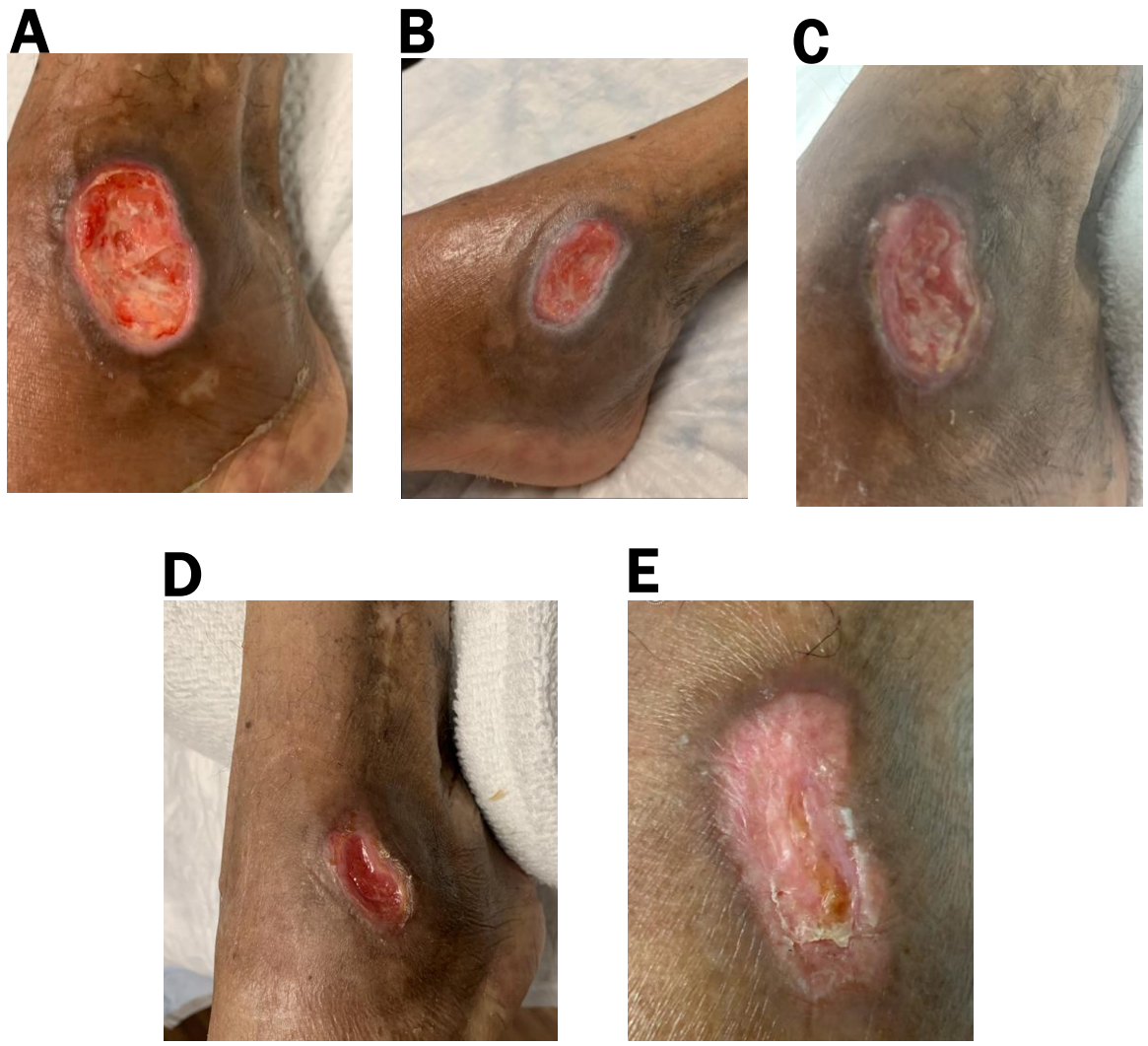
- **56y Female**
- Hx: DM (uncontrolled), Charcot arthropathy, HTN; 6 mos without improvement in wound
  - Initial presentation: ≈3x3cm
  - Application of OFM-HA
  - Wk 2: Significant PAR
  - Wk 3: Continued epithelialization and sharp debridement performed; continue offloading
  - Wk 6: 98% epithelialized, healed by wk 7 (not pictured)
  - Long-term follow-up (3 mos after epithelialization achieved; 1 application of OFM-HA)



Courtesy of Anthony J. LaLama, DPM
Podiatric Surgery, Ascension Providence Hospital. Southfield, MI

Case Example: Vasculitic Ulcer of Ankle

- **55y Female**
- Hx: Vasculitis, PVD, previous CVA, blindness, autoimmune on corticosteroids; no improvement for 6 wks prior to OFM-HA
  - Initial presentation: 5x2.5x0.2cm
  - Wk 5: Improved pain and wound area, 3rd OFM-HA applied
  - Wk 7: Noted integrating OFM-HA in wound bed, continued improved pain and PAR, 4th OFM-HA applied
  - Wk 10: 80% epithelialization noted, 5th and final application of OFM-HA applied
  - Wk 15: 100% epithelialized, no recurrence as of 7 months after epithelialization; 5 applications of OFM-HA



Courtesy of James E. Geiger, Jr., DPM, CWSP, FACCWS, FACPM, FACFAS
Northwestern Medicine Regional Medical Group. Palos Heights, IL

PVD = peripheral vascular disease; CVA = cerebrovascular accident.

Key Takeaways

- Hyaluronic acid is an active biologic component of wound healing that modulates inflammation, cellular migration, as well as microvascular and matrix remodeling[1,2]
- High molecular weight HA is associated with anti-inflammatory and pro-resolution signaling that may be particularly relevant in non-healing wounds characterized by chronic inflammation[3,4]
- Randomized clinical studies and recent meta-analyses support the use of HA-containing therapies in DFU management [5,6]
- Early real-world evidence suggests fewer applications to achieve closure[7,8]
- **OFM-HA combines extracellular matrix technology with hyaluronic acid biology, providing a mechanistically supported approach to DFU and complex wound management**

1. Litwiniuk M, et al. *Wounds*. 2016;28(3):78-88 **2.** Aya KL, Stern R. *Wound Repair Regen*. 2014;22(5):579-593. **3.** Jiang D, et al. *Physiol Rev*. 2011;91(1):221-264. **4.** Kaul A, et al. *Biomolecules.* 2021;18;11(8):1234. **5.** Lee M, et al. *Wound Repair Regen*. 2016;24(3):581-588. **6.** Yao L, et al. *Front Endocrinol*. 2025;16:1627558. **7.** Lai L, et al. *Adv Skin Wound Care*. 2025;38(10):E149-E155. **8.** Geiger JE, et al. *J Surg Case Rep*. 2026;26(3):rjag129.