

Placental and Dermal Tissues in Practice:

**Intersecting Clinical Evidence,
Application across Wound Etiologies,
and Reimbursement**

Supported by an educational grant from MTF Biologics

Faculty

- **Evan Adler, DPM, FACFAS**
Podiatrist, Bear Foot and Ankle, LLC, Ocean, NJ
Hackensack Meridian Health
Jersey Shore University Medical Center, Neptune, NJ
- **Jimmy Chim, MD**
Chief, Division of Plastic & Reconstructive Surgery
Banner University Medical Center, Phoenix, AZ
Assistant Professor of Surgery, University of Arizona College of Medicine, Phoenix, AZ
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Plastic and Reconstructive Surgery, Wound Care and Hyperbaric Medicine
Abrazo Arrowhead Hospital and Wound Clinic, Glendale, AZ
- **Edward S. Lee, MD, MS**
Division Chief, Plastic and Reconstructive Surgery
Residency Program Director, Integrated Plastic Surgery
Rutgers Health – New Jersey Medical School
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Faculty Disclosures

- **Evan Adler, DPM**
Consultant, Speakers Bureau: MTF Biologics
- **Jimmy Chim, MD**
Consultant: Medaxis; MTF Biologics
- **Michael N. Desvigne, MD, FACS, CWS, FACCWS, MAPWCS**
Advisory Board: Sanara MedTech; Smith+Nephew; Solventum, Medical Surgical Business; Tides Medical; Consultant, Speakers Bureau: Acera Surgical; Aroa Biosurgery; Integra Life Sciences; MolecuLight Inc.; MTF Biologics; Sanara MedTech; Smith+Nephew; Solventum, Medical Surgical Business; Urgo Medical
- **Edward S. Lee, MD, MS**
Advisory Board: MTF Biologics; Research: AbbVie; Plastic Surgery Foundation; American Orthopedic Foot and Ankle Society; Speakers Bureau: Avita Medical

Learning Objectives

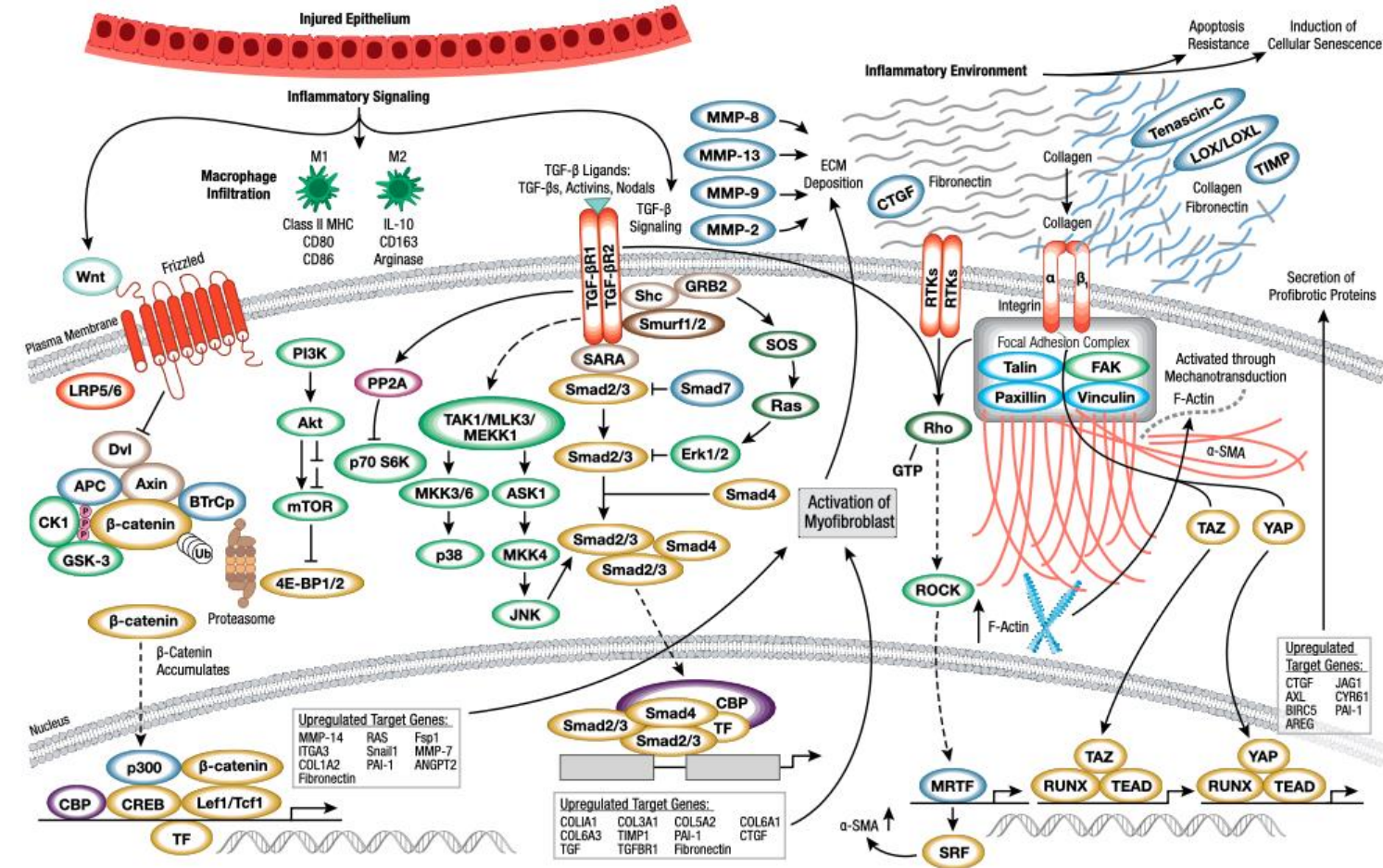
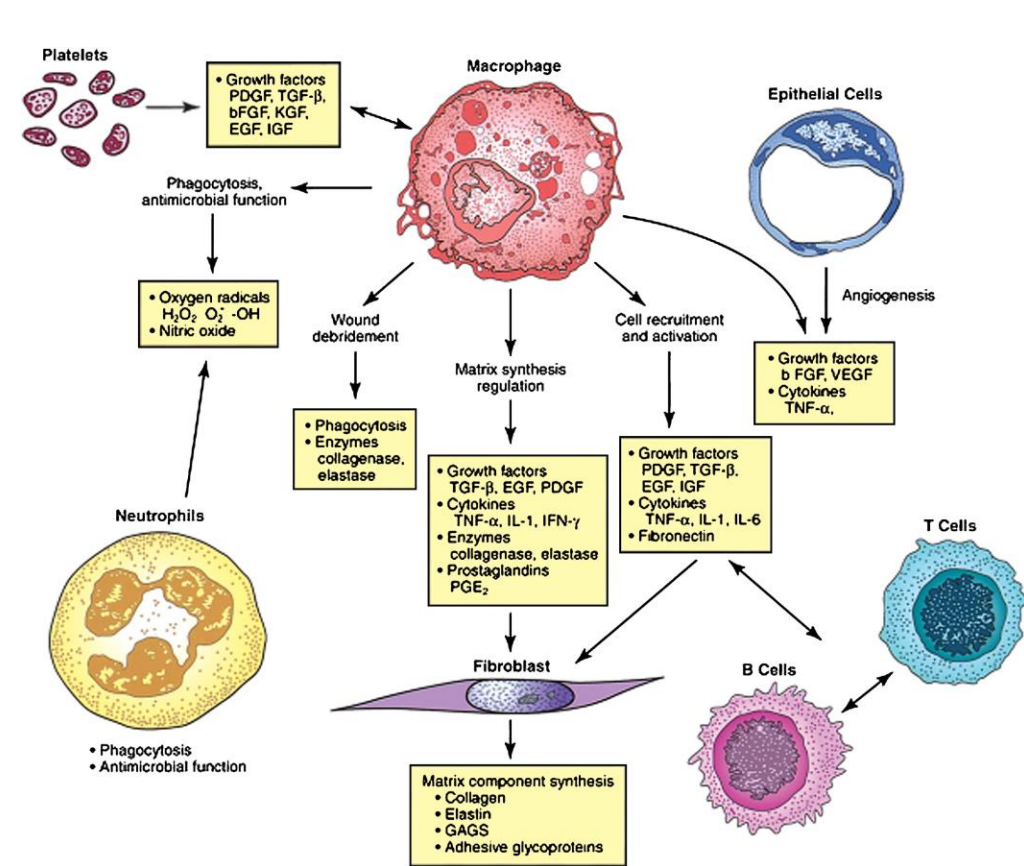
- Recognize the importance of scientific rationale and the strength of clinical evidence in the selection and use of skin substitutes
- Review the scientific data and clinical evidence supporting the use of aseptically processed, acellular human dermal grafts and placental membranes
- Analyze real-world case studies illustrating the use of aseptically processed allografts and placental membranes across diverse wound etiologies and practice settings throughout the continuum of care
- Describe key reimbursement considerations associated with the use of aseptically processed, acellular human dermal grafts and placental membranes

Welcome and Introduction

Jimmy Chim, MD

Chief, Division of Plastic & Reconstructive Surgery
Banner University Medical Center, Phoenix, AZ
Assistant Professor of Surgery
University of Arizona College of Medicine, Phoenix, AZ

Let's Do This!

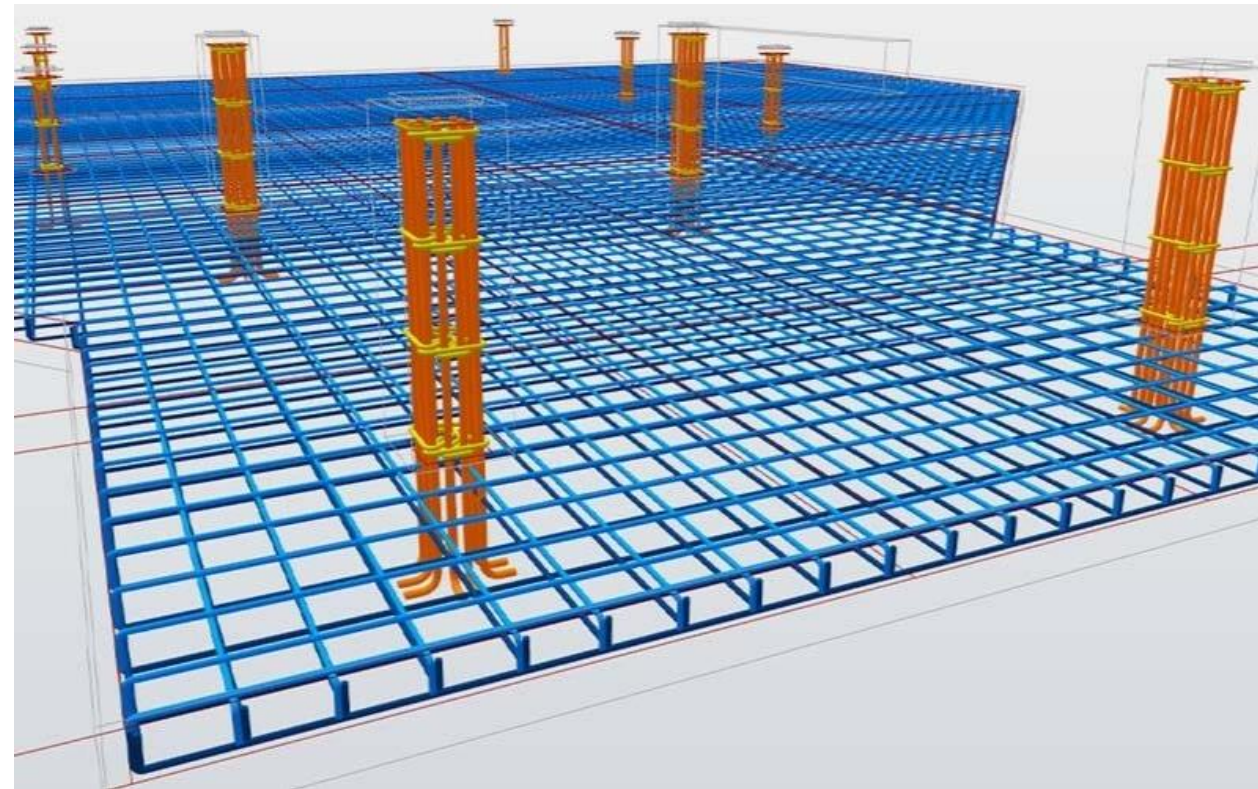


Science Is Important



What Can a Graft Do?

2 Categories

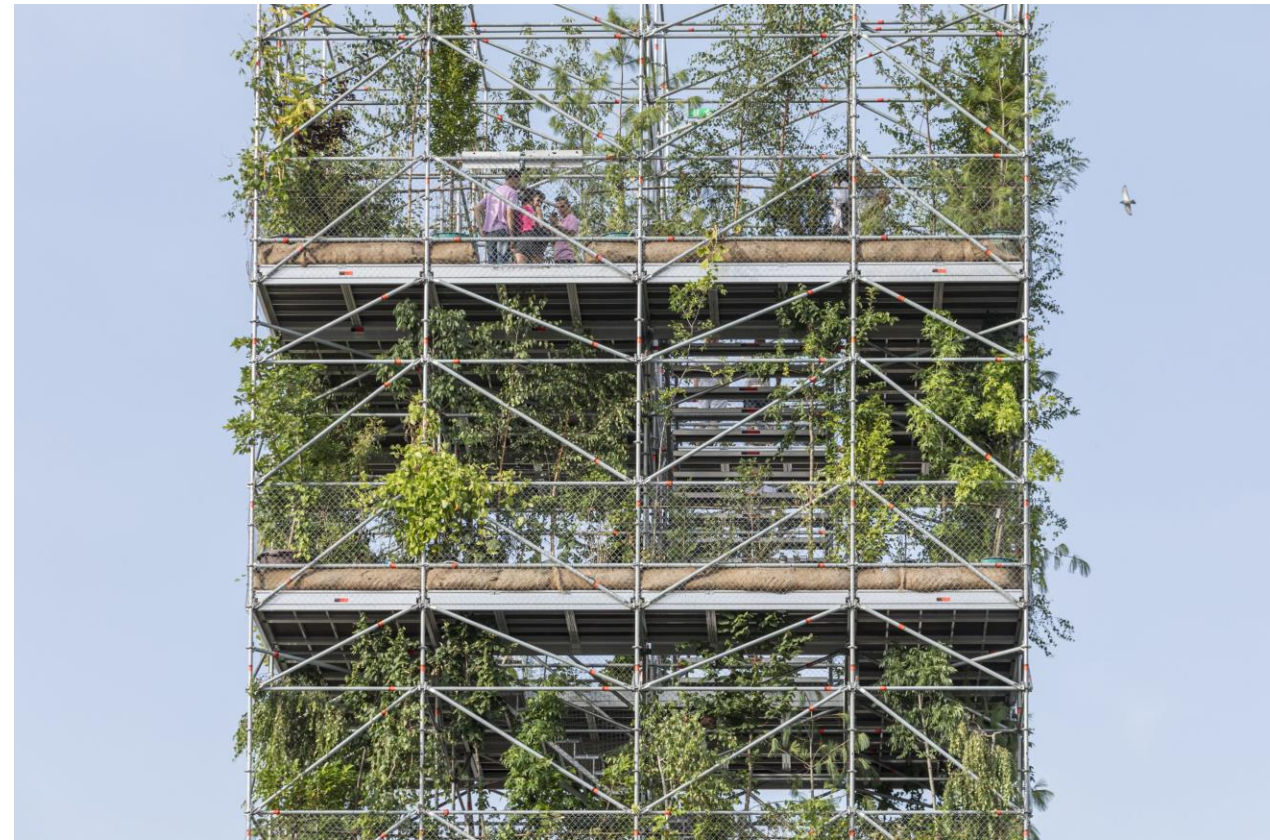


2 Categories

Placental Tissue

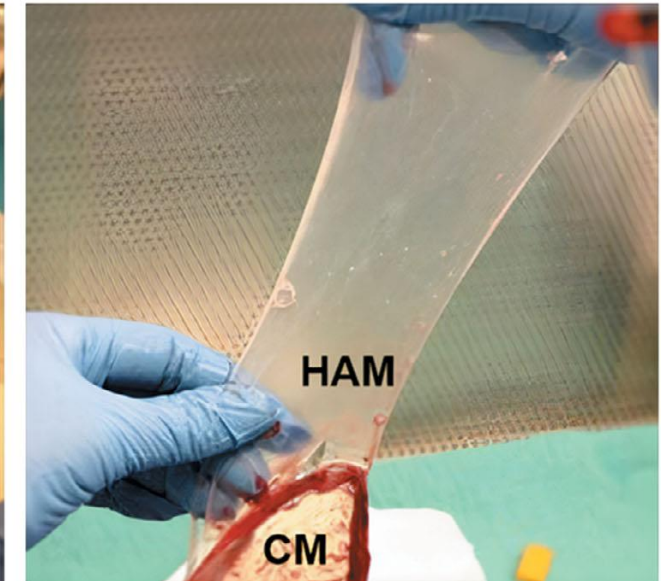


Reticular Acellular Dermis



Placental Tissue

- Wound dressing, 1910
 - Johns Hopkins
 - *JAMA*, 1913
- Described throughout 20th century
- Barriers to widespread use
 - Harvest
 - Preparation: Varied
 - Storage: Fresh, frozen, exp date?
 - Infectious transmission: HIV



Human Amniotic Membrane: A review on tissue engineering, application, and storage

Sara Leal-Marín¹ | Thomas Kern² | Nicola Hofmann³ | Olena Pogozhykh⁴ |
Carsten Framme² | Martin Börgel³ | Constanca Figueiredo⁴ |
Birgit Glasmacher¹ | Oleksandr Gryshkov¹

HAM = human amniotic membrane; CM = chorionic membrane.

Davis JW. *Johns Hopkins Med J*. 1910;15:307. Stern M. *JAMA*. 1913;60(13):973-974. Leal-Marín S, et al. *J Biomed Mater Res B Appl Biomater*. 2021;109(8):1198-1215.

Placental Tissue

- 2010s – dehydrated amniotics available
 - 2012: 1st case series
 - 2013: 1st PRCT with DFUs
 - Both studies demonstrated more expeditious wound closure with amniotic tissue application

Dehydrated amniotic membrane allografts for the treatment of chronic wounds: a case series

A prospective randomised comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers

Charles M Zelen¹, Thomas E Serena², Guilhem Denoziere³ & Donald E Fetterolf³

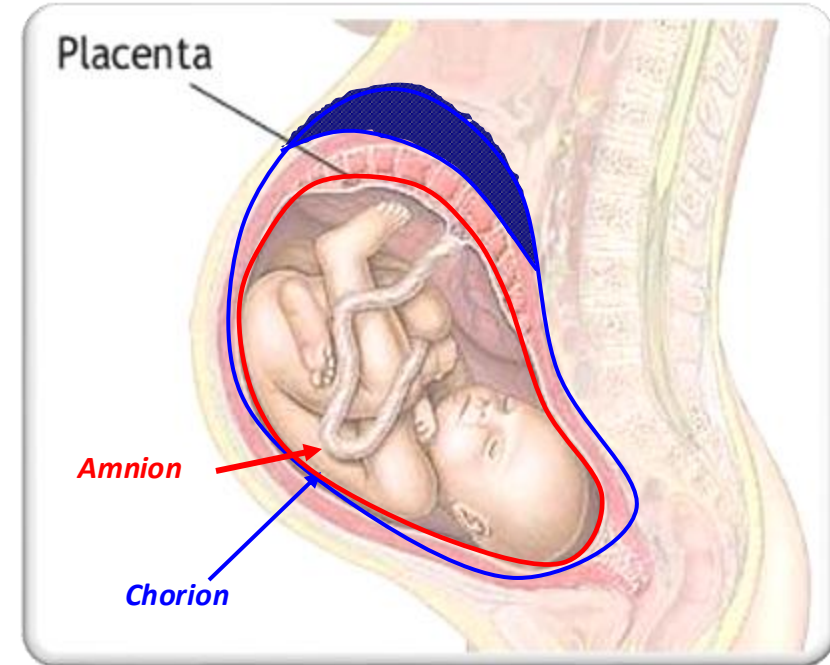
¹ Department of Clinical Research, Professional Education and Research Institute, Inc., Roanoke, VA, USA

² Department of Clinical Research, SerenaGroup Wound and Hyperbaric Centers, Warren, PA, USA

³ Department of Medical Affairs, MiMedx, Kennesaw, GA, USA

Placental Tissue

- Not your everyday tissue
- Protects the fetus during in-utero development
- No vessels or nerves
- Functions via diffusion
 - Perfect for topical application
- Contains
 - **ECM**
 - **Growth factors**



Placental ECM

Table 1. Properties of human amnion and chorion

Property	Amnion	Chorion
Physical		
Thickness	111 ± 78 μm	431 ± 113 μm
Max tensile force	0.166 (0.15–0.25 kg/cm)	0.117 (0.05–0.1 kg/cm)
Max tensile stress	30.2 kg/cm ²	5.9 kg/cm ²
Layers	Epithelial, basement membrane, compact, mesodermal, sponge	Mesodermal, pseudo basement membrane, trophoblast
Tissue-resident cells	Epithelial cells, fibroblasts, mesenchymal stem cells, macrophages	Fibroblasts, mesenchymal stem cells, macrophages, trophoblast cells
Cell number (average per placenta)	~ 20 million stromal ^a 50–70 million epithelial	25–40 million stromal ^a
<i>In utero</i> function	Barrier, cover	Stromal layer-barrier, cover; trophoblast-material exchange, secretory
Extracellular matrix		
Structural matrix	Collagens I, III, IV, V, VI, elastin	Collagens I, III, IV, V, VI, tropoelastin
Glycoproteins	Fibronectin, laminins, nidogen	Fibronectin, laminins, nidogen
Proteoglycans	Chondroitin, dermatan sulfate, hyaluronan, decorin, biglycan	Chondroitin, dermatan sulfate, hyaluronan, decorin, biglycan, versican, perlican
Selected growth factors ^b	EGF, HGF, TGF-β (1, 3), bFGF, KGF, NGF, VEGF, PDGF, PIGF, TGF-α	HGF, TGF-β1, TGF-α, bFGF, VEGF, PDGF, PIGF
	Mucin	Interferon α
	Defensins	Defensins
	TIMPS, CTGF, IL-1RA	TIMP-1
	Groα, sICAM, IL-6, IL-8, MCP-1, MIF, serpin E1, SDF-1a, IL-10, IL-4, G-CSF	IL-6, IL-8, IL-4, SDF-1a, IL-10, G-CSF

Use of Placental Membranes for the Treatment of Chronic Diabetic Foot Ulcers

Jonathan N. Brantley* and Thomas D. Verla

Department of Surgery, Hunter Holmes McGuire VA Medical Center, Richmond, Virginia.

^aEstimated based on 20 g and 25–40 g weight for wet amnion and chorion, respectively; ^bMost amniotic growth factors are also present in chorion. Brantley JN, Verla TD. *Adv Wound Care* (New Rochelle). 2015;4(9):545-559.

Placental ECM

- **Fibronectins**

- Cell signaling (glycoprotein family)
- Fibronectin assists with cell adhesion
- Can be spliced into 20 different isoforms

- **Hyaluronan (HA)**

- Carbohydrate component
- GF interactions
- Anti-inflammatory
- Anti-scarring
- Free-radical scavenger

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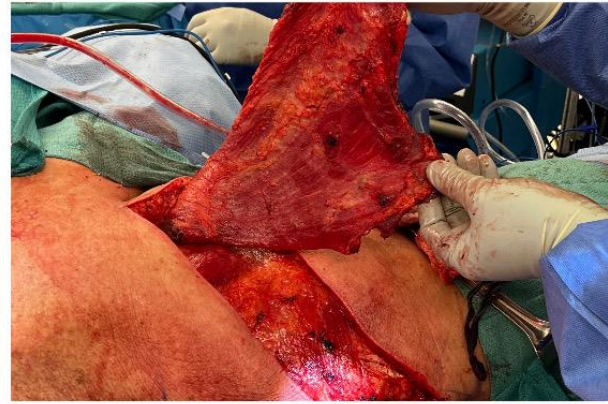
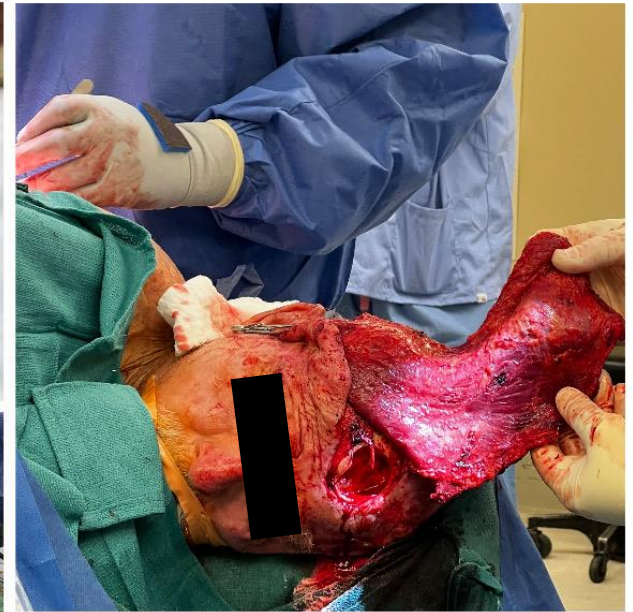
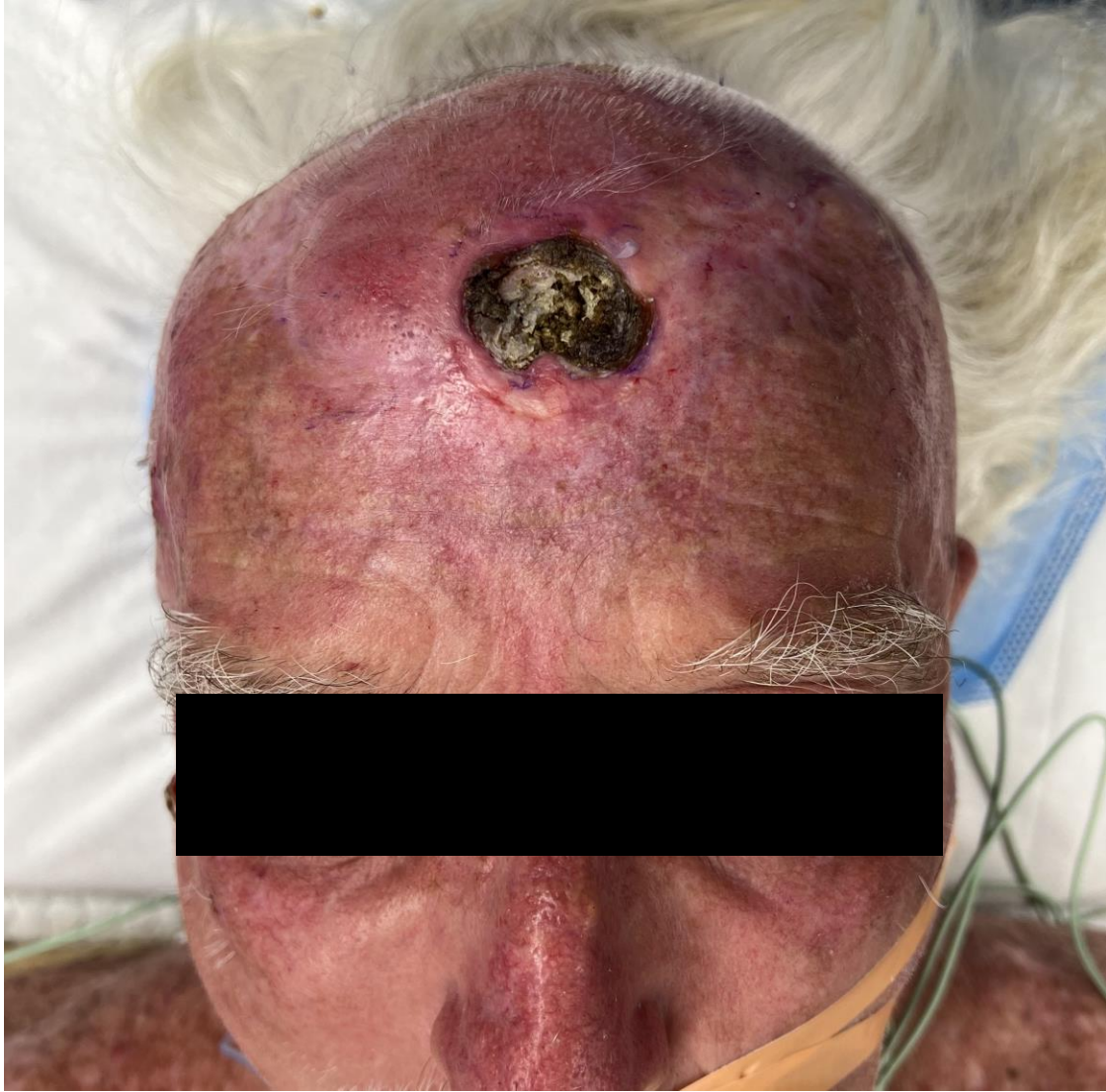
GF = growth factor.

Brantley JN, Verla TD. *Adv Wound Care* (New Rochelle). 2015;4(9):545-559.





Split-thickness skin graft (STSG) without placental optimization

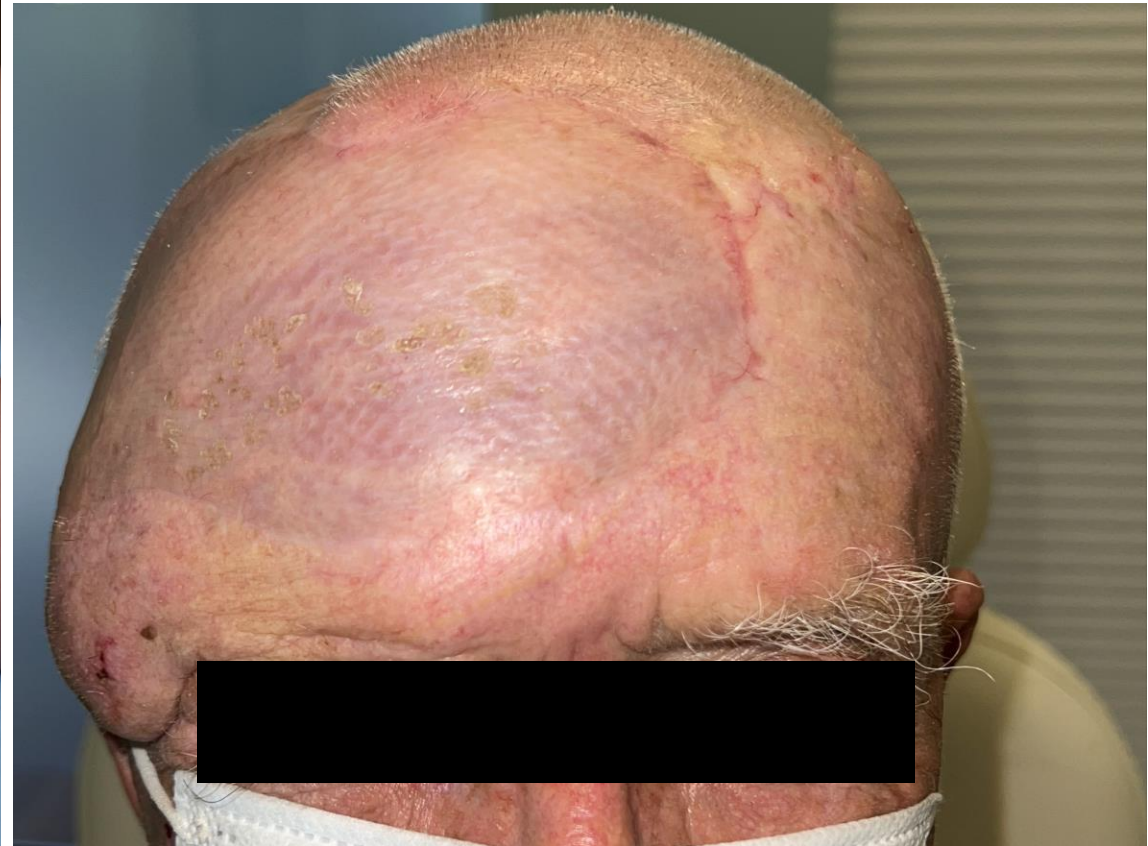








STSG w/o Placental Optimization



STSG w/ Placental Optimization

Antimicrobial Properties of Placental Tissue

Antimicrobial Properties of Amniotic and Chorionic Membranes: A Comparative Study of Two Human Fetal Sacs

Majid Zare-Bidaki ¹, Sajad Sadrinia ², Soheila Erfani ³, Ehsan Afkar ⁴, Nahid Ghanbarzade ^{3*}

1- Infectious Diseases Research Center, Faculty of Paramedical Sciences, Birjand University of Medical Sciences, Birjand, Iran

2- Faculty of Dentistry, Birjand University of Medical Sciences, Birjand, Iran

3- Faculty of Medicine, Birjand University of Medical Sciences, Birjand, Iran

4- Deputy of Research and Technology, Birjand University of Medical Sciences, Birjand, Iran

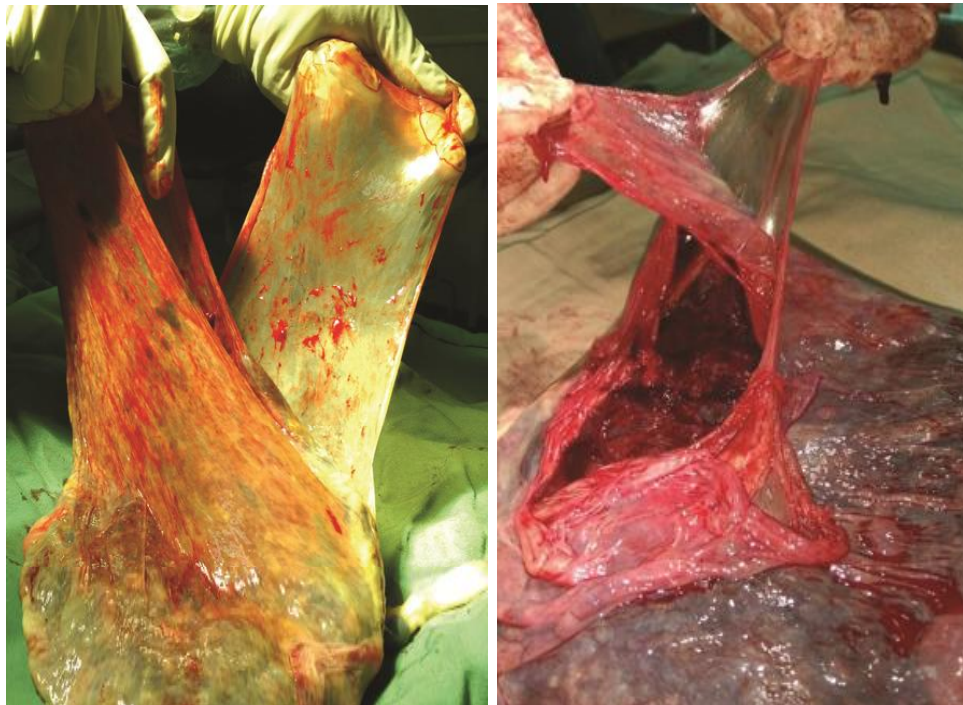


Figure 1. Peeling chorionic and amniotic membranes from each other in a placenta

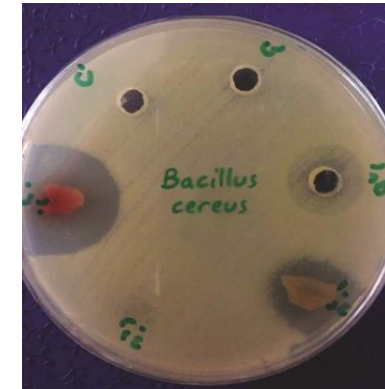


Figure 2. Formation of inhibitory zone of *Bacillus cereus* (ATCC11778) around amniotic tissue

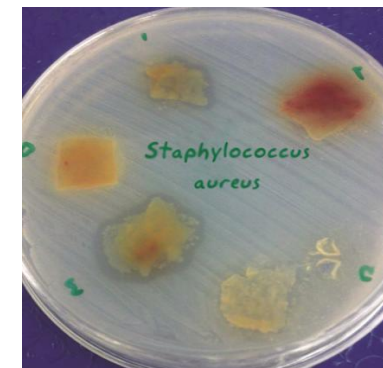


Figure 3. Formation of inhibitory zone of *Staphylococcus aureus* (ATCC29213) around amniotic tissue

Antimicrobial Properties of Placental Tissue

Aseptically Processed Dehydrated Human Amnion/Chorion Allografts* Possess Anti-microbial, Anti-inflammatory and Non-Immunogenic Properties that Support Wound Healing

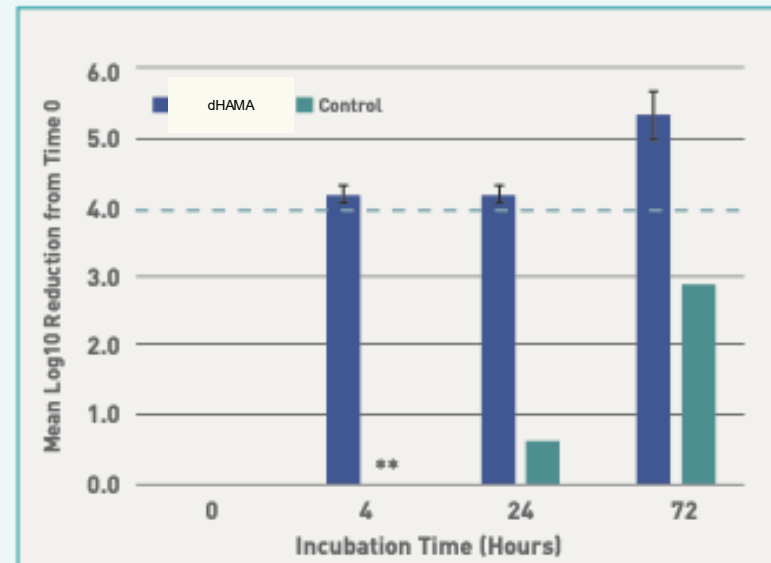
¹Dasgupta, A; ¹Phipps, A; ¹Eng, S; ¹Huang, YC; ¹Chnari, E
¹Musculoskeletal Transplant Foundation (MTF), Edison, NJ, USA

Antimicrobial Peptides Secreted From Human Cryopreserved Viable Amniotic Membrane Contribute to its Antibacterial Activity

Yong Mao¹, Tyler Hoffman¹, Anya Singh-Varma¹, Yi Duan-Arnold², Matthew Moorman², Alla Danilkovitch² & Joachim Kohn¹

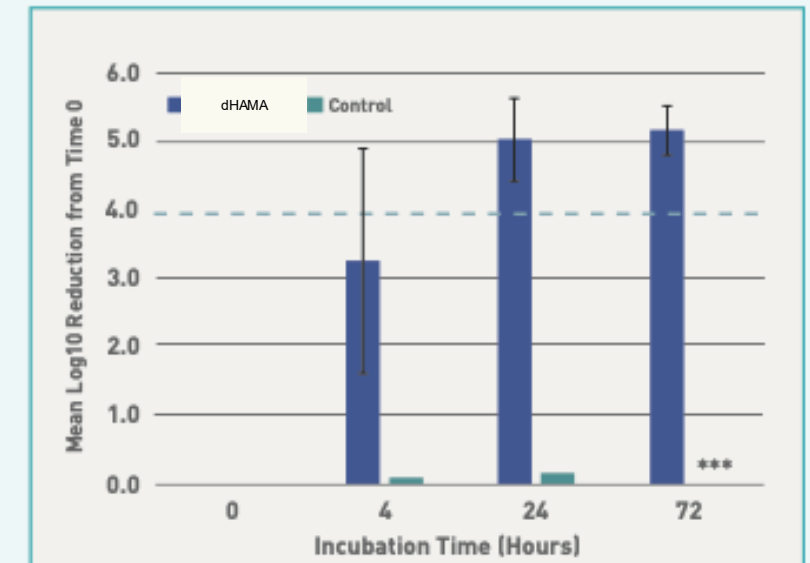
Sustained Inhibition of Bacterial Growth Over Time Upon Exposure to dHAMA

A) *S. pyogenes* (Gram positive)



**control unavailable at 4hrs

B) *P. aeruginosa* (Gram negative)



***growth observed (ie. Negative log reduction)

dHAMA = dehydrated human amniotic membrane allograft.

Mao Y, et al. *Sci Rep.* 2017;7(1):13722. Dasgupta A, et al. Presented at: Symposium on Advanced Wound Care (SAWC) Spring; April 13-17, 2016; Atlanta, GA.

Effects of Placental Tissue on Biofilms

Article

The Effect of Cryopreserved Human Placental Tissues on Biofilm Formation of Wound-Associated Pathogens

Yong Mao¹, Anya Singh-Varma¹, Tyler Hoffman² , Sandeep Dhall², Alla Danilkovitch² and Joachim Kohn^{1,*} 

¹ New Jersey Center for Biomaterials, Rutgers University, 145 Bevier Rd., Piscataway, NJ 08854, USA; maoy@dls.rutgers.edu (Y.M.); as2220@scarletmail.rutgers.edu (A.S.-V.)

² Osiris Therapeutics, Inc., Columbia, MD 21046, USA; THoffman@osiris.com (T.H.); SDhall@osiris.com (S.D.); ADanilkovitch@osiris.com (A.D.)

* Correspondence: kohn@dls.rutgers.edu; Tel.: +1-(848)-445-3888

72-97% reduction in biofilm

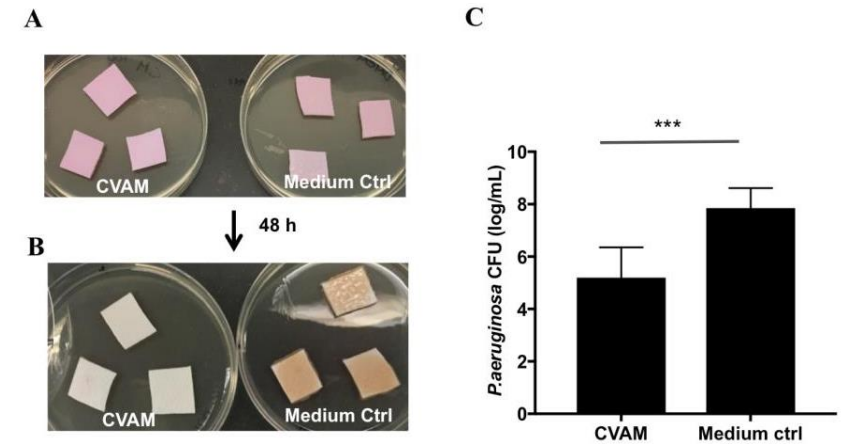
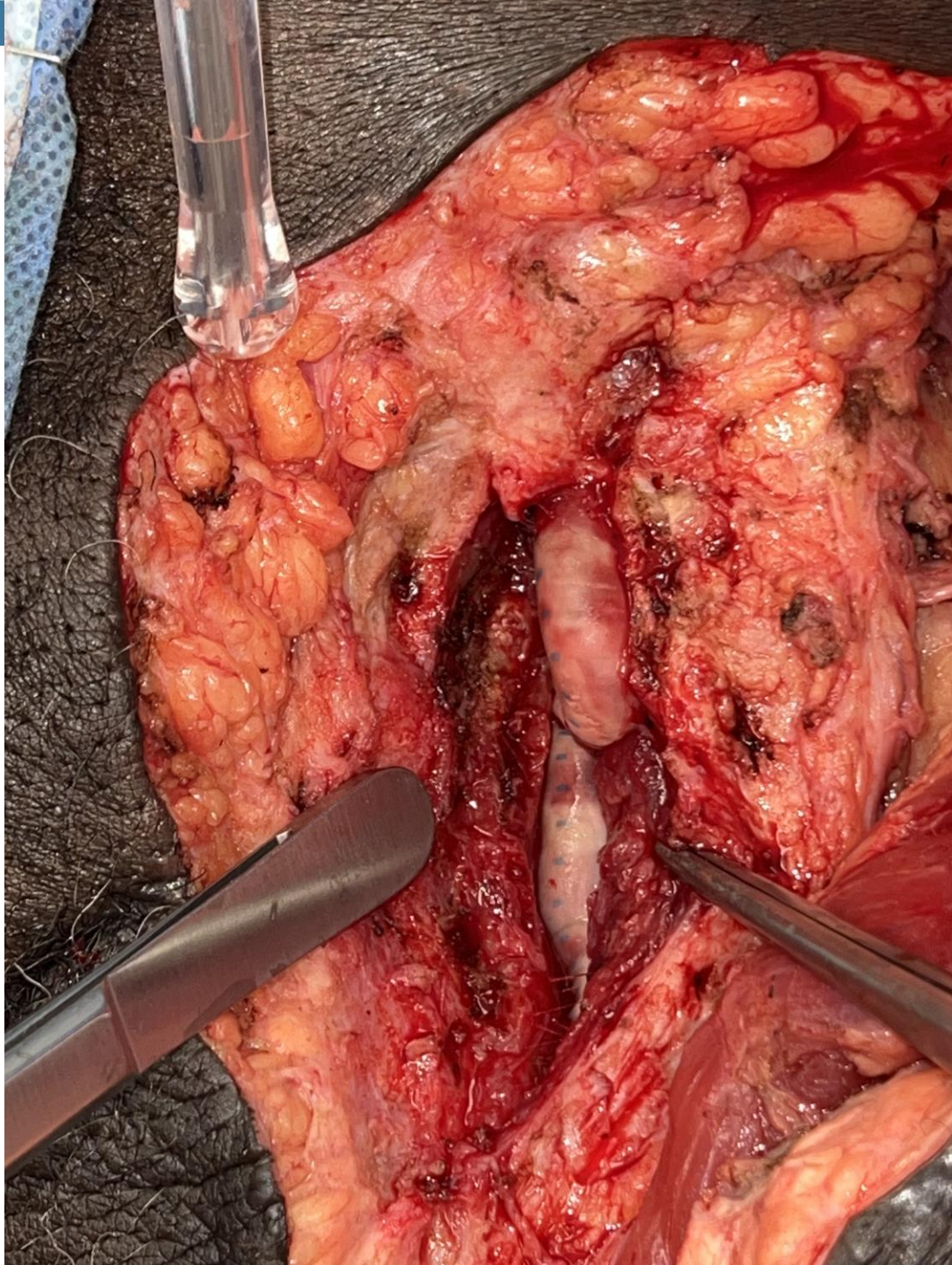


Figure 7. CVAM-derived conditioned media from reduced biofilm formation of *P. aeruginosa* in a porcine dermal tissue model. Porcine dermal tissue pieces treated with conditioned media derived from CVAM or with assay medium (control) (A). *P. aeruginosa* was used to inoculate the tissue pieces and incubated for 48 h (B). Biofilm bacteria were extracted and quantified by determining the CFUs (C). Data are presented as mean \pm SD of one representative experiment (n = 3). *** $p < 0.001$.







65y Female, +Hx of Radiation



Washout + Implant Exchange + Closure with Placental Tissue Optimization

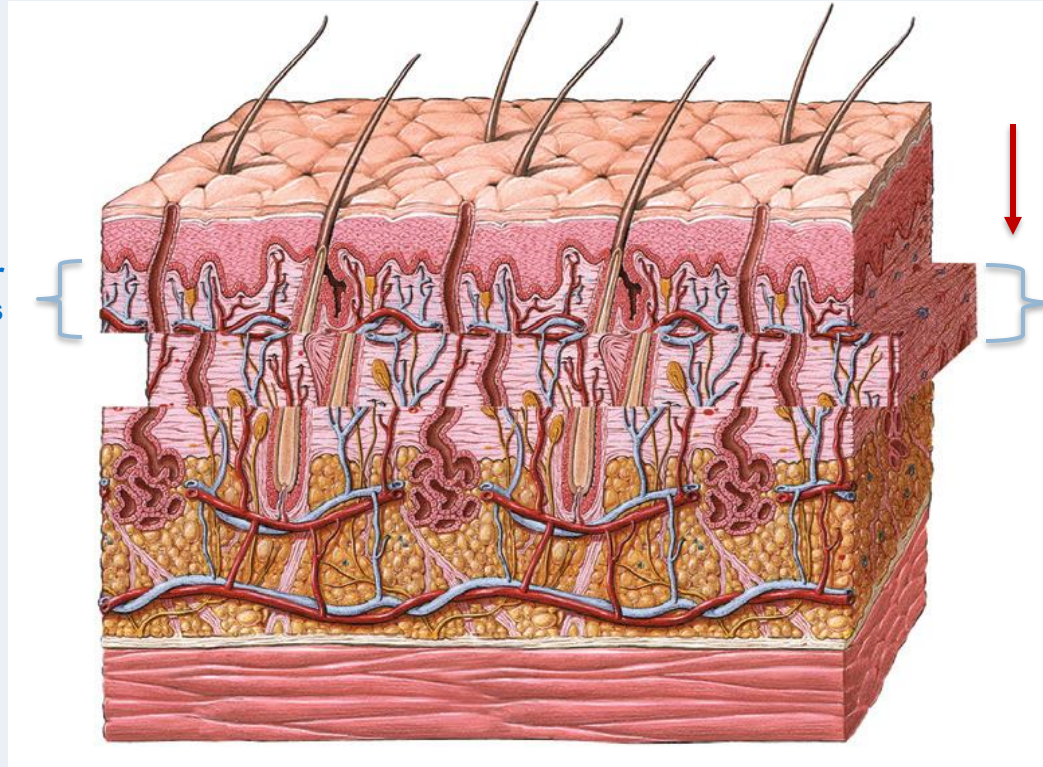


**65y Female, +Hx of Radiation:
2 Months s/p Implant Exchange +
Closure with Placental Tissue Optimization**



Human Reticular Acellular Dermal Matrix

Papillary or superficial dermis



Move away from epidermis,
structure opens up

Reticular dermis

Open structure leads to
greater cell attachment

ADMs in Wound Healing

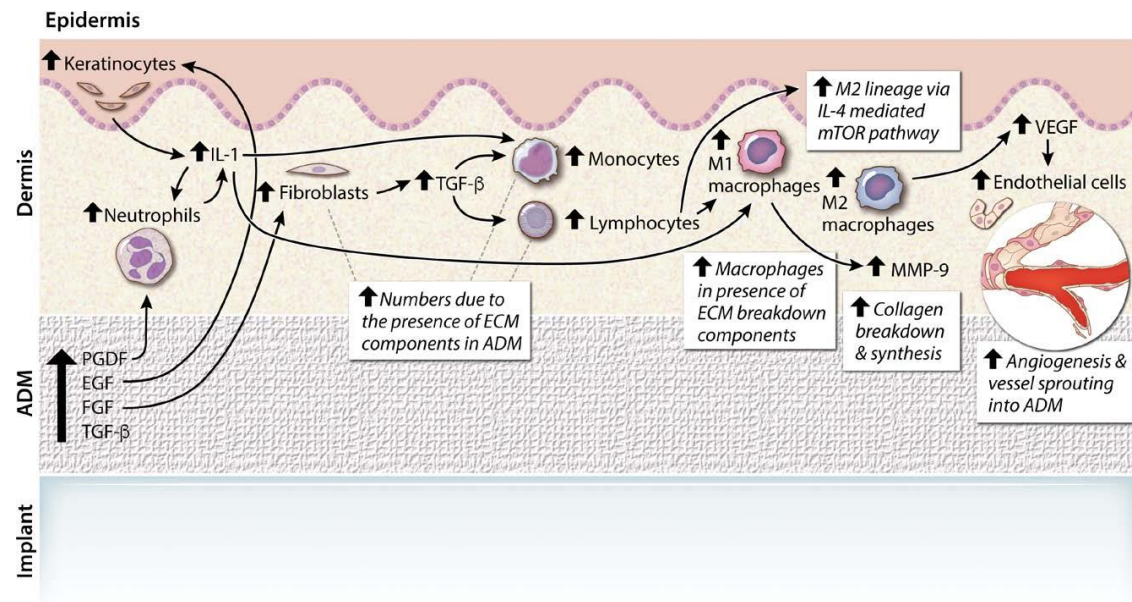
Acellular Dermal Matrix Favorably Modulates the Healing Response after Surgery

Miriam I. du Plessis, B.S.

Patrick S. Cottler, Ph.D.

Chris A. Campbell, M.D.

Charlottesville, Va.



- Cytokines
- Growth factors
- Receptors in ECM
- Increased expression
- EGF, FGF, PDGF, TGF

Fig. 4. Diagram of molecular and cellular mechanisms amplified by the presence of acellular dermal matrix. This figure demonstrates the relationships of the epidermis, dermis, acellular dermal matrix, and synthetic implant in a breast reconstruction clinical scenario. *Bold arrows pointing upward* represent the cellular constituents, growth factors, and mechanisms that are up-regulated because of the presence of acellular dermal matrix.

ADMs in Wound Healing

Acellular Dermal Matrix Favorably Modulates the Healing Response after Surgery

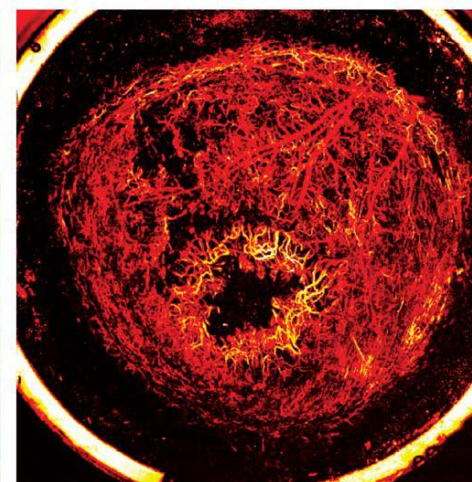
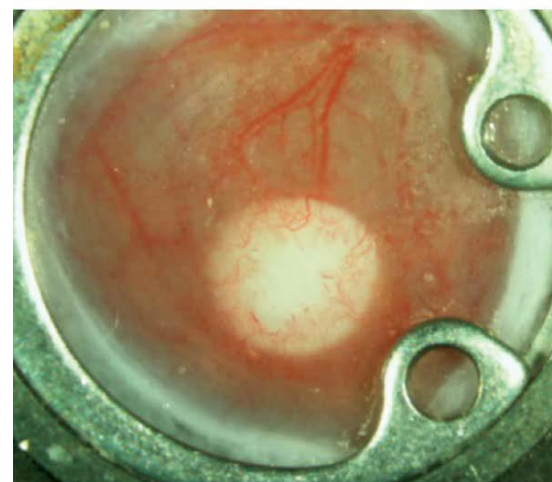
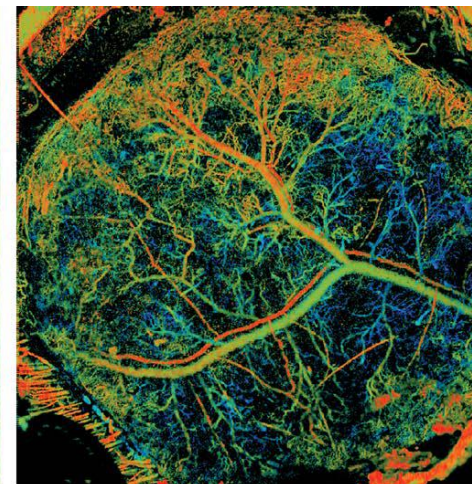
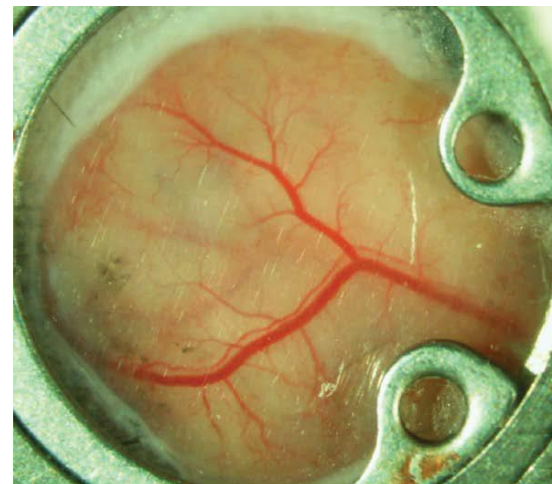
Miriam I. du Plessis, B.S.

Patrick S. Cottler, Ph.D.

Chris A. Campbell, M.D.

Charlottesville, Va.

- **65% vs 35%**
neovascularization
- **90%-100% vs 50%-60%**
oxygen saturation



Decellularized Human Allograft

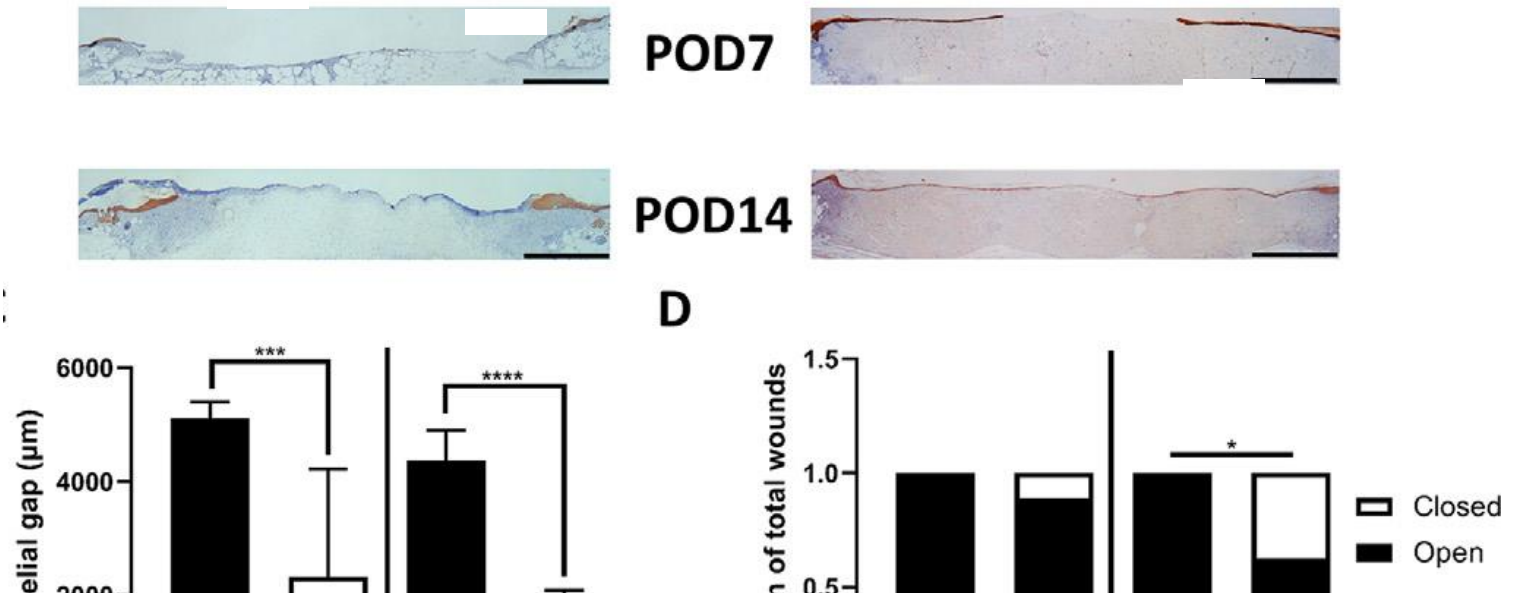
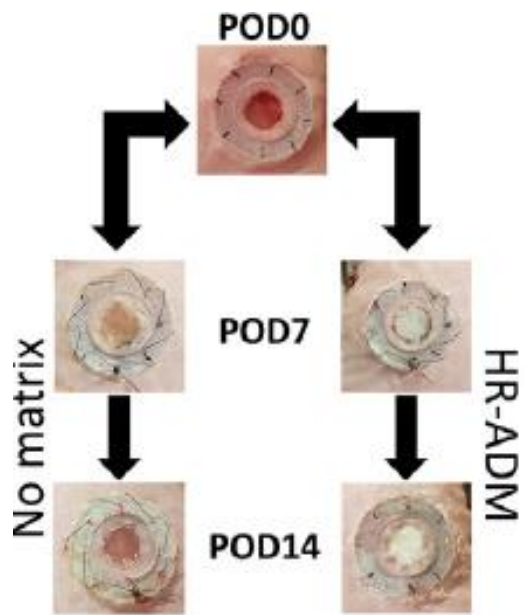
Application of decellularized human reticular allograft dermal matrix promotes rapid re-epithelialization in a diabetic murine excisional wound model

David Dolivo¹, Ping Xie¹, Chun Hou^{1,2}, Yingxing Li¹, Abigail Phipps³, Thomas Mustoe¹, Seok Hong^{1,*}, Robert Galiano^{1,*}

¹ Department of Surgery, Division of Plastic Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

² Department of Plastic and Cosmetic Surgery, First Affiliated Hospital of Guangzhou Medical University, Guangzhou, China

³ MTF Biologics, Edison, New Jersey, USA



Decellularized Human Allograft

Application of decellularized human reticular allograft dermal matrix promotes rapid re-epithelialization in a diabetic murine excisional wound model

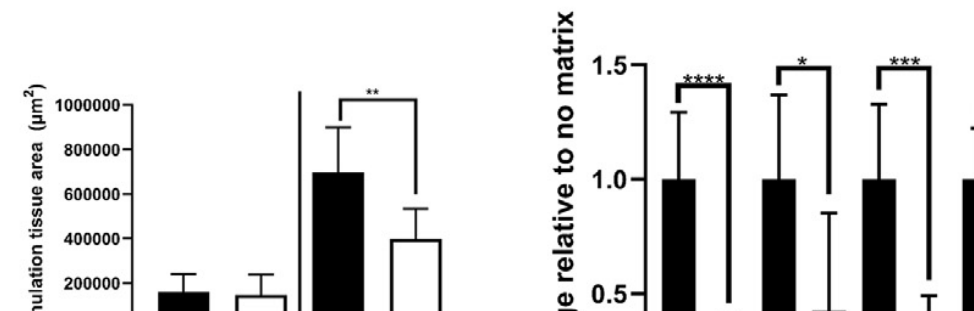
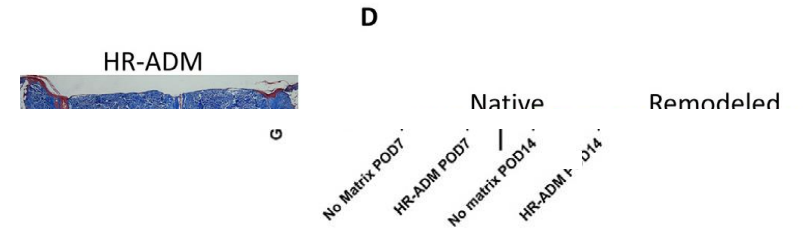
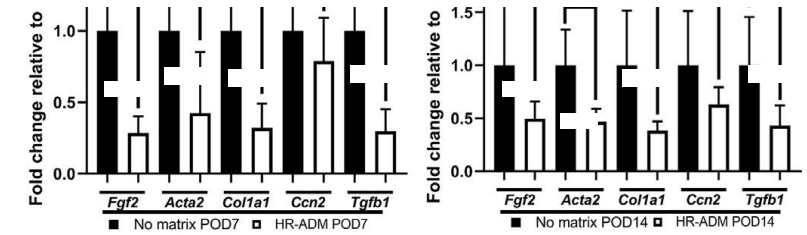
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³ MTF Biologics, Edison, New Jersey, USA

- **Normally a wound builds granulation tissue; the re-epithelialization occurs over top**
- **Reticular dermis actually *down-regulated granulation formation***
- **Replacement dermal scaffold for re-epithelialization**



92y Female s/p Fall

- GLF, on apixaban
- Likely developed pressure necrosis from hematoma
- A-fib
- HTN
- Malnourished
- Ex-smoker
- Severe pulmonary hypertension



POD #7







A Private Practice Approach: **Inpatient to Outpatient Management of Wound Healing**

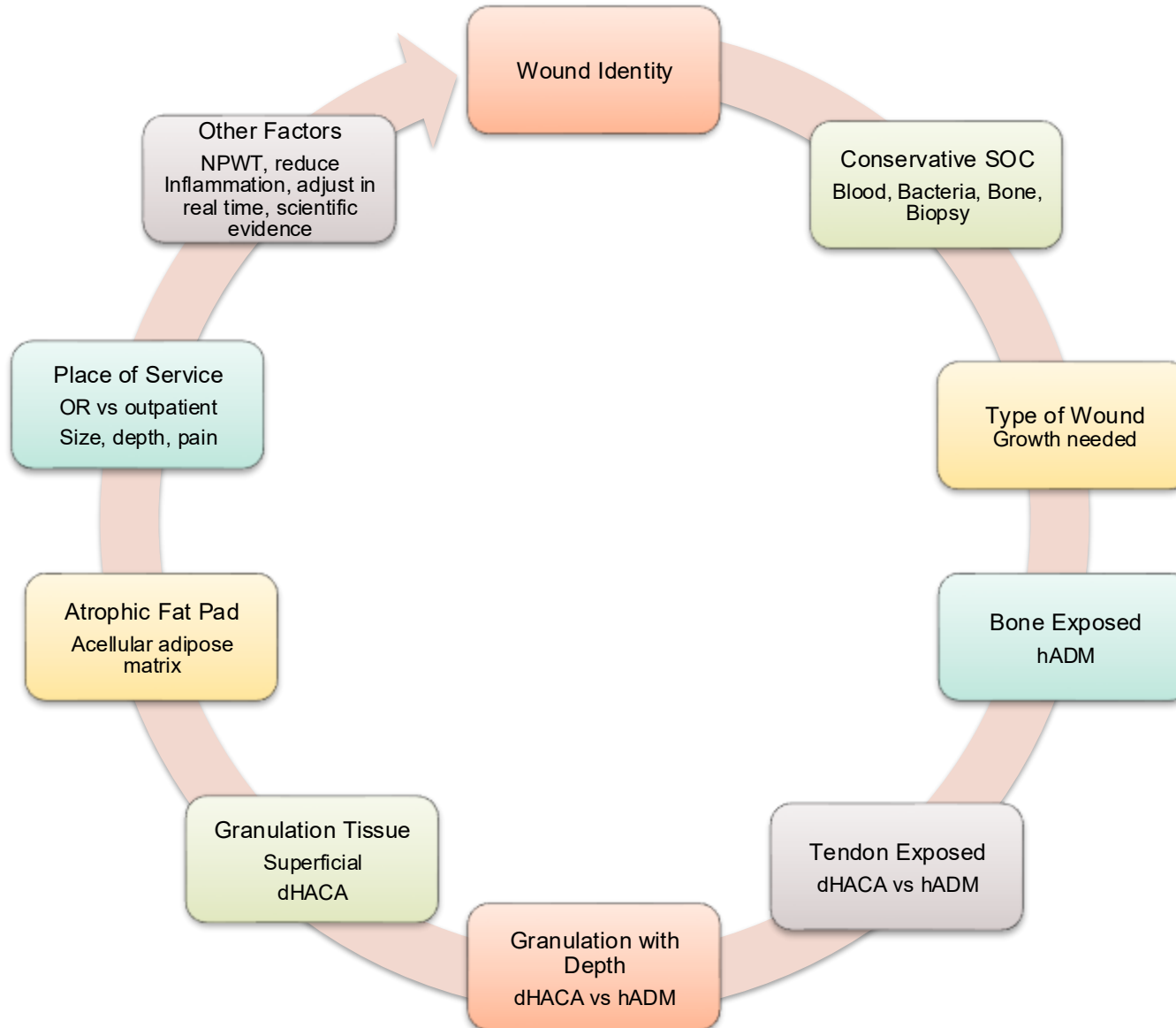
Evan Adler, DPM

Podiatrist, CEO Bear Foot and Ankle, LLC, Ocean, NJ

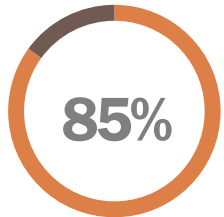
Hackensack Meridian Health Jersey Shore University Medical Center

Hackensack Meridian Health Wound Care Center

Wound Care Treatment Algorithm

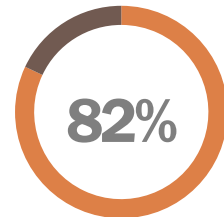


Summary of Clinical Outcomes



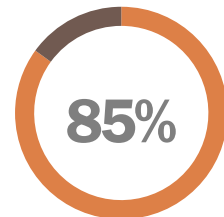
DiDomenico, et al. 40 Patient Prospective, Multi-center Blinded RCT in DFU

- **85%** vs 25% SOC-only wounds closed at 12 wks
- More than 3x the number of patients healed at 12 wks



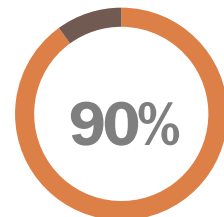
DiDomenico, et al. Retrospective, Crossover Study in DFU

- **82%** closed at 12 wks after failing SOC-only in original 40 Patient Prospective Study
- 60% wound area reduction in 2 treatments of AmnioBand® Membrane (allograft placental matrix or dHACA)



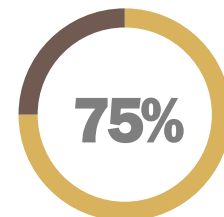
DiDomenico, et al. 80 Patient Prospective, Multi-center Blinded RCT in DFU

- **85%** vs 33% SOC-only wounds closed at 12 wks
- Complete closure in half the time as compared to SOC



Glat, et al. Prospective, Multi-center, Comparative RCT in DFU

- **90%** vs 40% TESS+SOC wounds closed at 12 wks
- Twice as many patients healed in 12 wks



Serena, et al. 60 Patient Prospective, Multi-center, Blinded RCT in Venous Leg Ulcers

- **75%** vs 30% wounds closed at 12 wks vs SOC-only compression bandages
- >80% mean wound area reduction with dHACA treatment at 12 wks

58y Male, DM 8.9 with TMA/hADM/filet of hallux, NPWT

4-15-20



4-16-20



4-16-20

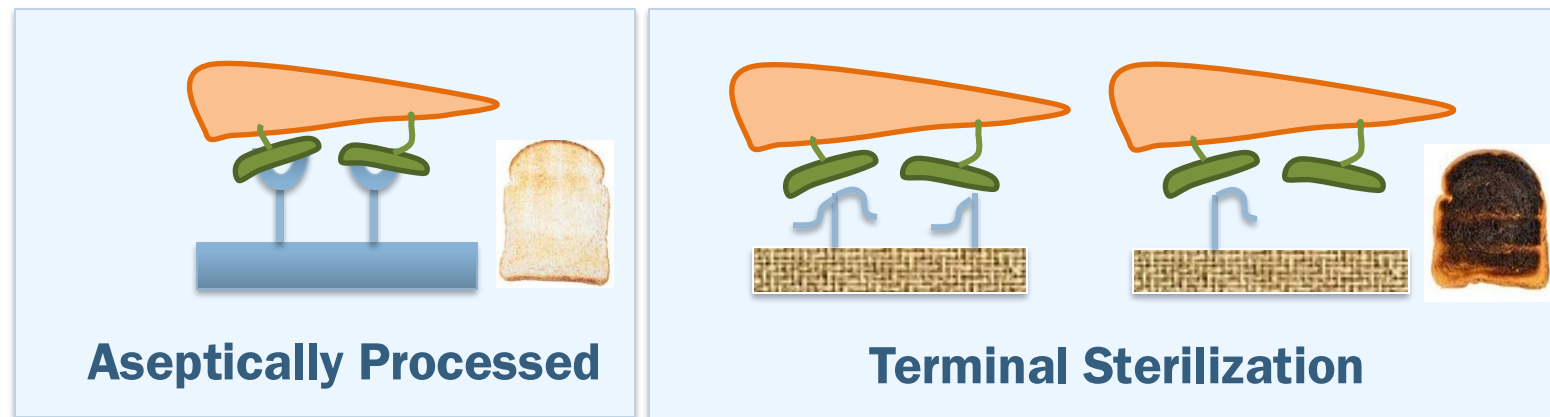


4-16-20



Processing Matters!

- **Terminal sterilization (irradiation) alters tissue properties of native tissue**
 - Denatures tissue structure and matrix proteins
 - Compromises graft quality for cell attachment and cell signaling function
- **Aseptic processing provides safe, high-quality tissue most similar to native (autograft) tissue**
 - Achieves the **same** sterility (SAL 10^{-6}) as terminally sterilized tissue
 - Preserves tissue structure, matrix proteins, and signaling cues
 - **Highest quality graft > solid foundation**



Failed flap with incorporating hADM

4-21-20



4-28-20



4-28-20



5-5-20



5-22-20



6-26-20



7-17-20
dHACA 3x4



8-7-20
dHACA 2x4



8-21-20
Healed



79y Female with CAD s/p fall with infected hematoma and TKA on ipsilateral knee

10-4-23



10-5-23



10-5-23



hADM, non-adherent layer and NPWT weekly changes

10-10-23



10-17-23



10-23-23



Transition to placental tissue vs STSG

11-28-23



12-5-23



2-5-24



80y Male, PMH: Obesity, COPD, equinovarus deformity with foot drop

- 2 wks s/p TTC fusion with IM nail 2 wks postop posterior heel DTI in rehab
- Plastics consulted for flap closure, but deemed poor surgical candidate
- Debridement down to hardware and hADM

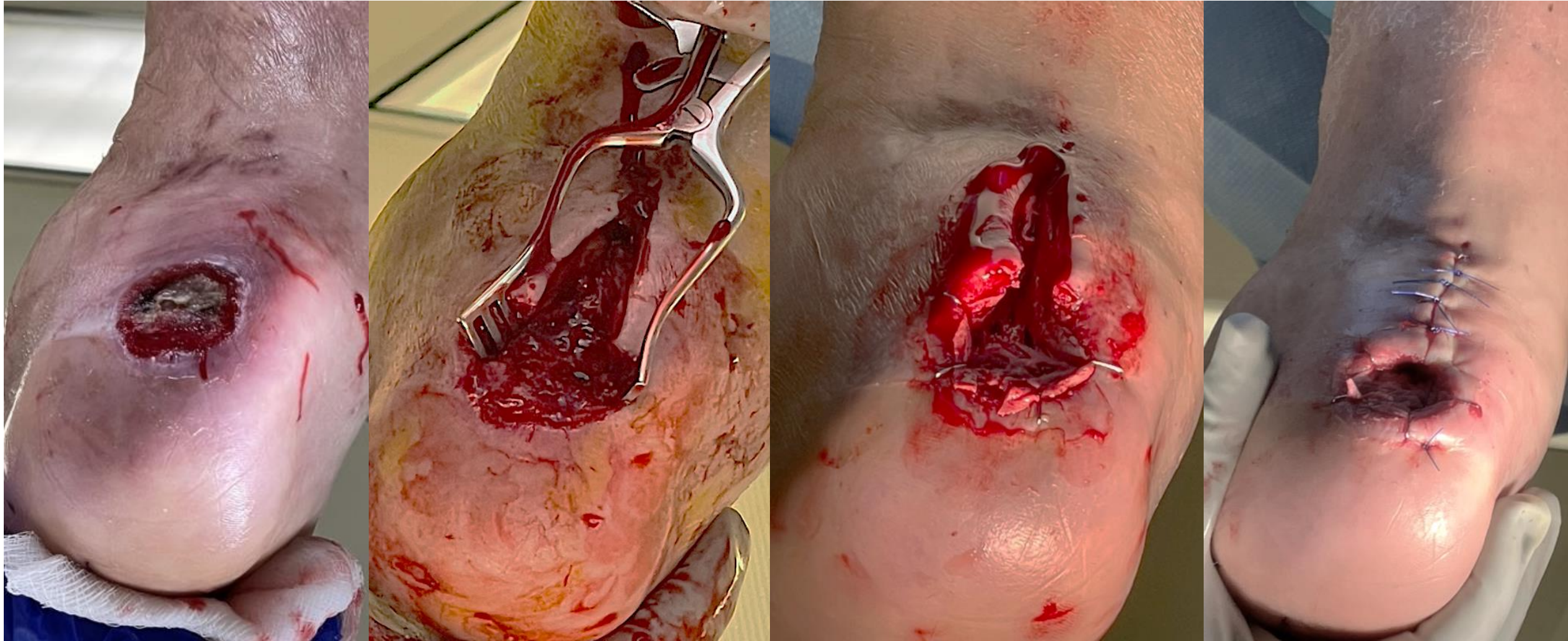
POV 2 wks



POV 4 wks



- Recurrent DTI 3 wks after hADM
- Developed Group B strep cellulitis w/bacteremia
- CT scan NEG for lucency around screw
- Bone debridement, excision of Achilles repeat hADM + NPWT w/vancomycin powder



- NPWT wkly 6 wks s/p hADM
- Hardware and bone covered at 4 wks postop
- Initiate dHACA applications

6-28-22



7-12-22



7-19-22



- d/c NPWT and dHACA every other wk

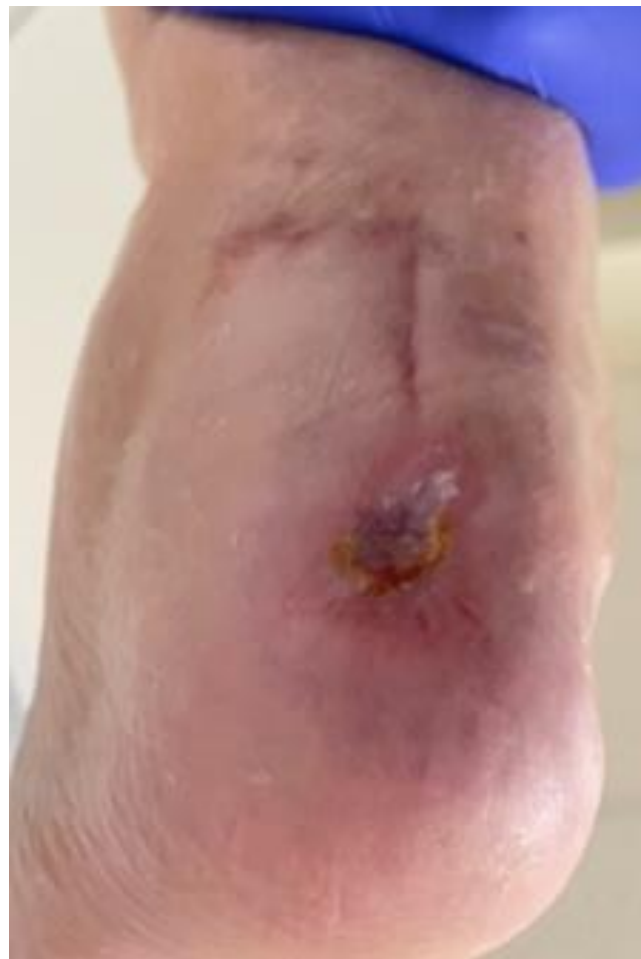
8-9-22



8-23-22



8-30-22



9-20-22

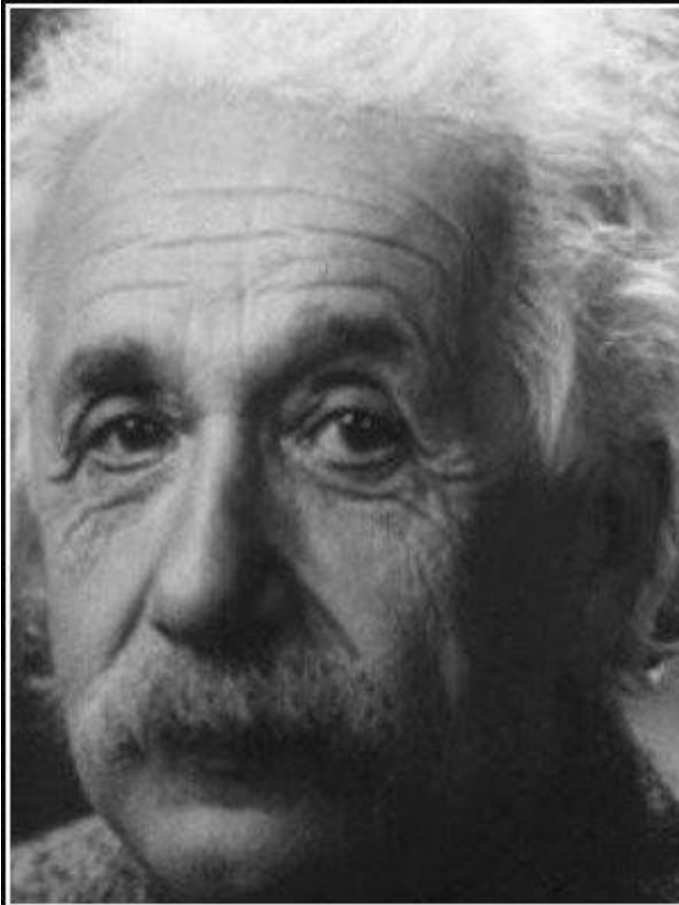


Reticular Acellular Dermis: Where Does It Fit in the Reconstructive Matrix?

Edward S. Lee, MD, MS

Division Chief, Plastic and Reconstructive Surgery
Residency Program Director, Integrated Plastic Surgery
Rutgers Health – New Jersey Medical School
The University Hospital, Newark, NJ

Clinical Pearls

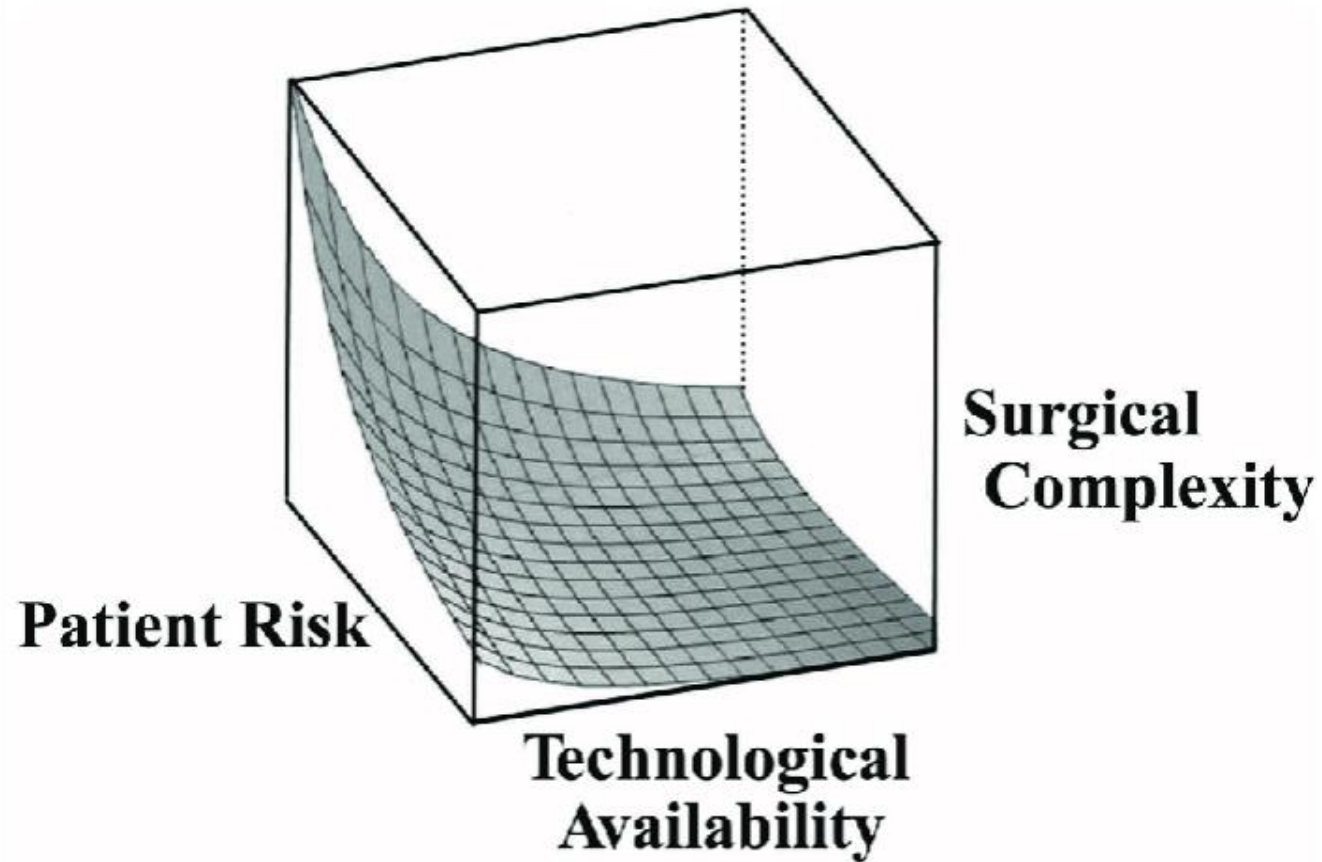


If I had an hour to solve a problem and my life depended on the solution, I would spend the first 55 minutes determining the proper question to ask, for once I know the proper question, I could solve the problem in less than five minutes.

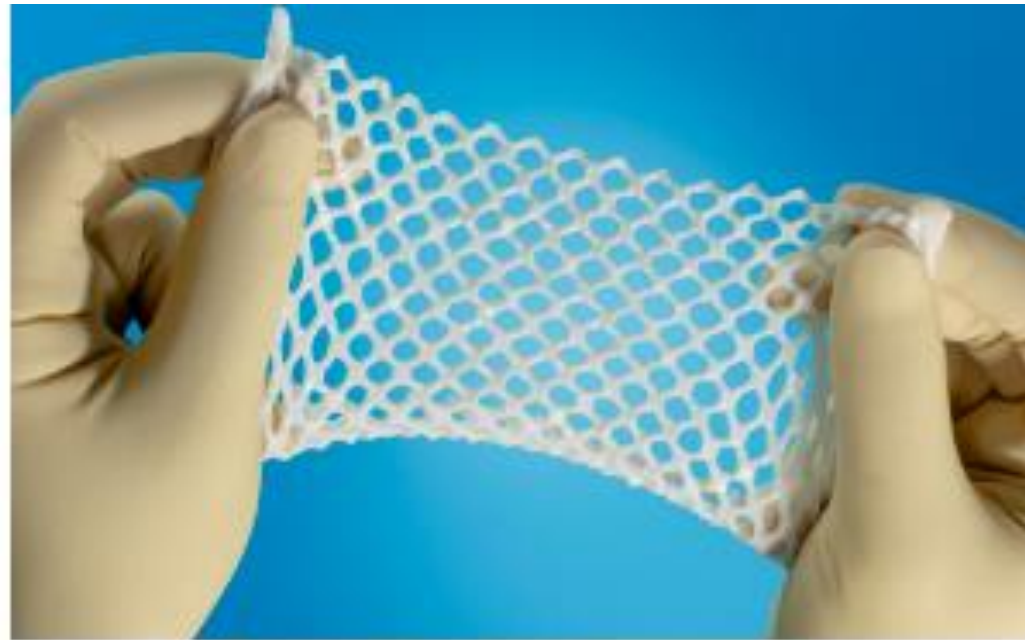
— *Albert Einstein* —

AZ QUOTES

Reconstructive Matrix



The optimal reconstructive strategy must be individualized using the "reconstructive matrix 5" to map a hyperbole unique for each patient. The axes of this three-dimensional model depend on the surgical complexity of the reconstructive challenge, the technological capabilities available for the reconstructive surgeon, and the patient risk factors that would include their comorbidities and expectations for restoration of both form and function.



The Greatest Closer of All Time

What Makes Him Special?



Do You See the Difference in the Grip?





Info



Watch later



Share

Press **esc** to exit full screen



SUBSCRIBE



0:40 / 2:40



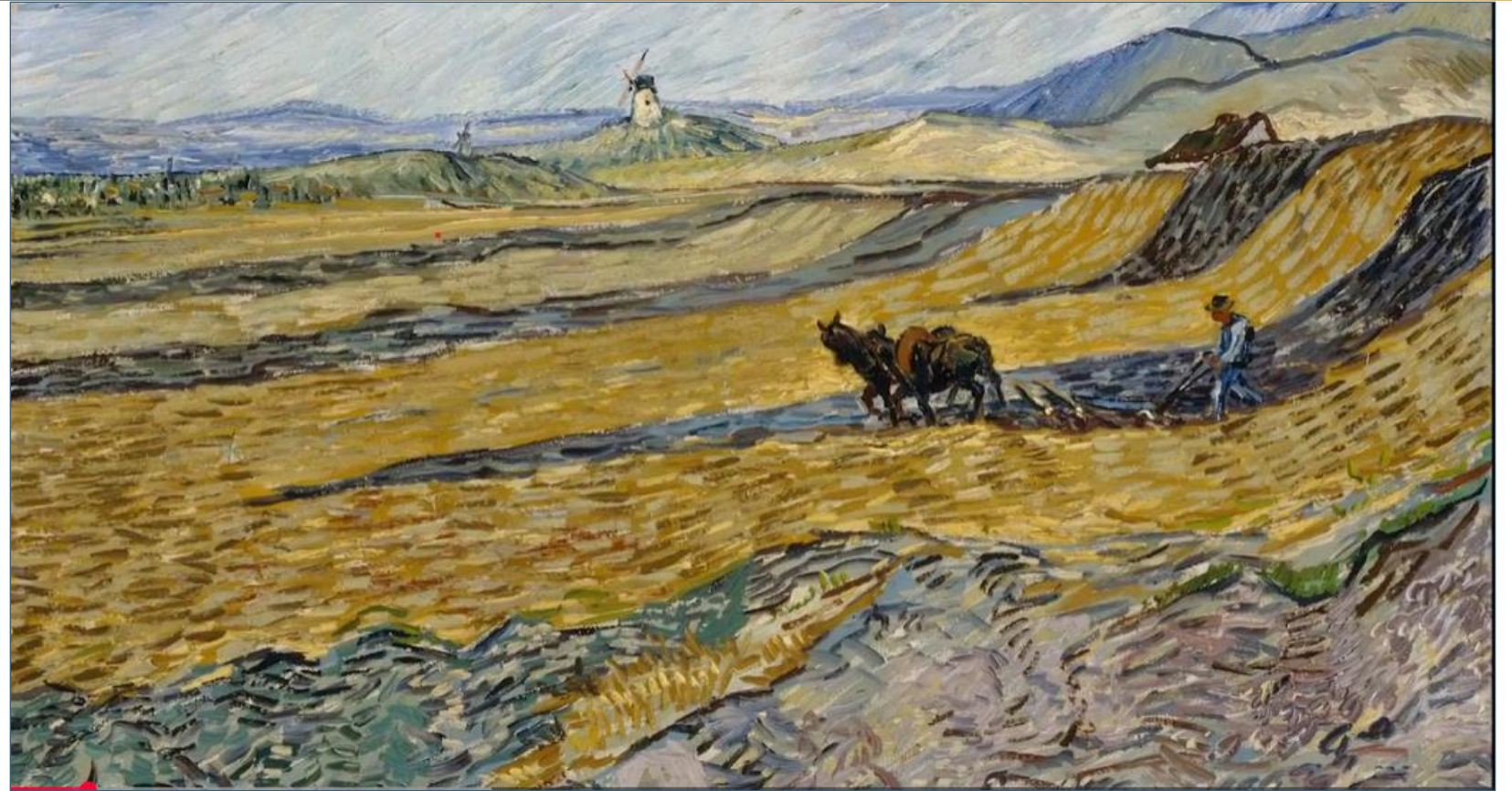
YouTube



Characteristics of the Greatest Closer of All Time?

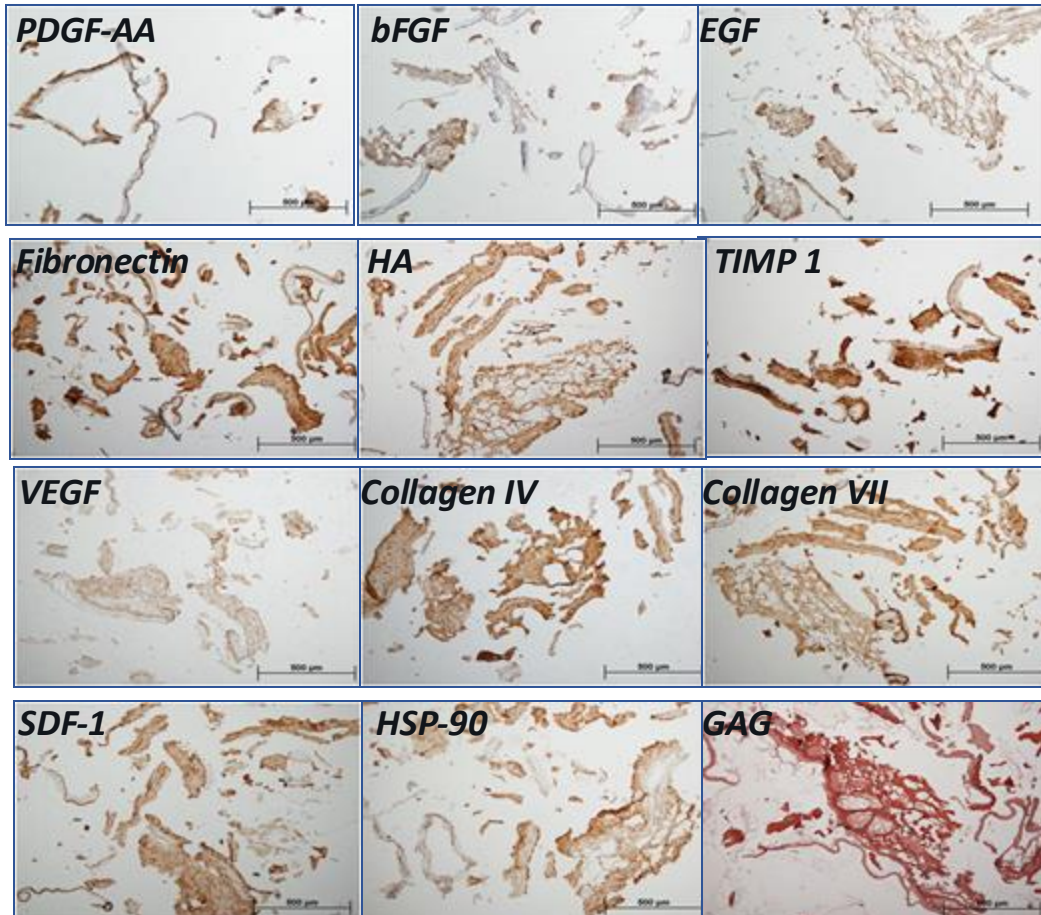
- ADM that looks like others, but isn't
- Epithelialization
- Fill soft-tissue defects
- Granulation tissue formation

- Blood flow
- Debridement
- Fluid control
- Microbiologic control
- Intrinsic and extrinsic factors



A great pitcher needs a great catcher — you've gotta prepare the soil before you can plant the crops.

Biological Components Preserved in Mini Membranes



Growth Factors and Cytokines	Native Function	Matrix Proteins	Native Function
B-defensin	Anti-microbial ⁷⁻¹⁰	Col I	Scaffolding for Cell Migration and Cell Attachment ²²⁻²⁴
IL-6; IL-10	Anti-inflammatory ¹¹⁻¹⁶	Col III	
PDGF-AA; PDGF-BB	Angiogenic ¹⁷⁻²¹	Col IV	
EGF	Cell Proliferation and Remodeling ¹⁷⁻²¹	Col VI	
FGF-2		Fibronectin	
TGF		Hyaluronic Acid	

- 75y female, s/p fall
- Multiple fractures, including open tibia... undergoes IM nail... but then keeps having cardiac events, no general anesthesia











Complicated: Diabetes, peripheral vascular disease, blood flow, infection, inflammation







- 57y Male
s/p MVA
- Multiple
fractures
- Open tib-fib
- Repaired,
local flap
- Abscess
- Refused
additional
surgery: “If
you cut me,
I’ll cut you!”



**Amnion/chorion
mini membrane**



**Reticular dermal
matrix**



**2 wks postop,
NPWT ongoing**

72y Female, Afib on anticoagulation, syncopal fall, tib-fib fracture, abscess, and osteomyelitis after another fall



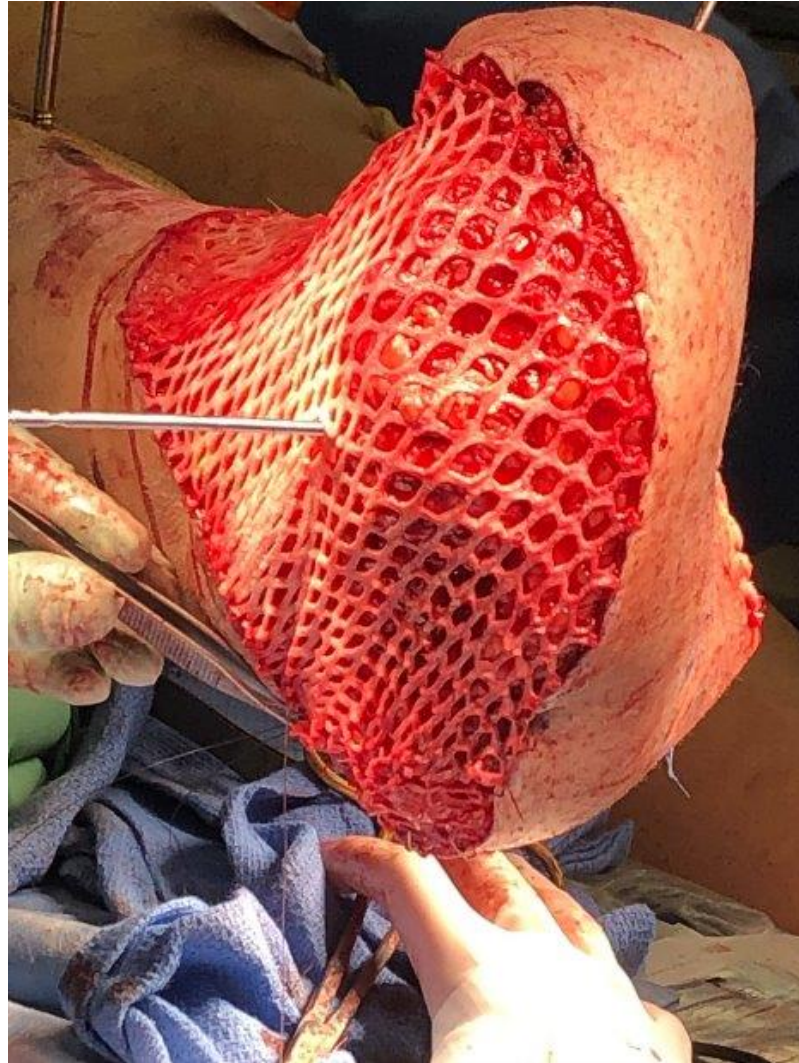
Success and Failure: Case AFM



Case AFM



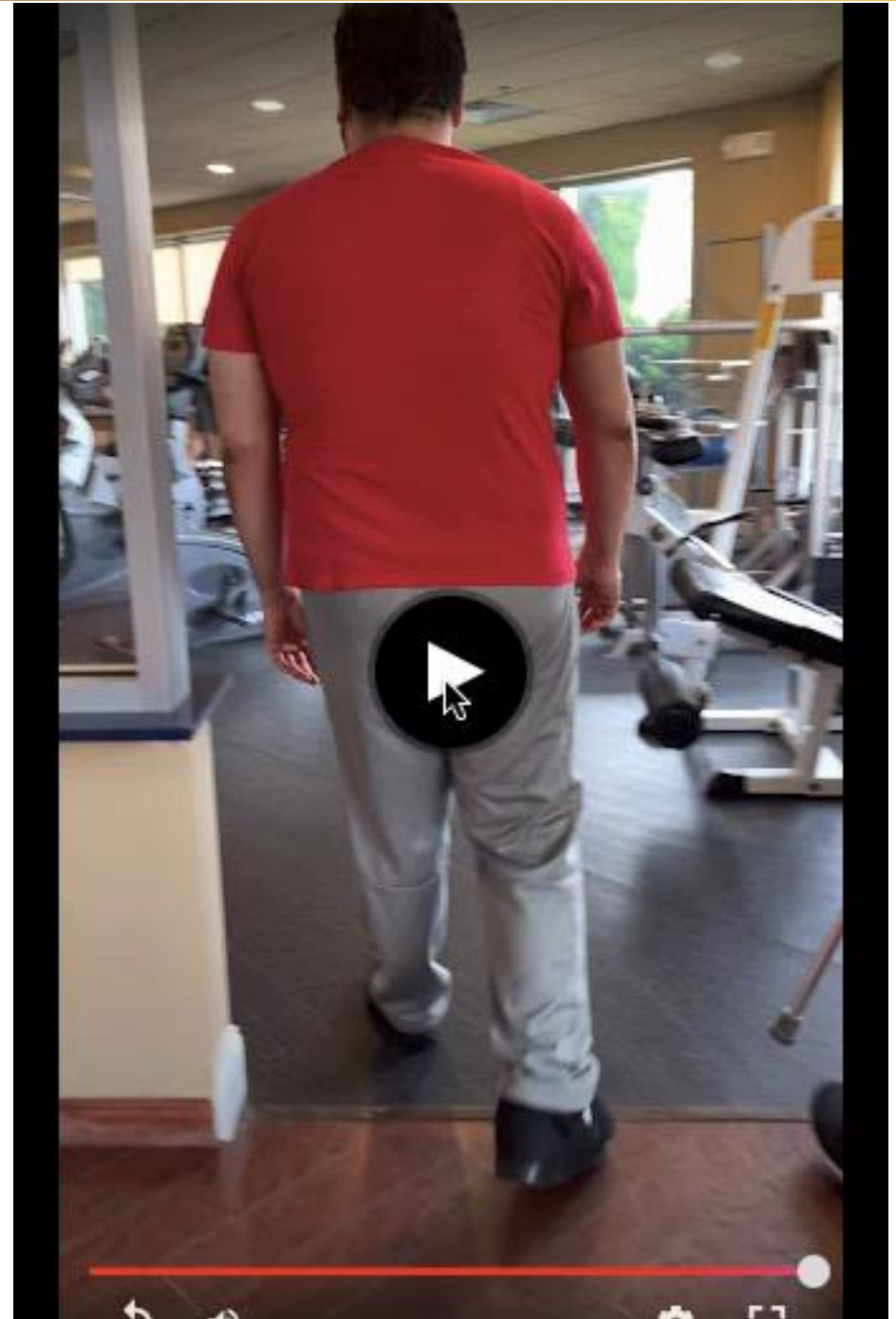
Case AFM



Case AFM



Case AFM



Clinical Pearls

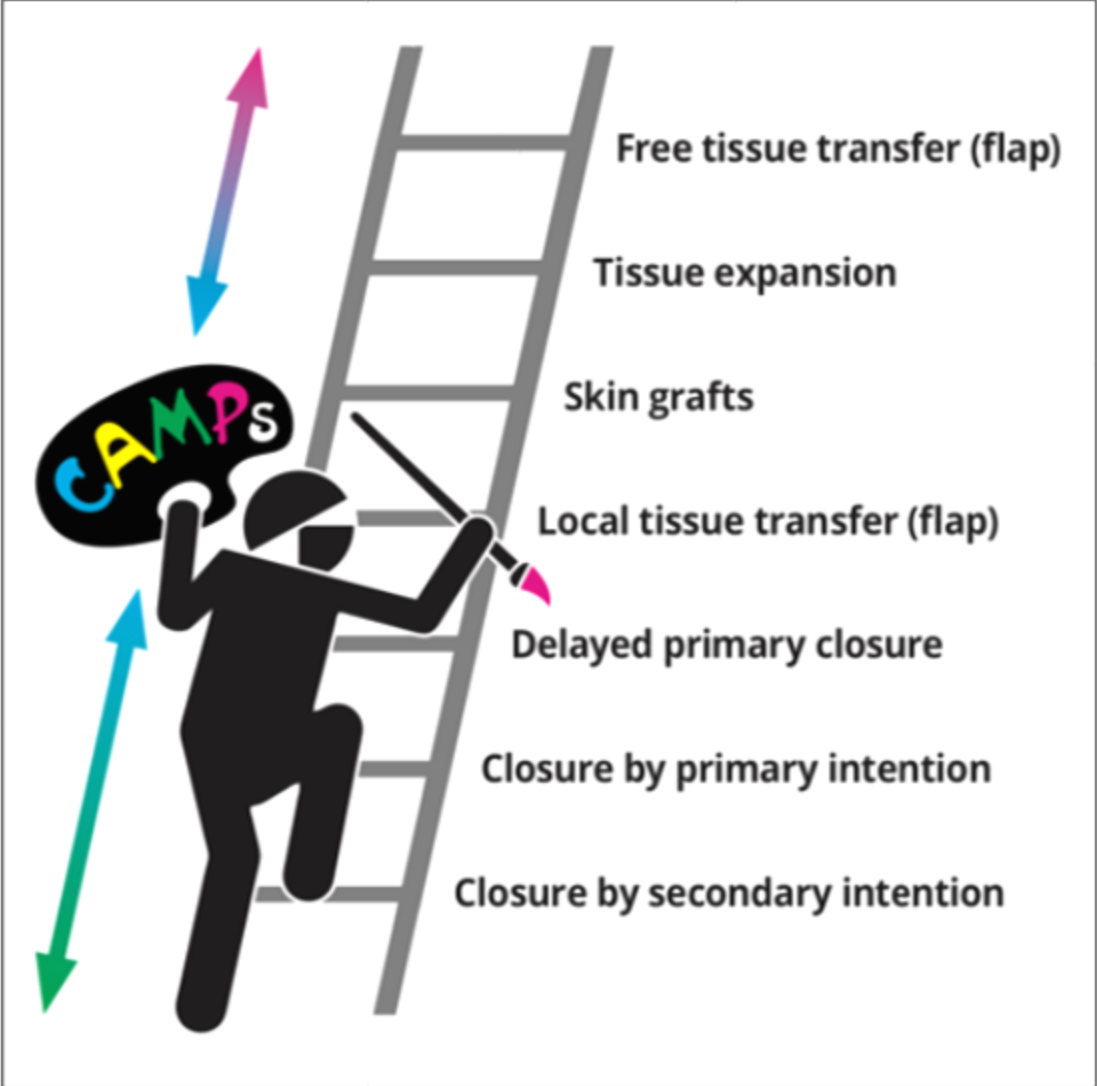
- Optimize the wound bed
 - Debridement
 - Host factors
- Level the playing field
- Will ADM or dHACM help?
 - Soft tissue fill
 - Accelerate granulation and re-epithelialization
 - Improve vascularity, edema, and microbiology

Reconsidering the Reconstructive Ladder

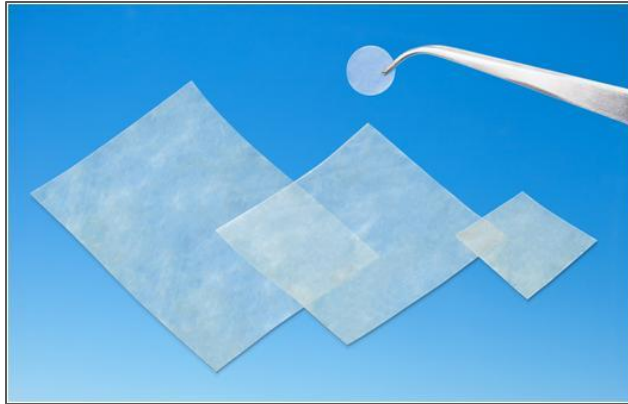
Michael N. Desvigne, MD, FACS, CWS, FACCCWS

Plastic and Reconstructive Surgery
Wound Care and Hyperbaric Medicine
Abrazo Arrowhead Hospital and Wound Clinic
Glendale, AZ

Reconstructive Ladder

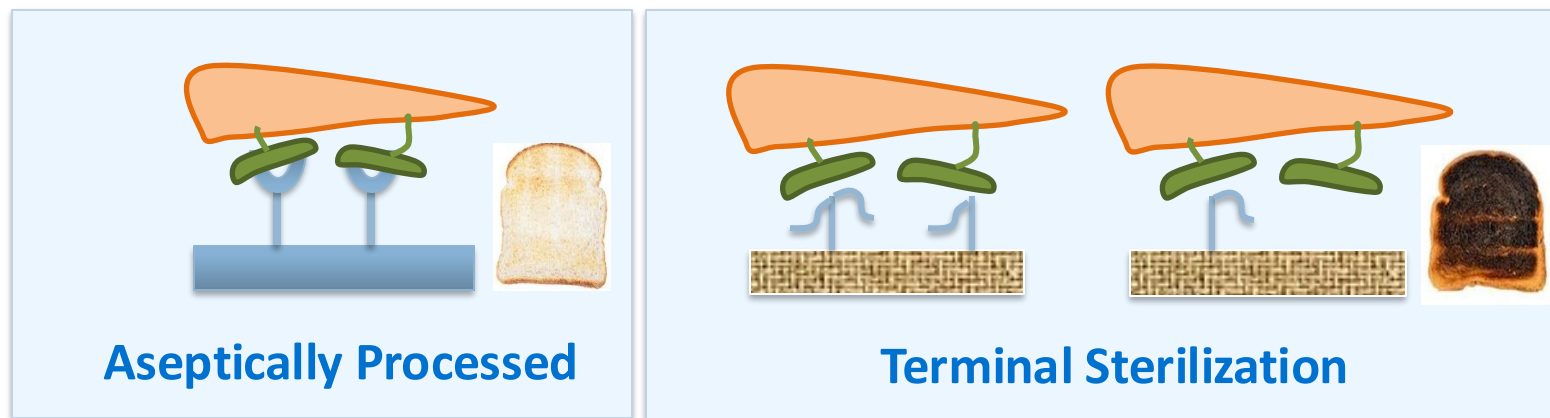


Placental, Dermal, and Adipose: Wound and Surgical Care Innovations



Processing Matters!

- **Provides safe, quality tissue most similar to native, autograft tissue**
 - Achieves the same sterility (SAL 10^{-6}) as terminally sterilized tissue
 - Preserves tissue structure, matrix proteins, and signaling cues
- **Terminal sterilization alters tissue properties of native tissue**
 - Denatured tissue structure and matrix proteins
 - Compromised binding sites for cell attachment and cell signaling function



Algorithmic Approach to Complex Wounds

- **Wound management**

- Debridement of non-viable tissue and bioburden control
- Cellular proliferation — wound bed preparation
- Dermal replacement — wound bed preparation and/or closure

- **Incisional management**

- Cellular proliferation — wound bed preparation to optimize healing
- Peri-incision optimization — reduce edema, reduce tension, recruit tissue

- **Anticipating post-surgical complications**

- Cellular proliferation — optimizing underlying wound bed
- Dermal replacement and/or soft tissue scaffolding — coverage of critical structures

- **Optimizing surgical outcomes**

- Cellular proliferation — optimize incisional healing
- Dermal replacement and/or soft tissue scaffolding — additional soft tissue support

Why Be Concerned about Surgical Incisions?

- 8.2 million people at risk for surgical site infection (SSI) annually
- SSIs are 21.8% of all healthcare-associated infections (HAIs)
- Complications with incisions can lead to serious consequences
 - Of the top 5 HAIs, SSI is 33.7% of the \$9.8 billion cost to the U.S. healthcare system year
 - SSIs increase average length of hospital stay to an extra 9.58 days at an additional cost of \$38,656
 - Other common complications include dehiscence, hematoma, and seroma formation

The Centers for Medicare & Medicaid Services emphasizes the need to decrease costs and improve care by identifying hospital-acquired conditions that will NOT be reimbursed, including 3 SSIs

SSI = surgical site infection; HAI = healthcare-associated infection.

Zimlichman E, et al. *JAMA Intern Med.* 2013;173(22):2039-2046. Magill SS, et al. *N Engl J Med.* 2014;370(13):1198-1208. Shepard J, et al. *JAMA Surg.* 2013;148(10):907-914. Riou JP, et al. *Am J Surg.* 1992;163(3):324-330. Wilson JA, Clark JJ. *Adv Skin Wound Care.* 2004;17(8):426-435. Abbas SM, Hill AG. *ANZ J Surg.* 2009;79(4):247-250.

High-Risk Patients

- Comorbidities
- Obesity
- Smoking
- Reoperation

Unaffordable Surgical Complications

- **Vascular**
 - Avoiding GRAFT exposure
- **Neurosurgery**
 - Avoiding CRANIUM or DURA exposure
- **Ortho and podiatry**
 - Avoiding HARDWARE or TENDON exposure
- **General surgery, surgical oncology**
 - Avoiding MESH exposure
- **Plastic surgery**
 - Avoiding IMPLANT exposure

Placental Allograft Mini Membrane



Biological Properties of Amnion/Chorion

From published literature, demonstrated to be

- Non-immunogenic: Cells do not express HLA-A and -B antigens
- Anti-adhesive/anti-scarring: Limits fibroblast activity, reduces risk of fibrosis
- Anti-inflammatory: Inhibits expression of inflammatory cytokines
- Anti-microbial: Adheres closely to wound, contains anti-microbial peptides

Case Summary: Panniculectomy

- 63y female with ventral hernia and excessively large pannus presents for hernia repair and panniculectomy
- Medical history: Chronic neck pain, HTN
- Surgical history: Previous hernia repair
- Treatment
 - Taken to OR for ventral hernia repair and panniculectomy
 - Salera[®] Mini Membrane (placental allograft) placed to optimize healing
 - NPT initiated with NPT incisional management immediately following closure

Panniculectomy (Day 1)



Panniculectomy (Day 1)



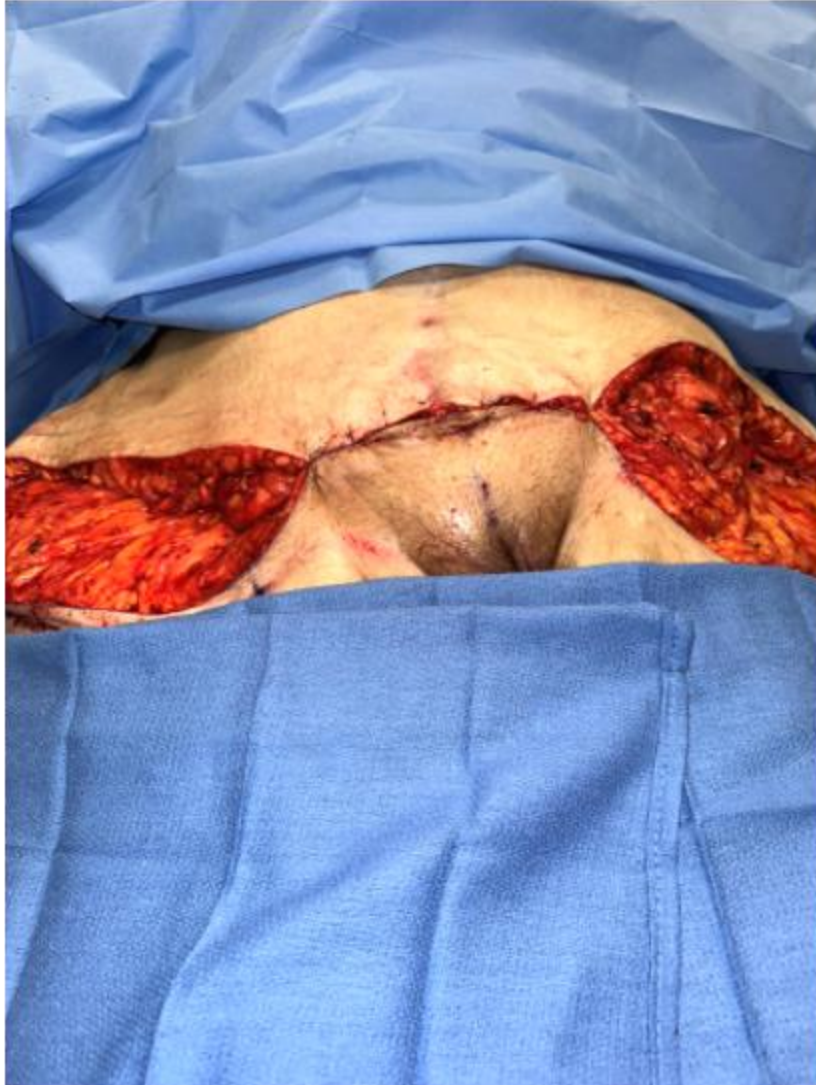
Panniculectomy (Day 1)



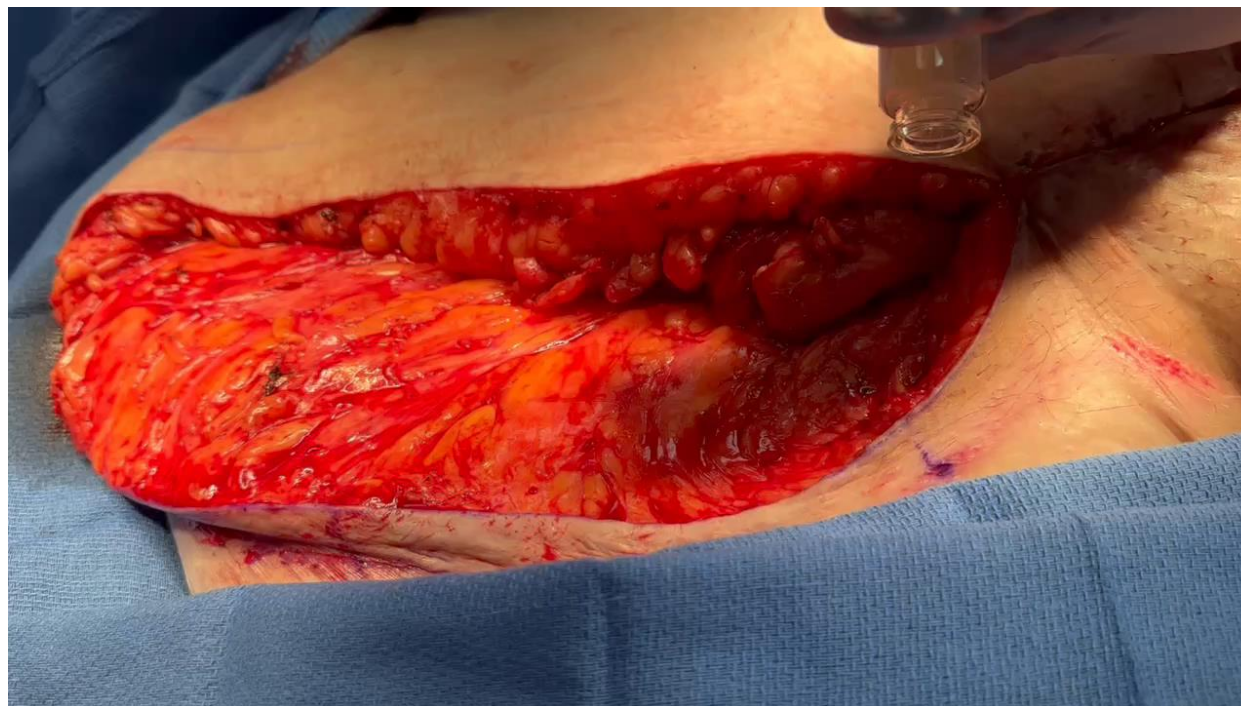
Panniculectomy (Day 1)



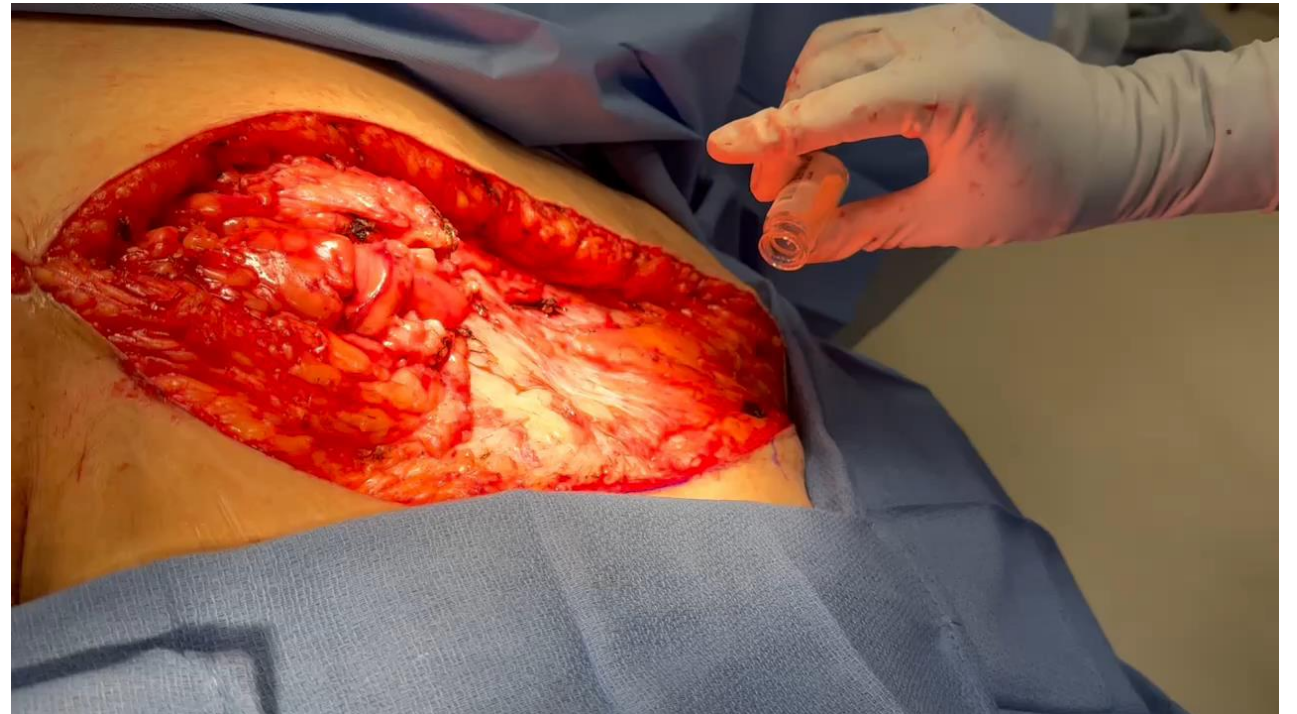
Panniculectomy (Day 1)



Panniculectomy (Day 1)



Panniculectomy (Day 1)



Panniculectomy (Day 1)



Panniculectomy (Day 1)



Panniculectomy (Day 14)



Panniculectomy (Day 21)



Panniculectomy (Day 28)

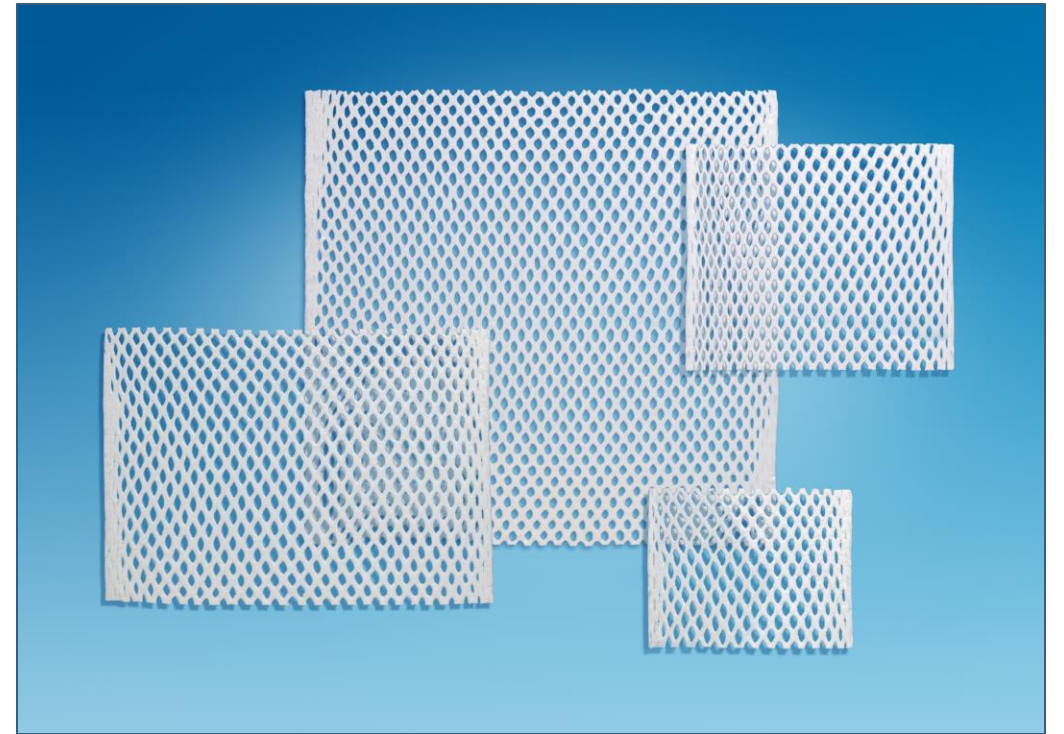


Panniculectomy (Day 28)



HR-ADM Key Benefits

- SomaGen[®] Meshed human reticular acellular dermal matrix (HR-ADM)
- Ready-to-use allograft saves OR time
- Pliable, conforms to the anatomy
- Compatible with advanced wound care modalities like NPWT
 - Designed to be used with NPWT
- Versatile meshing ratio addresses a variety of wound sizes/needs
- Available in 4 sizes that cover areas ranging from 48 cm² to 476 cm²
- 18-month shelf life at ambient temperature



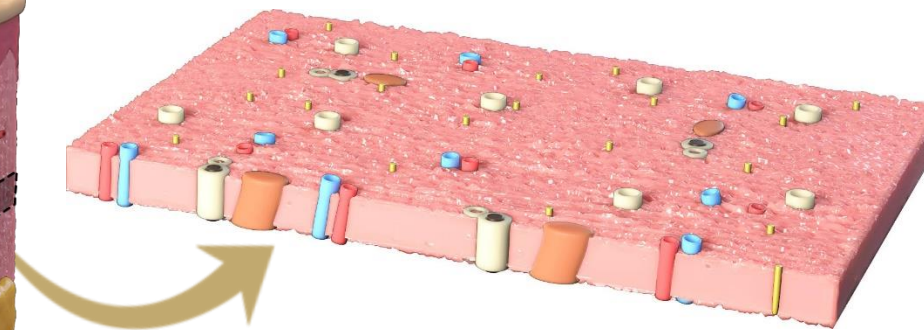
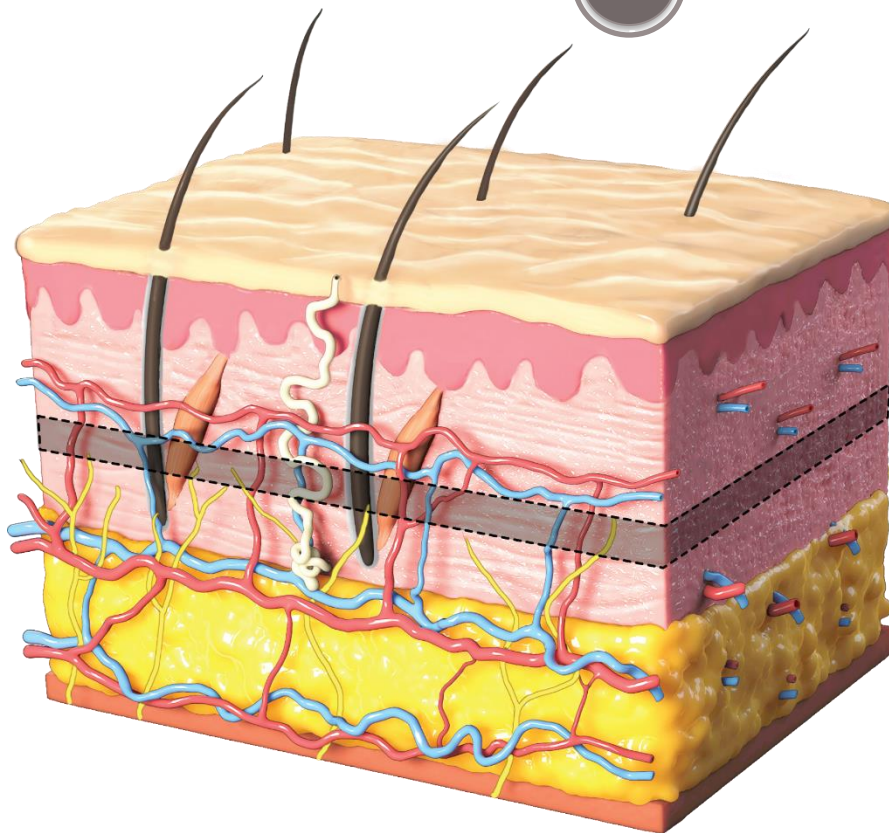
HR-ADM Meshed:

From donor to recipient...



2

Deep reticular layer isolated

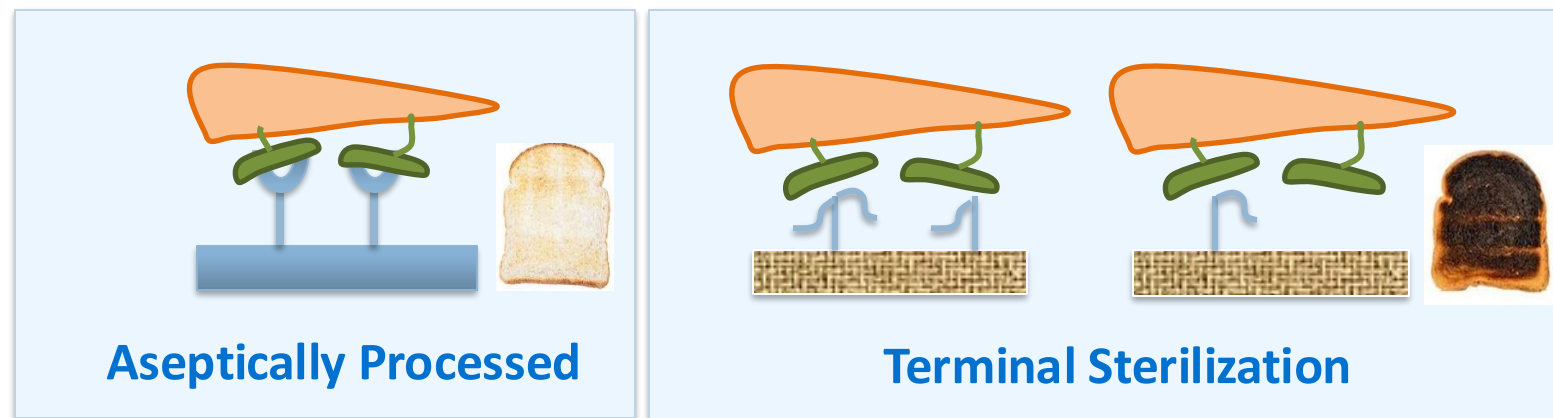


Novel Deeper Dermal Layer

- More open tissue structure
- Supports cell attachment/infiltration
- Facilitates graft integration

Processing Matters!

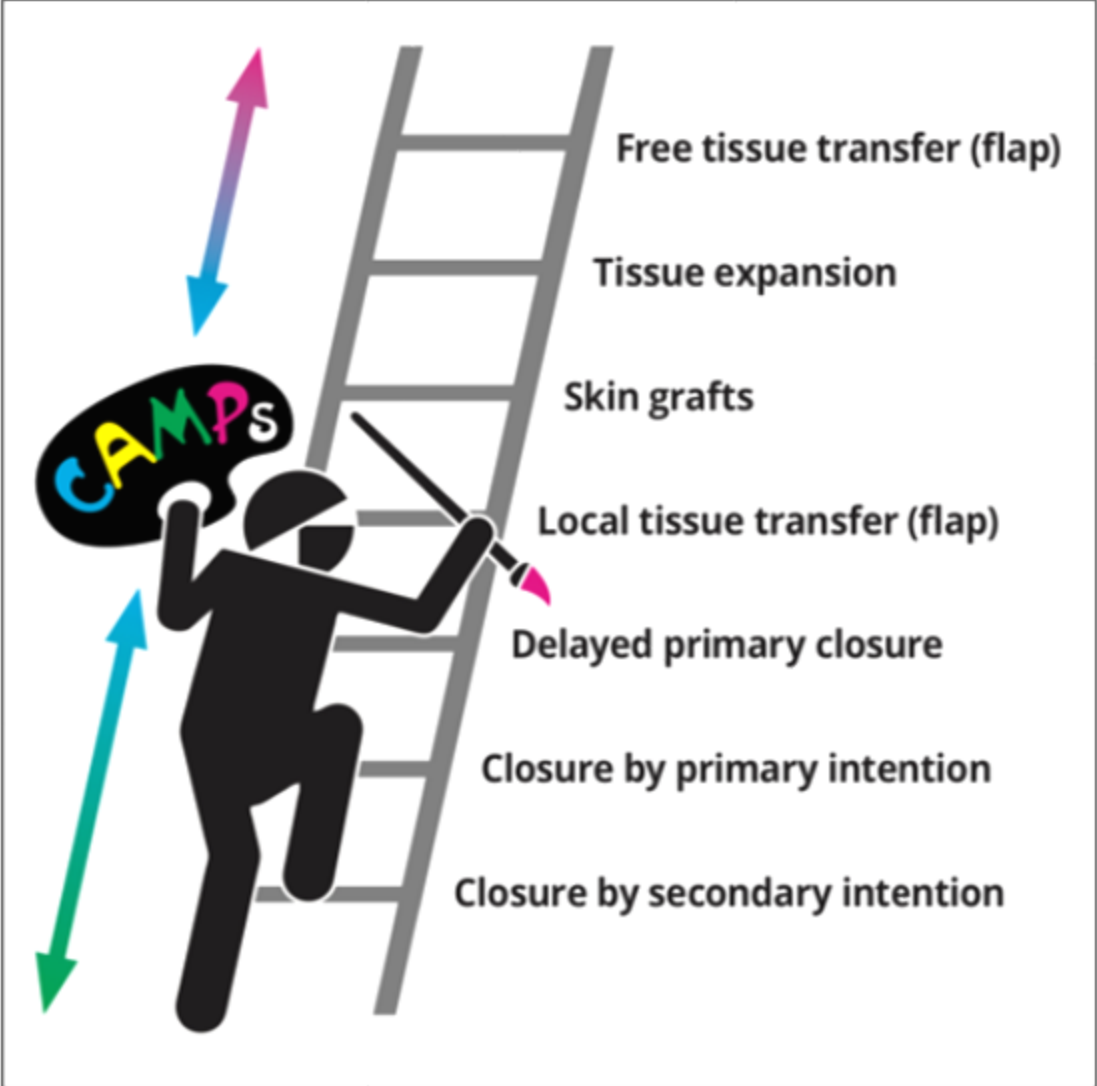
- **Provides safe, quality tissue most similar to native, autograft tissue**
 - Achieves the same sterility (SAL 10^{-6}) as terminally sterilized tissue
 - Preserves tissue structure, matrix proteins, and signaling cues
- **Terminal sterilization alters tissue properties of native tissue**
 - Denatured tissue structure and matrix proteins
 - Compromised binding sites for cell attachment and cell signaling function



HR-ADM Incorporates



Reconstructive Ladder



Case Summary: Melanoma Upper Back

- 57y Female presented to general surgery with a fungating tumor in the upper back, biopsy-proven melanoma
- Medical history: No CAD, DM, HTN
- Treatment
 - Taken to OR for excision and lymph node dissection
 - HR-ADM placed as tissue scaffolding for soft tissue replacement AND just in case Plan A fails
 - NO dHACA placed
 - NPT initiated with PREVENA™ (incisional NPT customizable dressing) immediately following closure

Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 1)



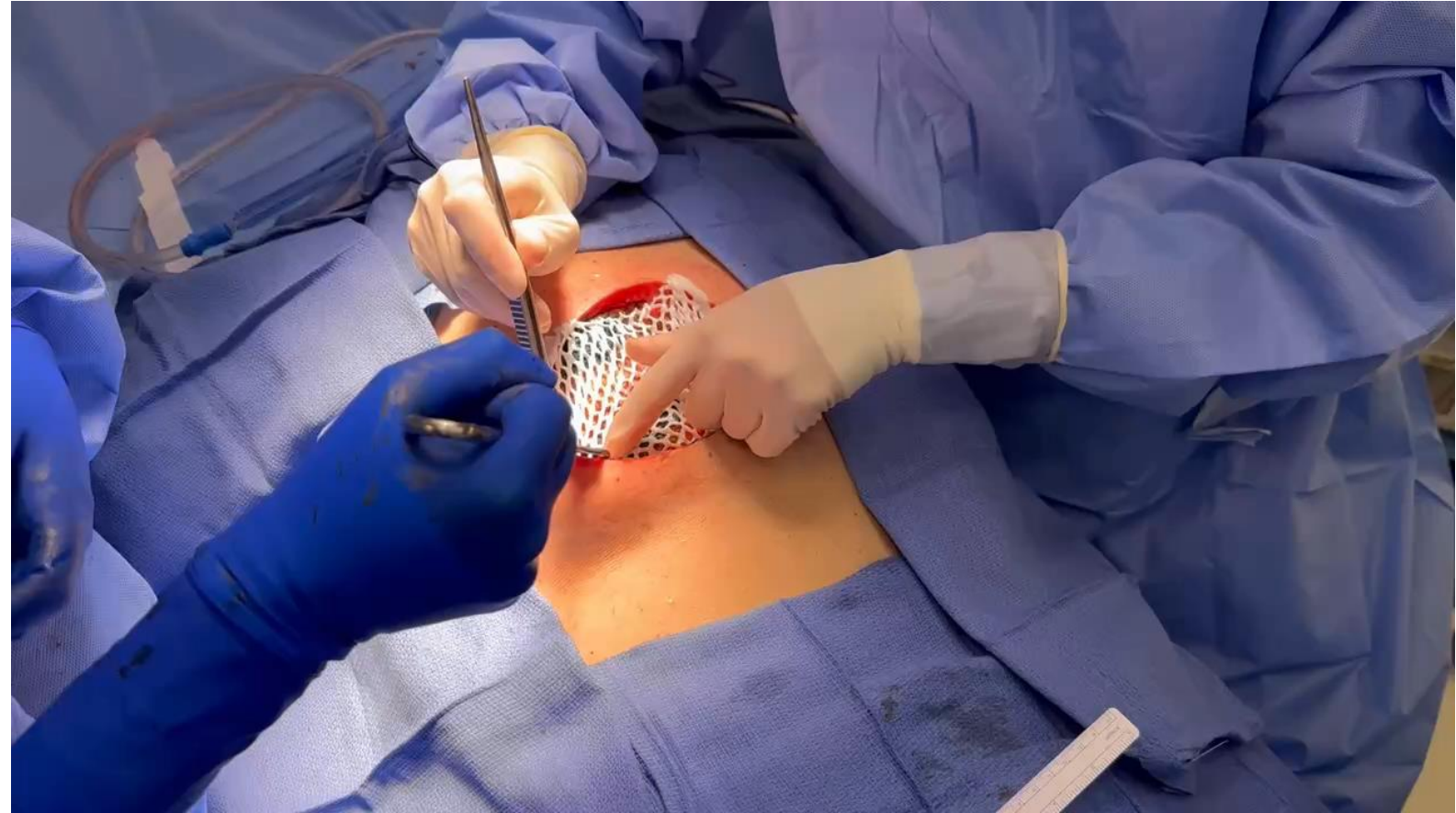
Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 1)



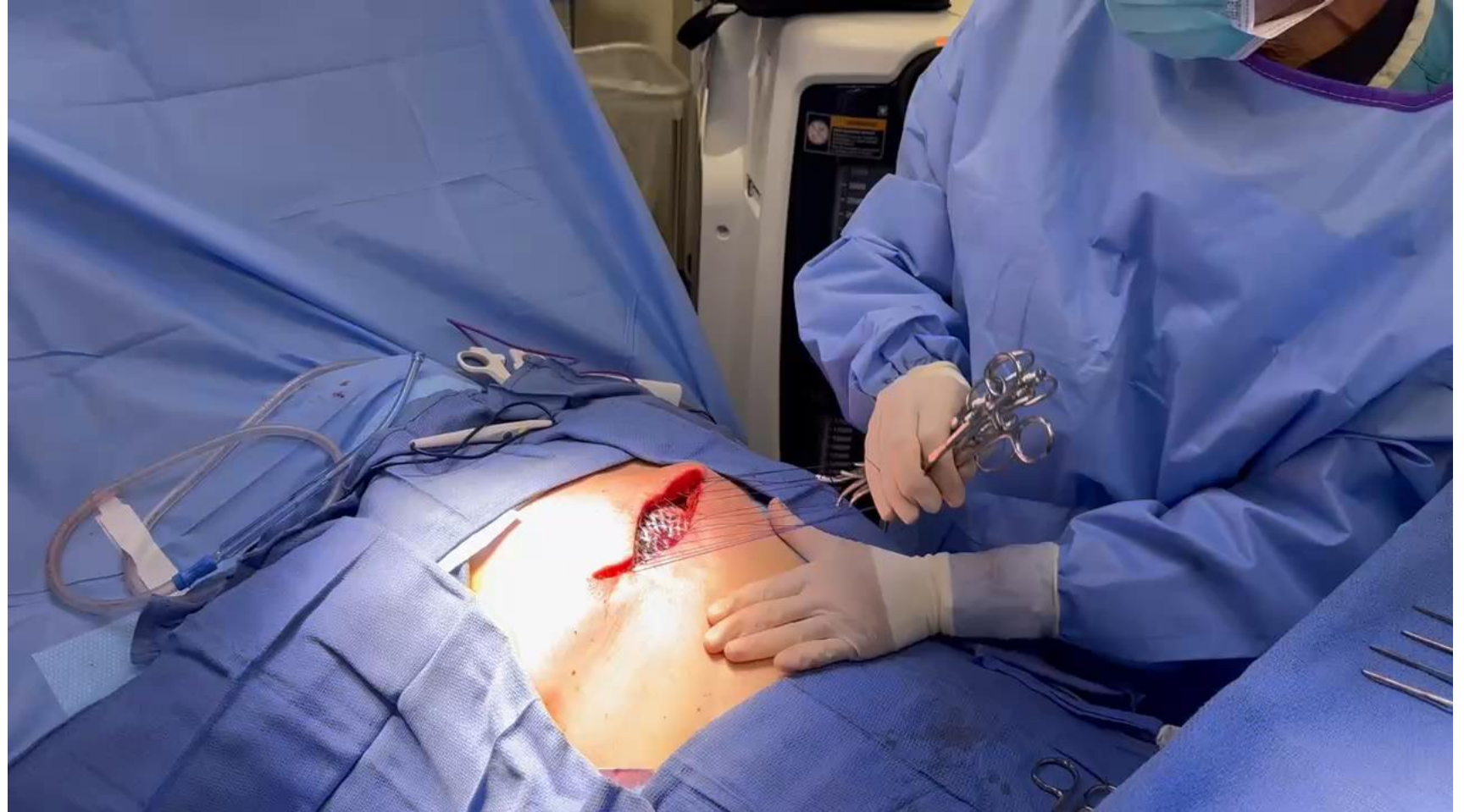
Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 1)



Melanoma, Upper Back (Day 14)



Melanoma, Upper Back (Day 21)



Melanoma, Upper Back (4 Wks)



Melanoma, Upper Back (6 Wks)



Melanoma, Upper Back (8 Wks)



Melanoma, Upper Back (12 Wks)



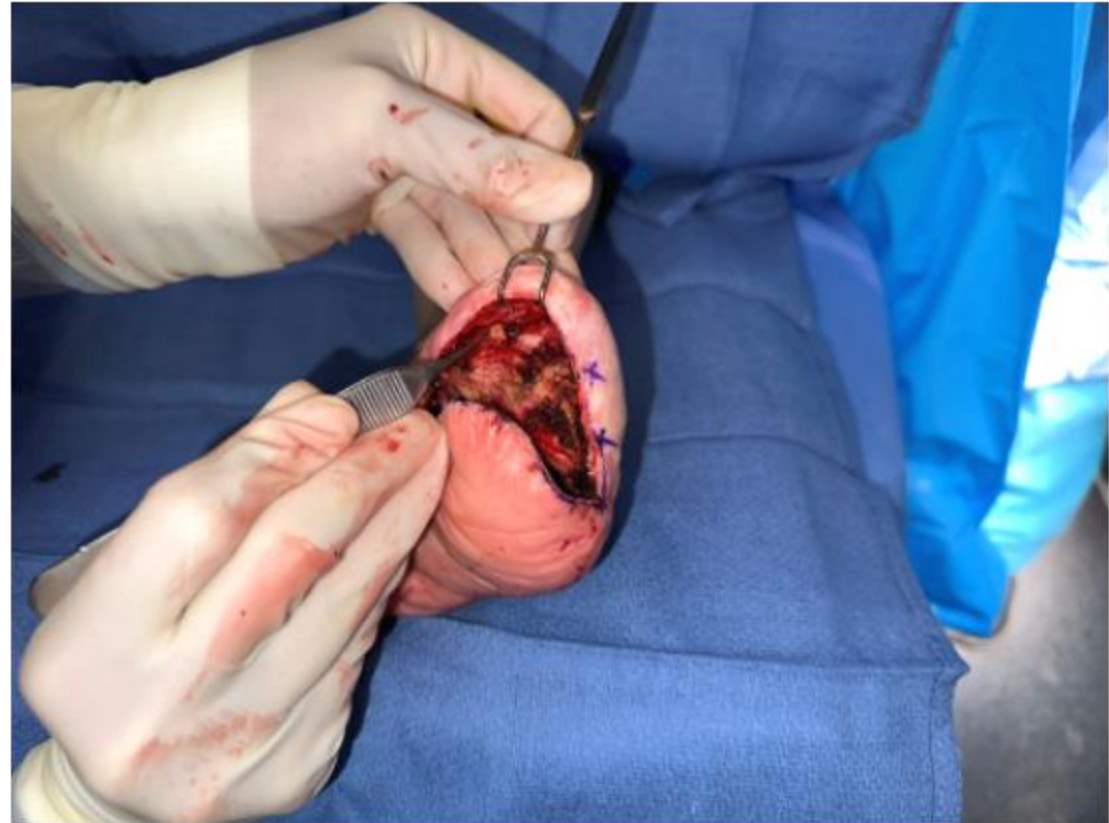
Case Summary: Painful Neuroma following Bilateral TMAs

- 46y Female s/p episode of severe sepsis requiring prolonged ICU care with pressor support. Underwent bilateral TMAs and upper extremity partial amputations. Developed painful neuroma left foot, limiting ambulation.
- Medical history: Previous gastric bypass for obesity
- Treatment
 - Taken to OR for revision TMA
 - Definitive closure performed with AlloPatch[®] (reticular dermal matrix) placed as tissue scaffolding over bone
 - Leneva[®] (adipose allograft matrix [AAM]) placed for additional soft tissue replacement
 - Placental allograft placed to optimize healing
 - NPT initiated with an incisional NPT immediately following closure

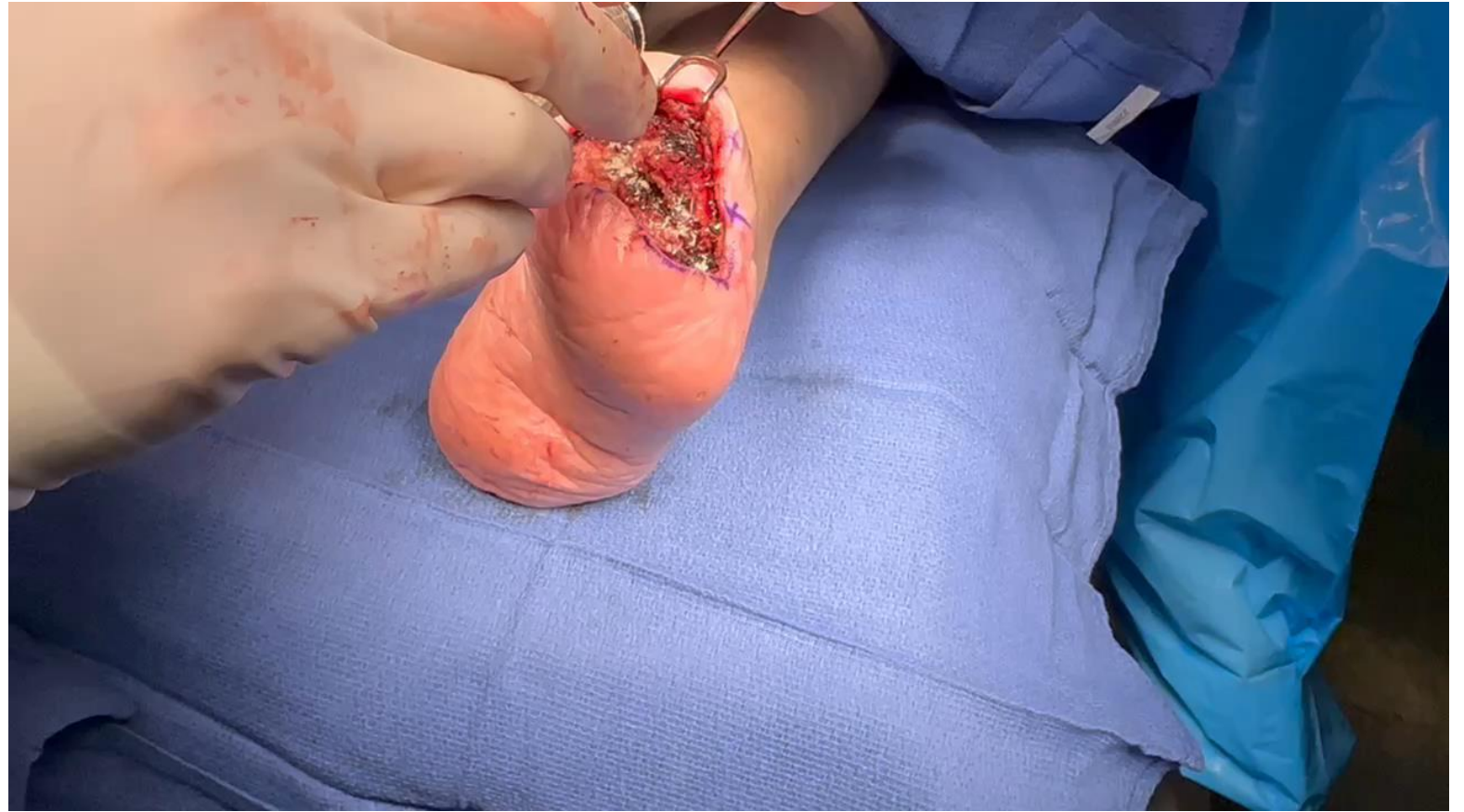
Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 1)



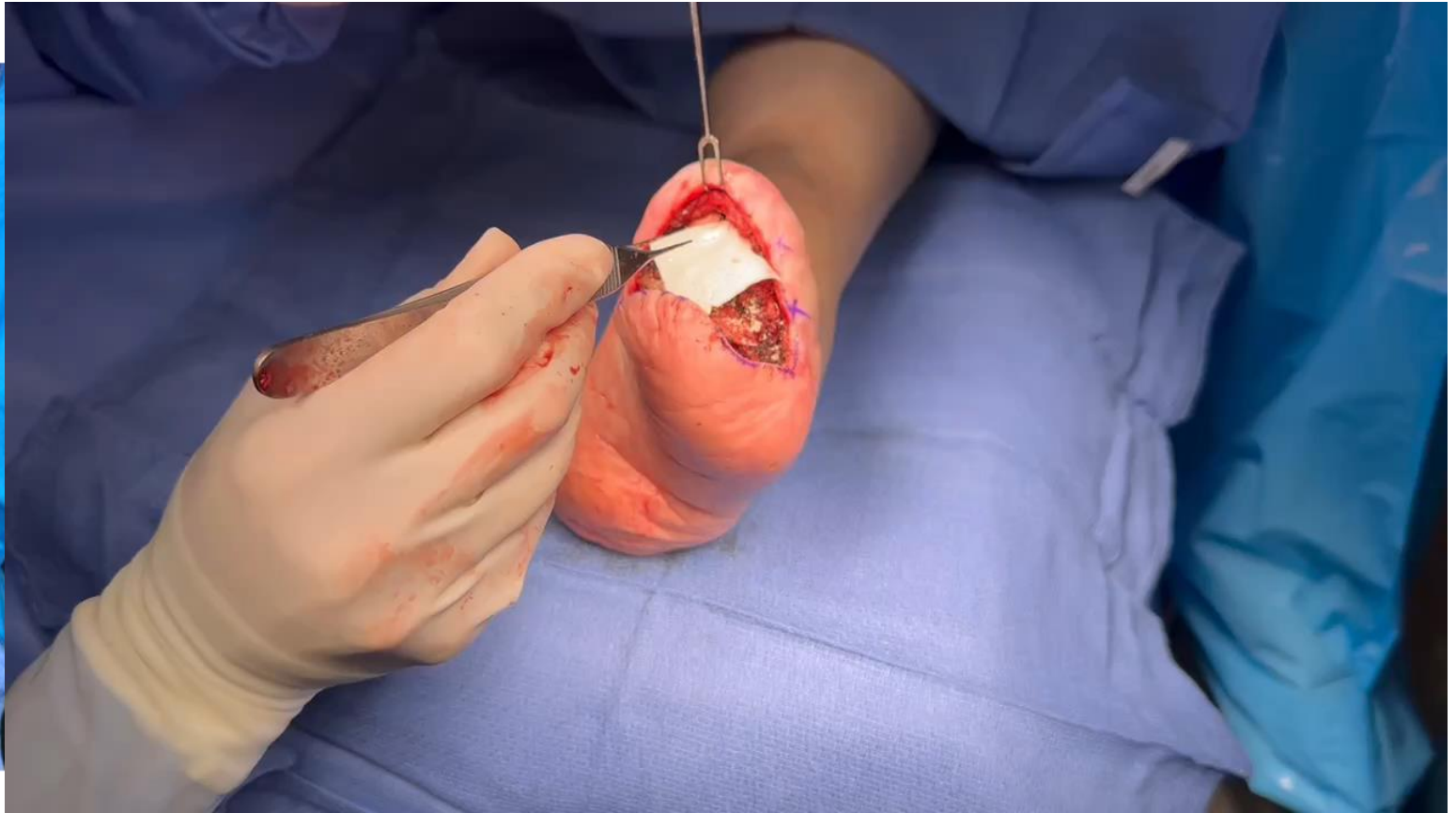
Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 1)



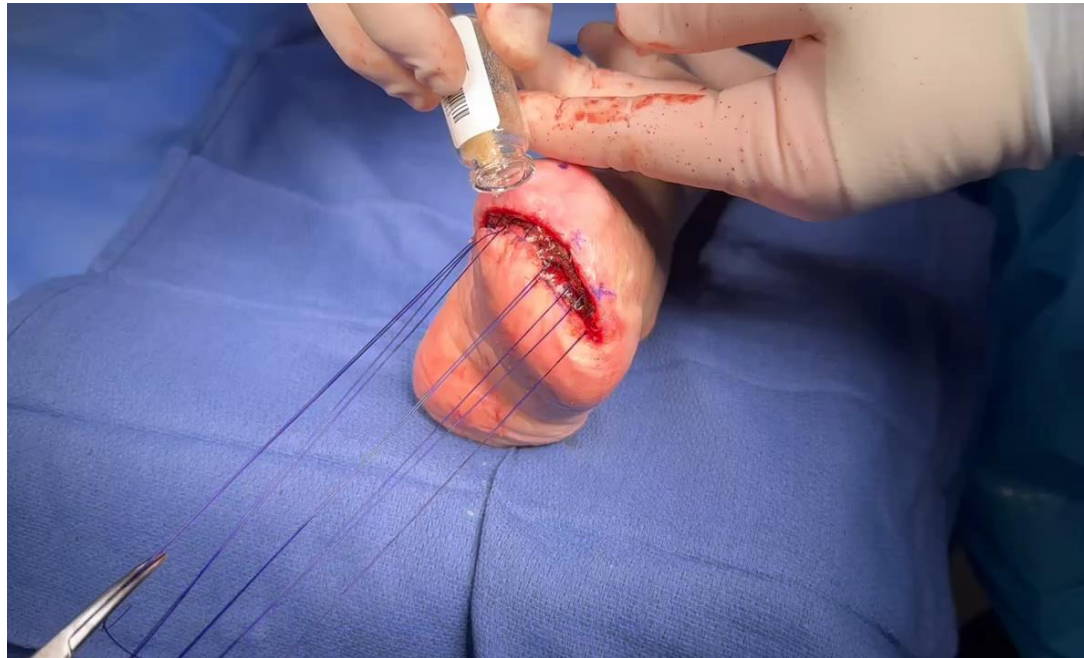
Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 1)

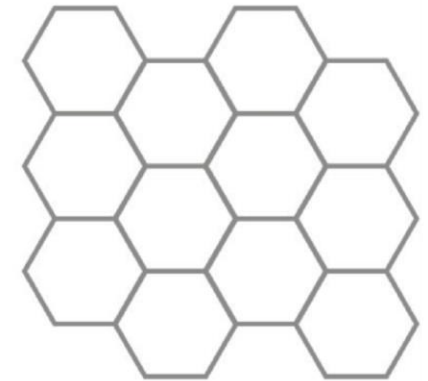
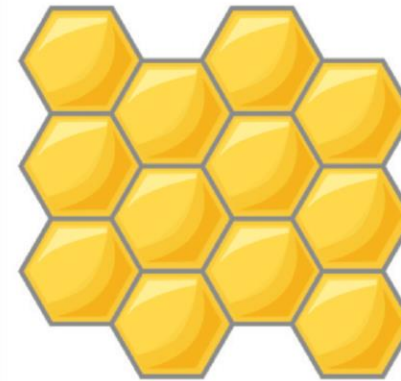


Adipose Allograft Matrix

- The adipose extracellular matrix (ECM) architecture, key growth factors and matrix proteins found in native tissue are retained
- Each lot of Leneva[®] is tested for endotoxin and for sterility per USP<71>

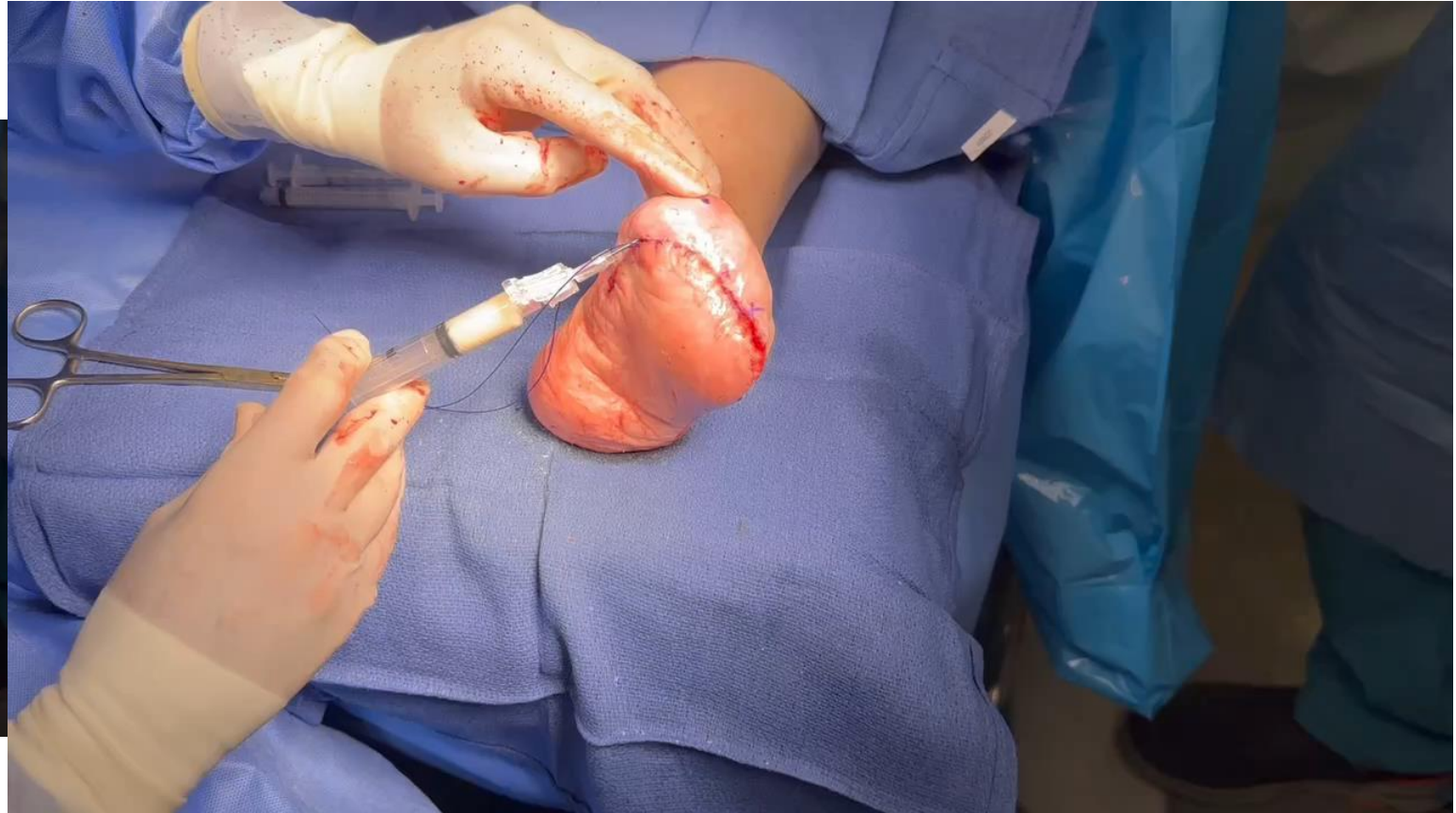
Native Adipose

Present in Leneva[®]



Native Function	Matrix Components	Native Adipose	Present in Leneva [®]
Angiogenesis	VEGF, FGF-1, FGF-2	√	√
Adipogenesis	IGF, BMP-9, FGF-2	√	√
Cell attachment and remodeling	Collagens IV, VI, I and III, GAGs, HA	√	√

Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 1)



Painful Neuroma, Left TMA (Day 7)



Painful Neuroma, Left TMA (Day 7)



Painful Neuroma, Left TMA (Day 14)



Painful Neuroma, Left TMA (Day 21)



Painful Neuroma, Left TMA (6 Wks)



Painful Neuroma, Left TMA (6 Wks)



**“The price of greatness
is responsibility.”**

- Winston Churchill

Summary

- Aseptically processed allografts, including placental and HR-ADM, may have benefits over terminally sterilized tissue by maintaining the integrity of the matrix proteins and extracellular matrices
- Use of an algorithm may assist in what tissue form may be beneficial based on the “goal” of therapy for wound management and surgical optimization
- Patients who are at high risk for surgical complications may benefit from the use of aseptically processed placental allograft to optimize healing
- The reconstructive ladder is evolving and now takes into consideration additional technologies to optimize surgical outcomes, including CAMPs
- The use of HR-ADM in these patients may help create a scaffolding for tissue ingrowth to help support flap transfer and/or allow for a lower stay on the reconstructive ladder
- Changes in reimbursement likely will favor more use of CAMPs in the operating room, with those products with proven science and data to support

Clinical Pearls

- Placental and dermal matrices are useful for wound management, as well as for surgical management and reconstruction
- Aseptic processing of placental and dermal allografts may have advantages over terminal sterilization to allow for maintenance of the integrity of the biologic matrices
- Reconsidering the reconstructive ladder with the use of placental, dermal, and adipose matrices has made less complex procedures an appealing alternative that may optimize surgical outcomes

Thank You