

Reeling in Results

Clinical Applications of Fish Skin Grafts in Chronic and Atypical Wounds

Supported by an educational grant from Kerecis

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Faculty Disclosures

- **Anamika Agrawal, DO:** Speaker's bureau – Kerecis
- **John C. Lantis II, MD, FACS:** Grant/research support – Biotissue; MediWound, Organogenesis Polarity; co-director – LBRC
- **Carrie McGroarty, PA:** Advisory board – Kerecis; consultant – Kerecis

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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 - This activity has been independently reviewed for balance

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Learning Objectives

- Describe the biological properties and mechanisms of action of fish skin grafts (FSGs), emphasizing how they support wound healing across a range of clinical indications
- Evaluate the clinical evidence supporting the use of FSGs, including illustrative case studies that demonstrate successful patient outcomes
- Examine the combined use of fish skin grafts and silicone dressings in wound management, differentiating their roles in tissue regeneration and exudate management, and evaluating their impact on healing outcomes and periwound skin protection in chronic and complex wounds
- Explore illustrative clinical case outcomes using fish skin grafts to manage chronic and atypical wounds
- Identify key reimbursement considerations and documentation requirements for the appropriate use of fish skin grafts in wound care

Fish Skin Grafts: Biological Properties, Mechanisms of Action, and Successful Outcomes

Anamika Agrawal, DO

Director of Wound Care Services

Emergency Resources Group

Jacksonville, FL

Intact fish skin grafts are a medical device approved by regulatory authorities globally and cleared by the FDA

Indications for Use

Burn

- Partial and full-thickness wounds
- Trauma wounds
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)

Contraindications

- Fish skin grafts should not be used in patients with known fish allergies

Private Office and HOPD

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds, including abrasions, lacerations, and skin tears
- Surgical wounds, including donor site/grafts, post-Mohs surgery, post laser surgery, podiatric, wound dehiscence
- Draining wounds

Soft Tissue Reinforcement

- For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery

Contraindications

- Where load-bearing support from the mesh is required, such as the repair of any hernia
- Intraperitoneal organ contact
- Bridging defects

Surgical

- Partial and full-thickness wounds
- Pressure ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds
- Surgical wounds
- Draining wounds

Patented Processing

Preserving the capability of nature

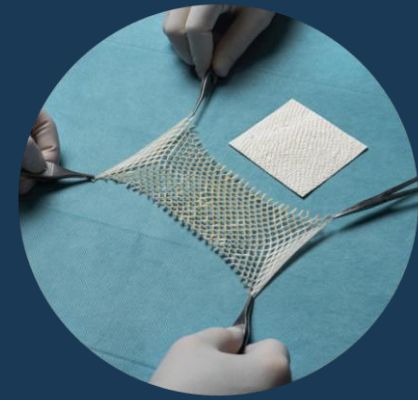


Fish Skin

- Homologous to human skin
- NO known risk of viral disease transmission

Patented Process

- Gentle processing
 - No strong alcohols or detergents
 - No mechanical pressing or tampering
 - No chemical cross-linking
- Made from byproduct of Icelandic fisheries
- Cost effective



Intact Fish Skin Products

- Preserves structure and elements
- Recruits host cells
- Supports regeneration of human tissue

Supporting Evidence

Four Hallmarks of Tissue Engineering

What does the body need to regenerate tissue—not just repair it?

- Three-dimensional structure



— Intact structure provides framework to promote tissue regeneration with limited scarring

- Intact molecular organization



— Fish skin is homologous to human skin

- Natural mechanical properties



— Naturally strong, handles like skin, easy to suture or staple

- Preserved molecular content



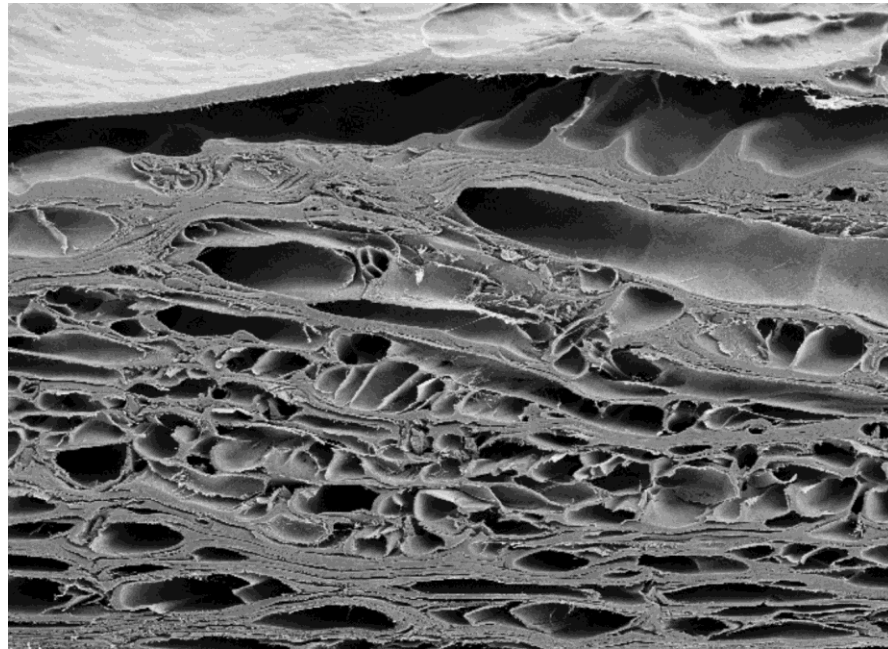
— Chemical complexity of fish skin promotes rapid cell ingrowth and neovascularization

Intact fish skin grafts fulfill all hallmarks

Natural Molecular Organization



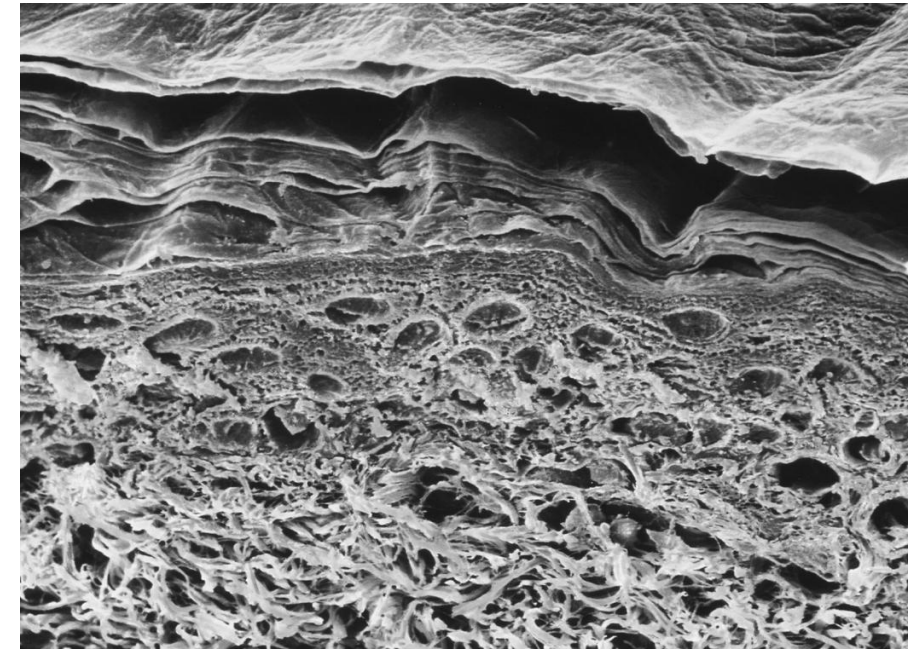
Intact Atlantic Cod Skin



100 μm

for

Human Skin



100 μm

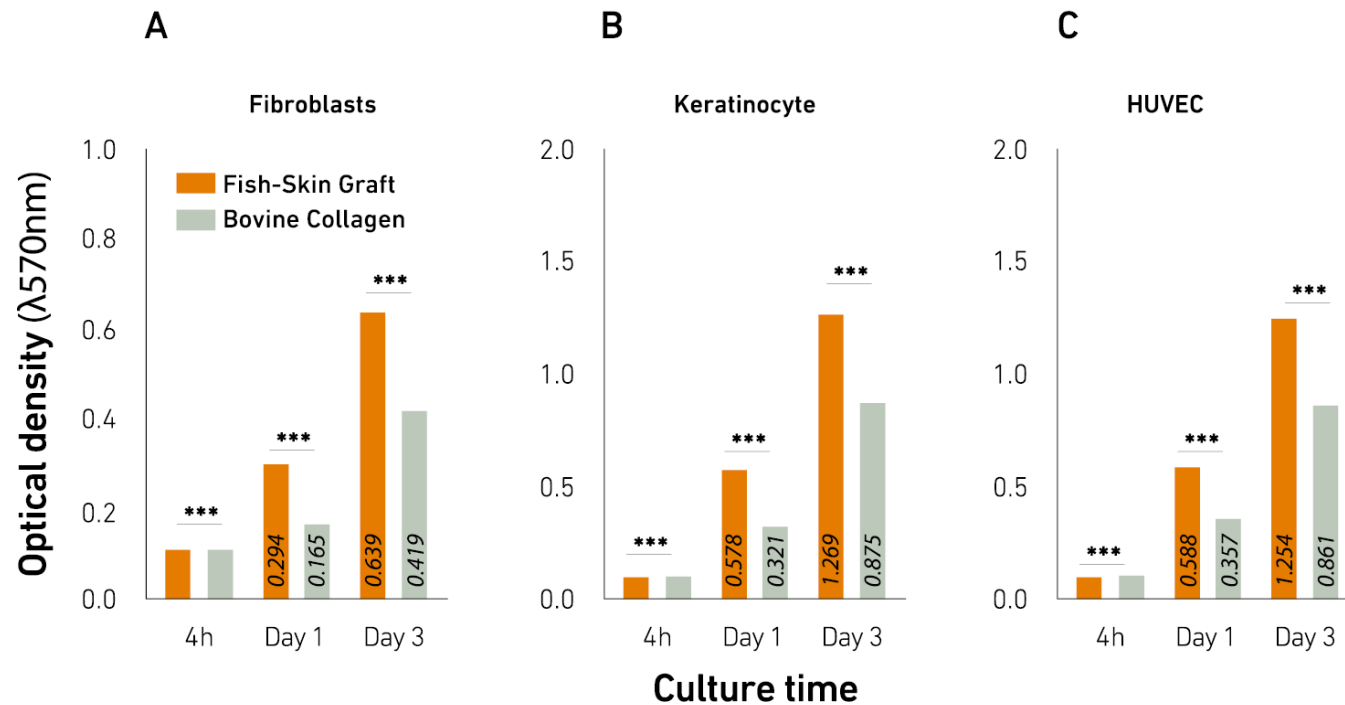
Epidermis

Dermis

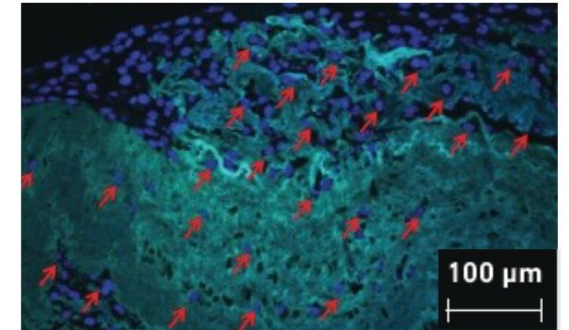
Natural Homologous 3D Structure



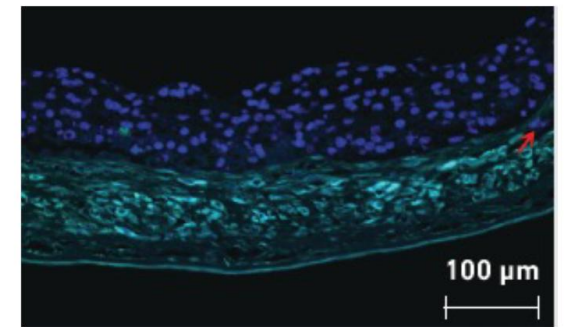
- 10x greater porosity – significantly more cell ingrowth



Intact
Fish Skin



Amnion /
Chorion



Natural Mechanical Properties

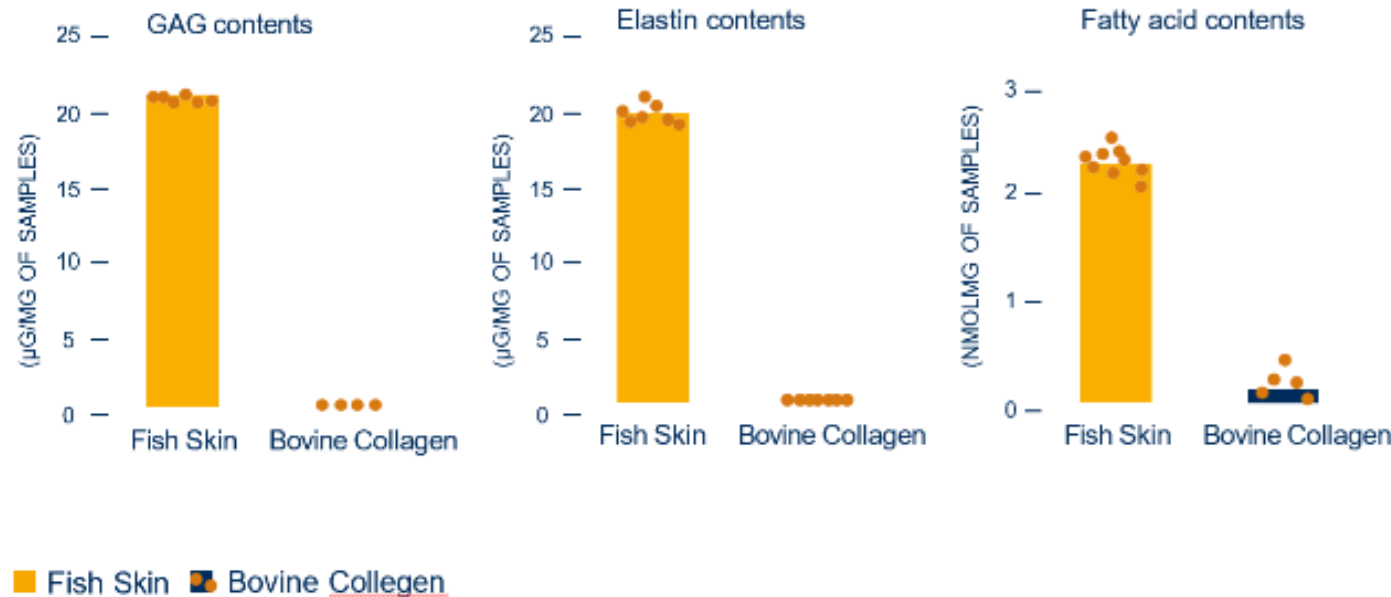
- Fish skin is robust, thick, easy to handle, mesh and apply



Preserved Molecular Content



- Comparison of human skin, intact fish skin graft, and mammalian tissue graft

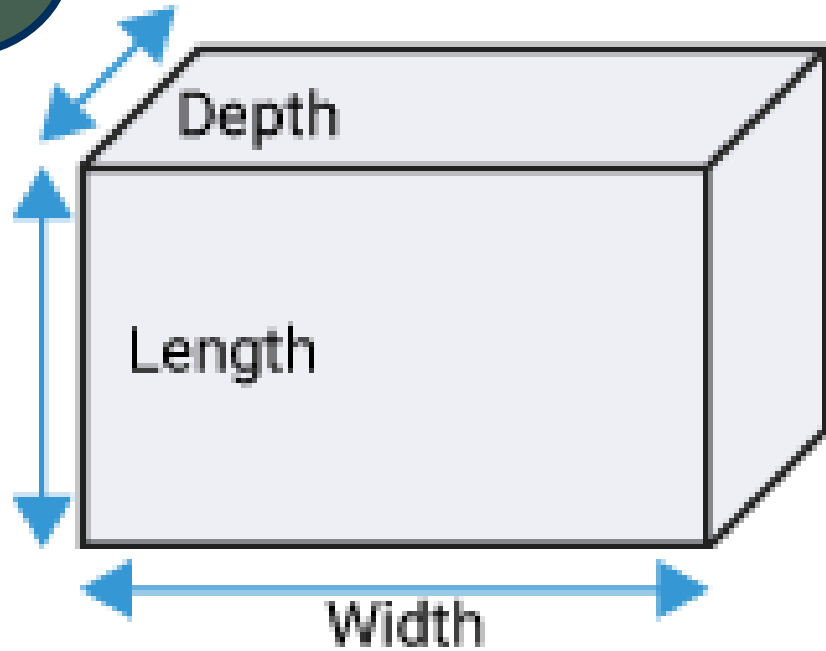


	Human Skin	Fish Skin
Collagen	✓	✓
Elastin	✓	✓
Fibronectin	✓	✓
Proteoglycans	✓	✓
Glycans	✓	✓
Lipid	✓	✓

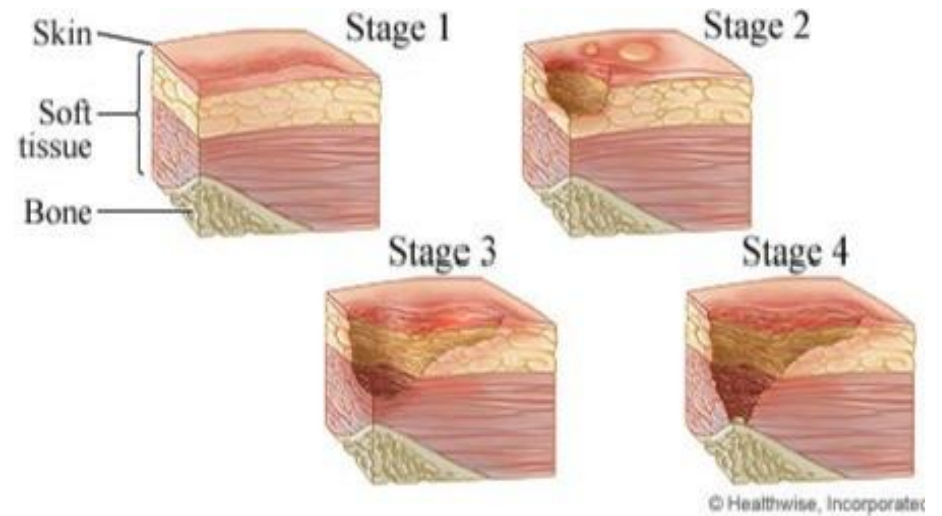
Documentation Requirements

MUST Have Measurement

1.



2.



Documentation

- **Clean and free** of necrotic debris or exudate
- **Medical management** for diabetes when diabetes present
- **Comorbidities** and what is being done to **address** each
- **Duration of ulcer** (4 weeks/ 30 days)
- **Time** under your care

Documentation

- **Clean and free** of necrotic debris or exudate
- **Medical management** for diabetes when diabetes present
- **Comorbidities** and what is being done to **address** each
- **Duration of ulcer** (4 weeks/ 30 days)
- **Time** under your care
- Why the wound has **failed to respond to standard wound care**
- What **interventions** failed
- **Med list**
- **PMH**
- Explanation of product and **why it was selected**
- **Risks and complications** of the procedure

Documentation

- **Clean and free** of necrotic debris or exudate
- **Medical management** for diabetes when diabetes present
- **Comorbidities** and what is being done to **address** each
- **Duration of ulcer** (4 weeks/ 30 days)
- **Time** under your care
- **Free of infection**
- **Free of necrosis**
- **No osteomyelitis**
- Conditions that have been **treated** and **resolved prior** to the institution of skin substitute **therapy**
- **Why the wound has failed to respond to standard wound care**
- **What interventions failed**
- **Med list**
- **Past medical history**
- **Explanation of product and why it was selected**
- **Risks and complications** of the procedure

Documentation

- **Clean and free** of necrotic debris or exudate
 - **Medical management** for diabetes when diabetes present
 - **Comorbidities** and what is being done to **address** each
 - **Duration of ulcer** (4 weeks/ 30 days)
 - **Time** under your care

 - Free of **infection**
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 - No **osteomyelitis**
 - Conditions that have been **treated** and **resolved prior** to the institution of skin substitute **therapy**
- Why the wound has **failed to respond** to **standard wound care**
 - What **interventions** failed
 - **Med list**
 - **Past medical history**
 - Explanation of product and **why it was selected**
 - **Risks and complications** of the procedure

 - What has been done for **edema / stasis**
 - **Debridement** performed
 - **Offloading**

Documentation

- **Clean and free** of necrotic debris or exudate
 - **Medical management** for diabetes when diabetes present
 - **Comorbidities** and what is being done to **address** each
 - **Duration of ulcer** (4 weeks/ 30 days)
 - **Time** under your care

 - Free of **infection**
 - Free of **necrosis**
 - No **osteomyelitis**
 - Conditions that have been **treated** and **resolved prior** to the institution of skin substitute **therapy**

 - **HbA1c**
 - **Arterial studies**
- Why the wound has **failed to respond** to **standard wound care**
 - What **interventions** failed
 - **Med list**
 - **Past medical history**
 - Explanation of product and **why it was selected**
 - **Risks and complications** of the procedure

 - What has been done for **edema / stasis**
 - **Debridement** performed
 - **Offloading**

Incident to Supply | Wastage

- No more reporting wastage (~~JZ & JW~~)
- Only bill for “administered” product
- LCDs state **“Use the size that best fits”** if multiple sizes available
- Documentation is KEY
 - Documentation that the size was the best fit
 - Include: Area, depth, irregular edges, need for overlap for fixation, undermining, tunneling, cavity wounds



“Due to irregular geometry and curved plantar surface, trimmed graft required an additional 2 cm² to fully cover wound edges without overlap or gaps.”

Case Studies

S/P Mohs Surgery

- 56-yo female
- Past medical history
 - Diabetes mellitus
 - S/p Mohs procedure for SCC
- Wound history
 - 8 months prior to presentation at wound care clinic
 - Previously treated with wet to dry, calcium alginate, collagen product

Initial Presentation



Undermining of 2 cm from 12 o'clock – 12 o'clock

Follow Up



1st IFSG Application



2nd IFSG Application

Follow Up



3rd IFSG Application



4th IFSG Application

Healed
4 IFSG
Applications

Healed



Venous Leg Ulcer

- 72-yo female
- Past medical history
 - Diabetes mellitus
 - Venous insufficiency
 - Congestive heart failure (CHF)
 - Lymphedema
- Wound history
 - Chronic recurring venous leg ulcer (VLU) with recurring infections
 - 7-months old
 - Stalled despite IV antibiotics, debridement, collagen, compression wraps, and lymphedema pump usage, and optimal diuretic therapy

Initial Presentation



Follow Up



1st IFSG Application



2nd IFSG Application



3rd IFSG Application

Healed, 3 IFSG
Applications

Healed



S/P Mohs Surgery

- 84-yo male
- Past medical history
 - Prostate cancer, s/p radiation
 - Venous insufficiency, s/p ablations
- Wound history
 - Non-healing wound s/p Mohs surgery for basal cell carcinoma (BCC)
 - 3-months old
 - Previously treated with calcium alginate and antibiotic ointment

Initial Presentation



Follow Up



1st IFSG Application



2nd IFSG Application

Follow Up



3rd IFSG Application



4th IFSG Application

Healed,
4 IFSG
Applications

Healed



Chronic Wound

- 69-yo female
- Past medical history
 - Rheumatoid arthritis
 - Venous insufficiency
- Wound history
 - Wound from vein ablation procedure
 - 1-year old
 - Previously treated with debridement and collagenase
 - Elevated inflammatory markers

Initial Presentation



Follow Up



1st IFSG Application



2nd IFSG Application



3rd IFSG Application

Healed, 3 IFSG
Applications

Healed



Where IFSG Data Is, Where It Is Going, and Real-World Evidence

John C. Lantis II, MD, FACS

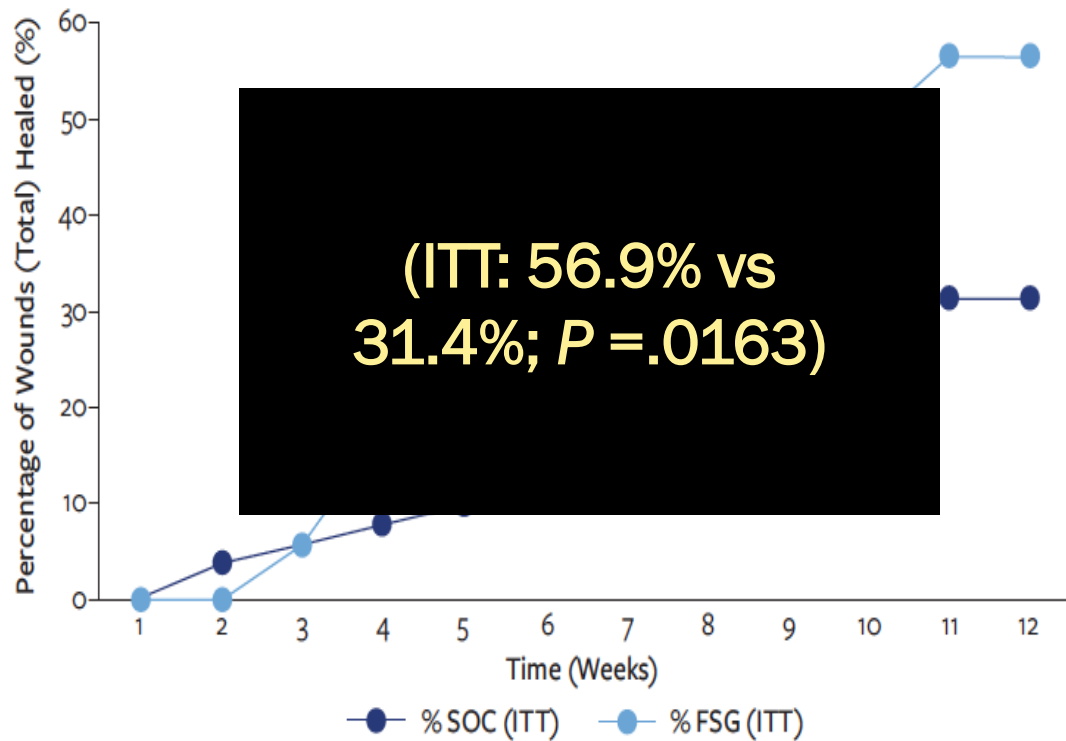
Site Chief, Professor of Surgery

Mount Sinai West Hospital and Icahn School of Medicine

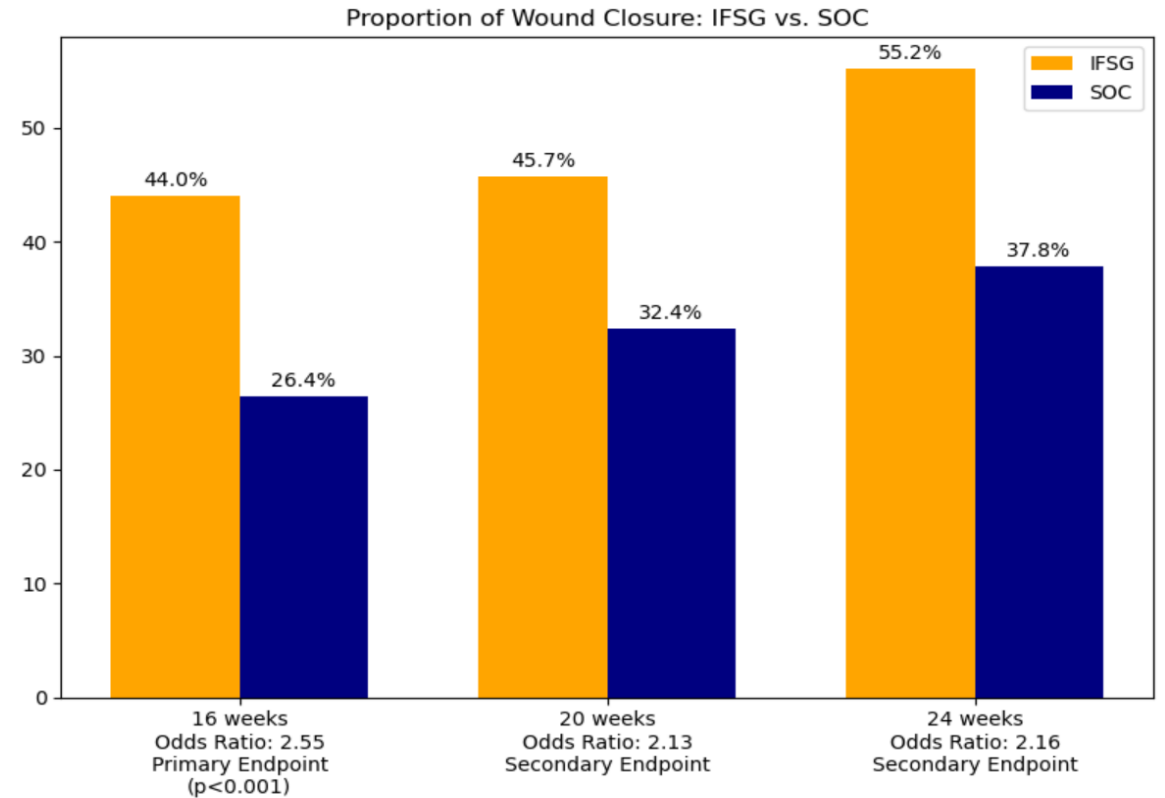
New York City, NY

Diabetic Foot

LEGG Trial 102 UT 1 Pts



ODINN Trial 262 UT 2 and 3 Pts



ITT = intention to treat; SOC = standard of care.

Lantis li JC, et al. *NEJM Evid.* 2024;EVIDoa2400171. Lantis li JC, et al. *Wounds.* 2023;35(4):71-77. Dardari D, et al. *Int Wound J.* 2026;23(3):e70847.

Representative Case from the LEGG Study



TV 1 – 2.7 cm(2)



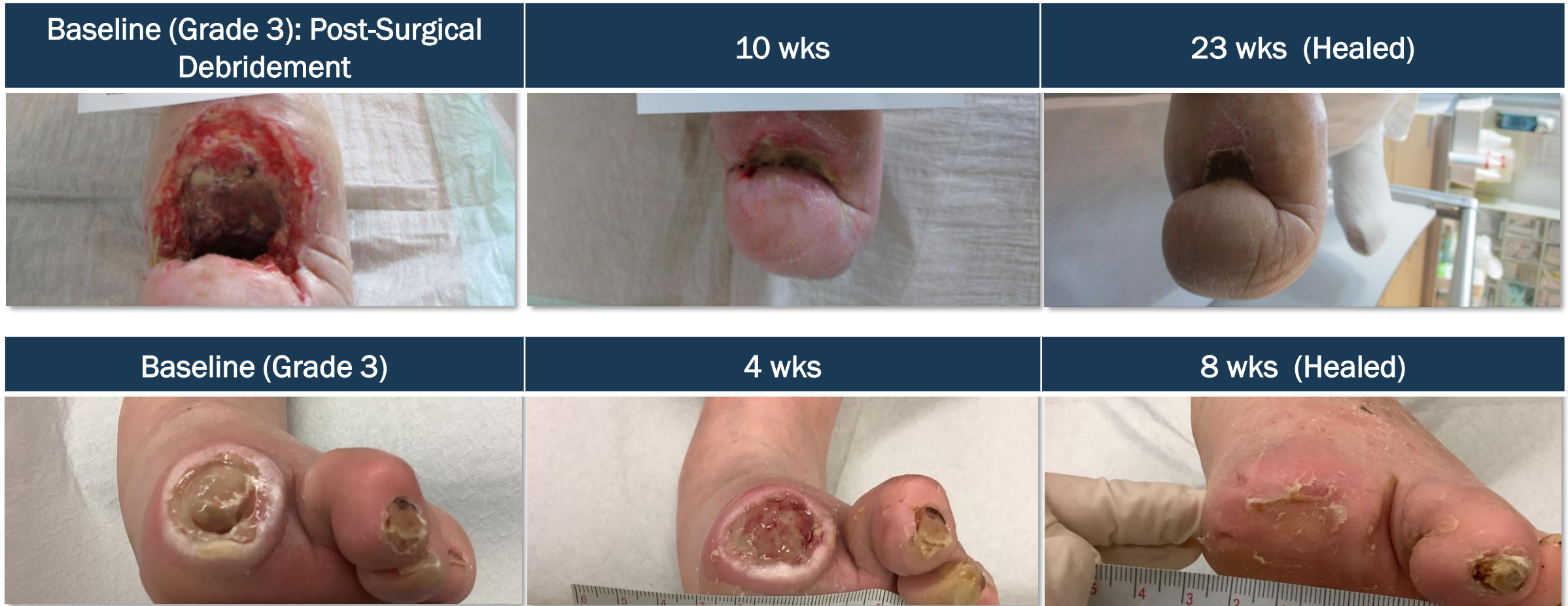
TV 4 – 0.7 cm(2)



TV 11

Absolute Closure Rate

- 44% in IFSG group vs 26.4% in SOC group



THOR Trial (Venous Leg Ulcer)

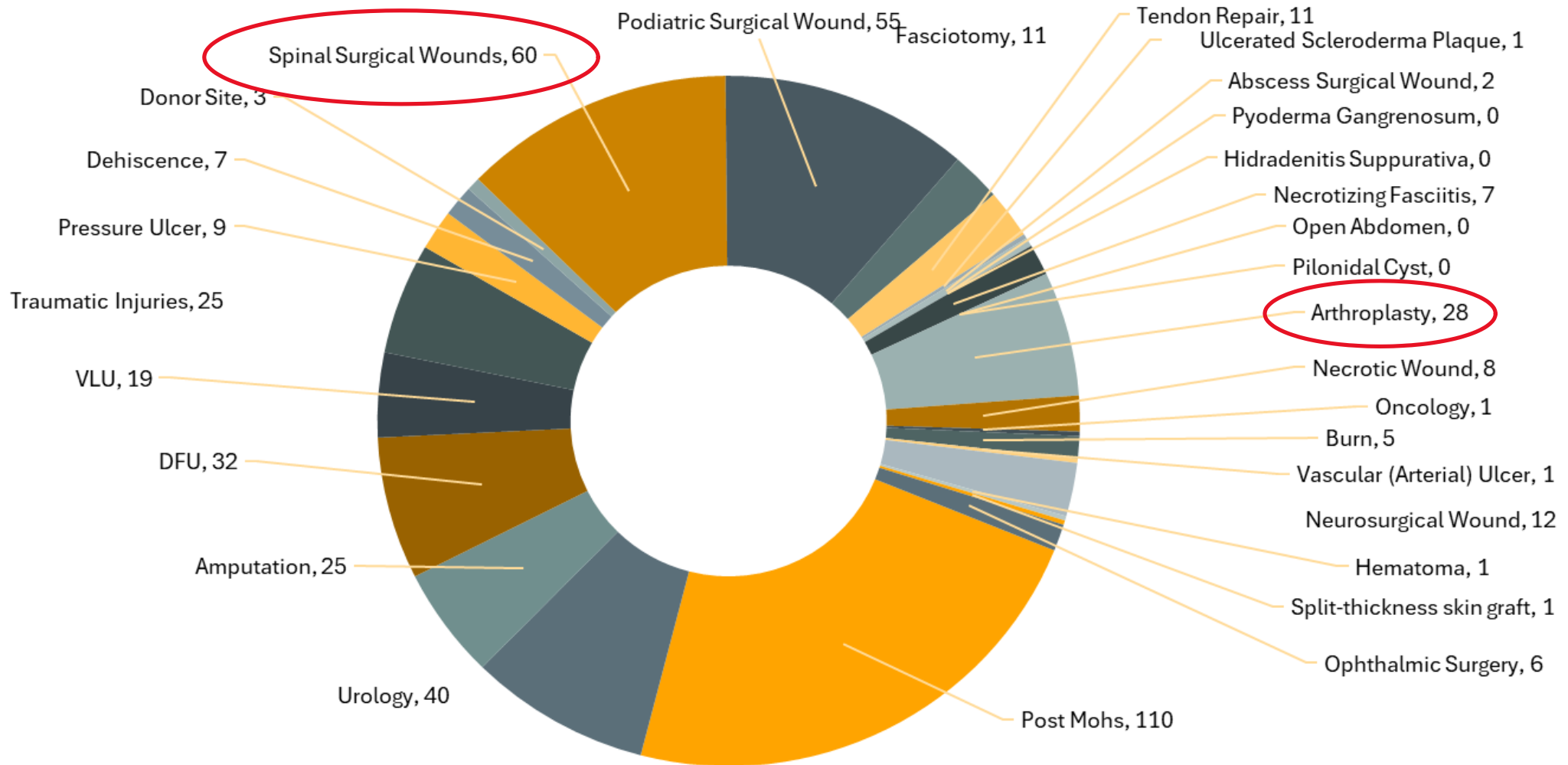
- THOR Trial (NCT06693570)
- This study will be conducted at up to 30 investigational sites throughout the United States
- Up to 150 patients with nonhealing VLUs. This study is anticipated to be completed within 18 months
- Time to closure of the target ulcers that heal within 12 weeks; percentage wound area reduction measured weekly
- **14 active sites**
- **91 randomized**
- **29 healed**
- **32 not healed**
- **9 withdrawn**
- **1 lost to follow up**

LOGI (Deep Partial Thickness Burn Trial)

- The LOGI Study: Protocol for an Open-label, Controlled, Randomized, Multicenter Study Evaluating Intact Fish Skin Graft in Promoting AutoLogous Skin Tissue ReGeneration of Deep Partial-thickness Burns
- Collaborator
 - American Burn Association
 - Study Principal Investigator: John Kubasiak, MD, FACS, FABA
- NCT07326657
- To determine whether use of IFSG can decrease the amount of autograft tissue needed for treatment of deep partial-thickness burns
- Up to 10 site study

**Currently
Recruiting Sites**

ISACOD Registry Cases as of March 1, 2026



Investigator-Initiated Studies (IIS)	Status
Efficacy of fish skin for tissue reinforcement and surgical site healing in <u>neuromodulation surgeries</u>	Study complete Manuscript accepted
<u>Gender affirming vaginoplasty</u> utilizing fish skin	Start-up CTA executed
"Feasibility and acceptability of using a fish skin for healing of <u>complex obstetric lacerations / vaginal tear</u> after childbirth	Start-up (grant)
Closure of cryptoglandular <u>fistula-in-ano</u> with fish skin	Start-up CTA executed
Retrospective, study evaluating time to graft between fish skin and <u>BTM</u> in complex full thickness acute traumatic wounds or burns	Study complete Manuscript pend.
Retrospective study on FT wounds, <u>burns</u> , and <u>length of stay</u> using data from large healthcare registry	Data analysis
Porcine study to evaluate fish skin <u>mechanism of action</u> for the healing of full thickness burn wounds	Manuscript pending
Use of fish skin to improve wound healing and expedite discharge at a county safety-net hospital. <u>Length of stay, FT wounds</u>	Start-up CTA executed
The effect of fish skin to prevent wounds associated complications in adult complex <u>spinal deformity</u> patients	Start-up (grant) CTA executed
Exudate metabolomics from used IFSG dressings	Contract executed start-up

BTM = biodegradable temporizing matrix; FT = full thickness; CTA = clinical trial agreement.

IIS	Status
<u>Flap reconstruction extension</u> with fish skin	Study complete Manuscript accepted
<u>Preclinical study</u> looking at fish skin for chest wall support	Start-up CTA executed
Retrospective <u>abdominal repair</u>	Start-up (grant)
Fish skin in dorsal hand trauma (3 potential publications)	Start-up CTA executed
Craniofacial muscle regeneration	Study complete Manuscript pending
Treatment of soft tissue radionecrosis with intact fish skin graft	Data analysis
Augmentation of trauma celiotomy for incision site hernia reduction	Manuscript pending
Evaluation of acellular fish skin xenografts for treating acute and chronic wounds	Start-up CTA executed
Acellular fish skin as a biological dressing for wounds of the distal limbs in horses	Start-up (grant) CTA executed
<u>Flap reconstruction extension</u> with fish skin	Contract executed start-up

Real World Data

What EHR Data Tells Us

- 516 wounds, 28 clinics from 13 states
 - Chronic ulcer: 168 (32.5%)
 - Venous leg ulcer: 122 (23.6%)
 - Diabetic foot ulcer: 104 (20.1%)
 - Pressure ulcer: 68 (13.1%)
 - Traumatic wound: 26 (5.0%)
 - Surgical: 11 (2.1%)
 - Arterial ulcer: 9 (1.7%)
 - Others: 8 (1.5%)
- Earliest date of use: 12/2015 (data pulled through 9/2023)
 - 19 clinics/8 states
 - Majority of use in 2022 and 2023

Outcome of Intact Fish Skin in Pressure Ulcers

Outcome	Number	Percentage
Healed	24	72.7%
Transferred or lost to FU	8	24%
Amputation (minor)	1	3%
Died	0	0%
TOTAL	33	100.00%

15 Variable Matched Cohort: Pressure Ulcer

Outcome Description	IFSG-treated group	Control group
Healed (-97.0% to -100.0%)	18 (45.0%)	11 (33.3%)
Better (-10.1% to -96.9%)	9 (22.5%)	11 (33.3%)
No Change (10.0% to -10.0%)	2 (5.0%)	0 (0.0%)
Worse ($\geq 10.1\%$)	5 (12.5%)	2 (6.1%)
Lost to Follow-up	0 (0.0%)	2 (6.1%)
Transferred	6 (15.0%)	5 (15.2%)
Death	0 (0.0%)	2 (6.1%)
Missing	0	7

Outcome of Intact Fish Skin in DFUs

Outcome	Number	Percentage
Healed	48	78.6%
Transferred or lost to FU	10	16.3%
Amputation (major)	3	4.9%
TOTAL	61	100.00%

Outcome of Intact Fish Skin in VLUs

- A matched cohort included 129 IFSG-treated VLUs and 129 SOC-treated VLUs. Baseline balance was standardized mean differences;
- IFSG wounds were older and trended larger
- Healing occurred in 85.3% of IFSG wounds (110/129) vs 75.2% of SOC wounds (97/129)
 - (The absolute difference (+10.1%) was below statistical significance [$p=0.0801$])
- SOC-treated VLUs increased in size on average more than IFSG-treated VLUs ($p=0.0036$)

Outcome of Intact Fish Skin in Chronic Ulcers

Outcome	Number	Percentage
Healed	80	70.7%
Transferred or lost to F/U	26	23%
Amputation (major)	3	2.6%
Died	4	3.5%
TOTAL	113	100.00%

Patient Outcomes

- Simple DFUs – doubles number of patients closed
- Deep and complex DFUs – improves closure rate by 66%
- VLU halfway enrolled
- Deep partial thickness burn
- **Real world data**
 - Venous leg ulcer – associated closure rate and faster time to closure in stalled VLUs
 - Pressure ulcers – associated with significantly higher closure rates than expected
 - Other chronic wounds – associated with significantly higher closure rates than expected

Clinical Case Outcomes Using Fish Skin Grafts to Manage Chronic and Atypical Wounds

Carrie McGroarty, PA

Co-Medical Director

WakeMed Wound Care Center

Raleigh, NC

Venous Leg Ulcer

- Initial presentation
 - 77-yo female with right lower extremity wound for approximately 30 days presenting to wound clinic
 - She endorses 50/10 pain on oxycodone and cephalexin from ED
- Wound dimensions
 - 7.4cm x 7.5cm x 0.1 cm
 - 55.5 sq cm



Fish Skin Graft Application



Follow Up



Healed



5 weeks post application



Initial Presentation



- 85-yo female, traumatic avulsion to RLE
 - Presented to ED 8/6/24
 - Presented to wound clinic 8/21/24
- 2.9 cm x 2.8 cm x 0.1 cm
- 8.12 sq cm

Follow Up

Wound progression first

8/21/2024	1	2.9	2.8	0.1	8.12	0.812
<u>8/28/2024</u>	1	2.5 (13.8%)	2.8	0.1	7 (14%)	0.7 (13.8%)
9/4/2024	2	2.4 (17.2%)	2.6 (7.1%)	0.1	6.24 (23%)	0.624 (23.2%)
9/25/2024	5	2.4 (17.2%)	2.2 (21.4%)	0.1	5.28 (35%)	0.528 (35%)
10/9/2024	7	2.5 (13.8%)	2.2 (21.4%)	0.1	5.5 (32%)	0.55 (32.3%)
10/17/2024	9	2.2 (24.1%)	2.1 (25%)	0.1	4.62 (43%)	0.462 (43.1%)
10/23/2024	9	2 (31%)	1.9 (32.1%)	0.1	3.8 (53%)	0.38 (53.2%)
10/29/2024	10	1.9 (34.5%)	1.7 (39.3%)	0.1	3.23 (60%)	0.323 (60.2%)
11/13/2024	12	1.9 (34.5%)	1.3 (53.6%)	0.1	2.47 (70%)	0.247 (69.6%)
11/21/2024	14	1 (65.5%)	0.8 (71.4%)	0.1	0.8 (90%)	0.08 (90.1%)
12/5/2024	16	0.9 (69%)	0.6 (78.6%)	0.1	0.54 (93%)	0.054 (93.3%)

Fish skin graft application on 10/9/24



Follow Up



Date: 10/17/24



Date: 10/23/24

- Post application of fish skin graft
 - Days 8-14
 - No debridement/ weekly dressing changes
 - Fish skin re-applied 10/23

Follow Up



Date: 10/29/24



Date: 11/13/24

Follow Up



Date: 11/21/24

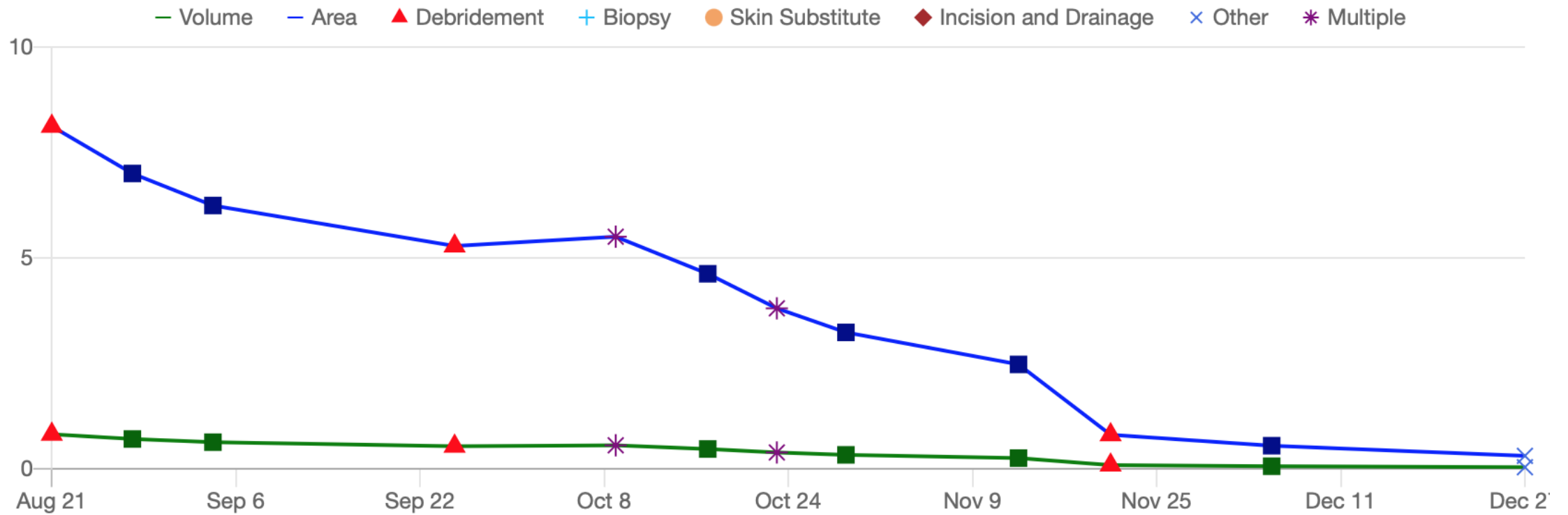


Date: 12/27/24

Silicone placed over incorporating graft

Healed

Wound Area/Volume Progress



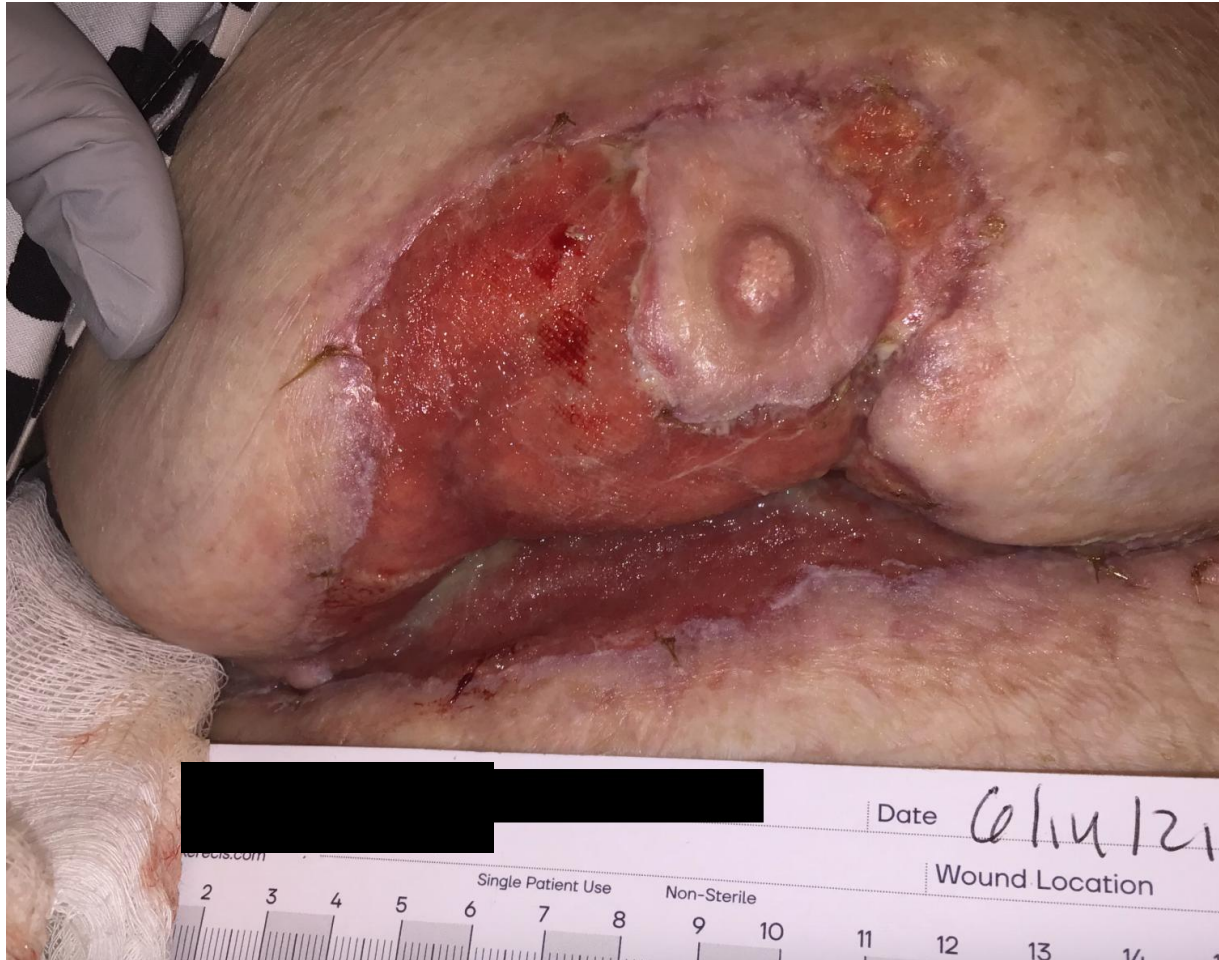
Initial Presentation



- 72-yo female s/p breast reduction presenting to wound clinic for wound dehiscence
- Wound dimensions
 - 5.9cm x 9cm x 11cm
 - 53 sq cm

Date: 6/6/24

Follow Up



- **1 week** after fish skin graft application and negative pressure wound therapy

Date: 6/14/24

Follow Up



- 5 weeks after fish skin graft application and negative pressure wound therapy discontinued

Date: 7/8/24

Healed



Date: 8/1/24

- **8 weeks** after fish skin graft application and negative pressure wound therapy

Initial Presentation



Date: 11/11/24

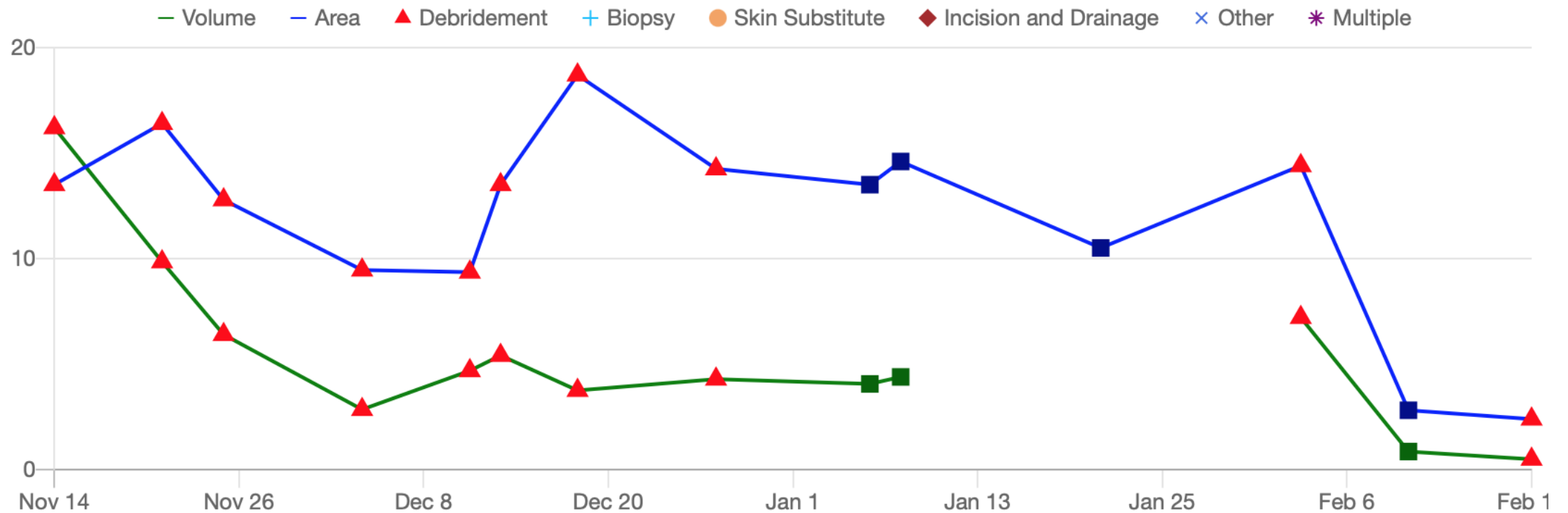


Date: 11/19/24

- 53-yo male with past medical history of IDDM. Presented to the ED with left foot osteomyelitis. Left trans metatarsal amputation 10/16/24
- Wound dimensions
 - 1.5cm x 9cm x 1.2cm
 - 16.2 sq cm

Pre-Application

Wound Area/Volume Progress



Pre-Application



- Despite advanced wound care and serial debridement wound continues to increase in size
- Bone and tendon exposed

Date: 12/13/24

Application



- Wound measurements
 - 8 x 2 cm
 - 16 sq cm

Date: 12/31/24

Application

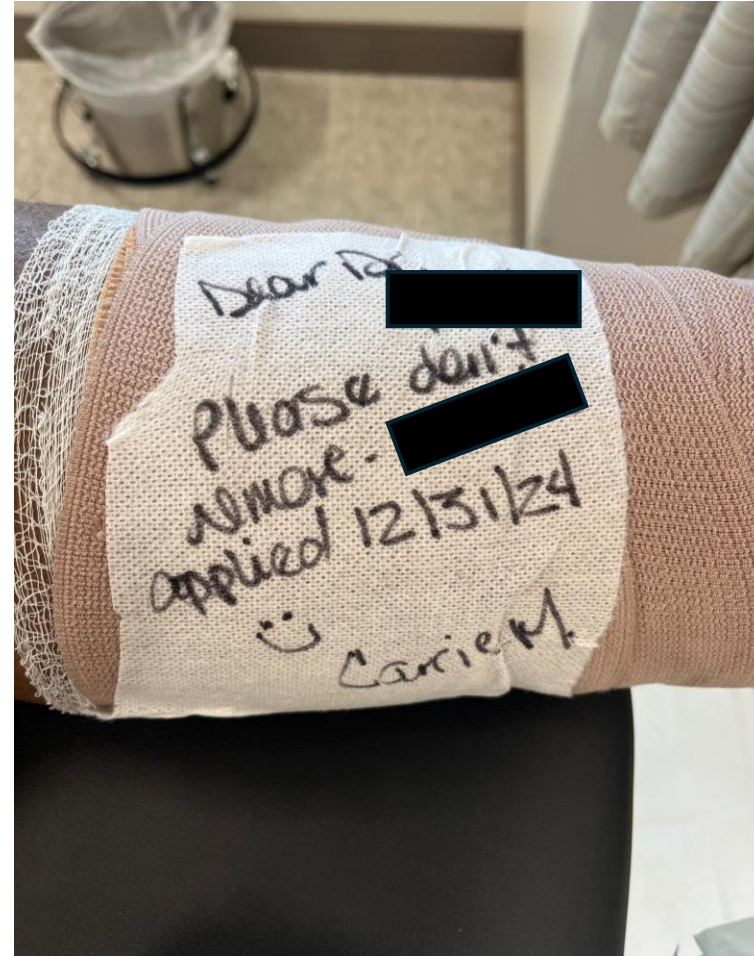
Fixation method: Sterile strips



Date: 12/31/24

Application

- Compression and a note to ortho...



Date: 12/31/24

Follow Up



Date: 1/6/25



Date: 1/13/25

Follow Up



- Third fish skin graft applied at this visit on 1/26/25

Application



Date: 1/27/25



Date: 2/3/25

- Third fish skin graft application was on 1/26/25
- Re-application on 2/3

Follow Up



Date: 2/18/25

- Wound care visit 2/18/25
- Wound dimensions
 - 0.7cm x 3.4cm x 0.2cm
 - 82% area closed
 - 97.1% volume
- Fish skin graft applications
 - 12/31/24
 - 1/13/25
 - 1/26/25
 - 2/3/25

Follow Up



- 5/29/25
- Final visit with orthopedic team

Left Breast Soft Tissue Radionecrosis

- 79-yo female
- Past medical history
 - Breast cancer
 - Left breast mastectomy
 - Chemotherapy/left breast radiation
- **Presented with wounds to left breast post op May 2025**

Presentation 9/25/25



11/5/25



1-Wk FU and Application of Second Fish Skin Graft



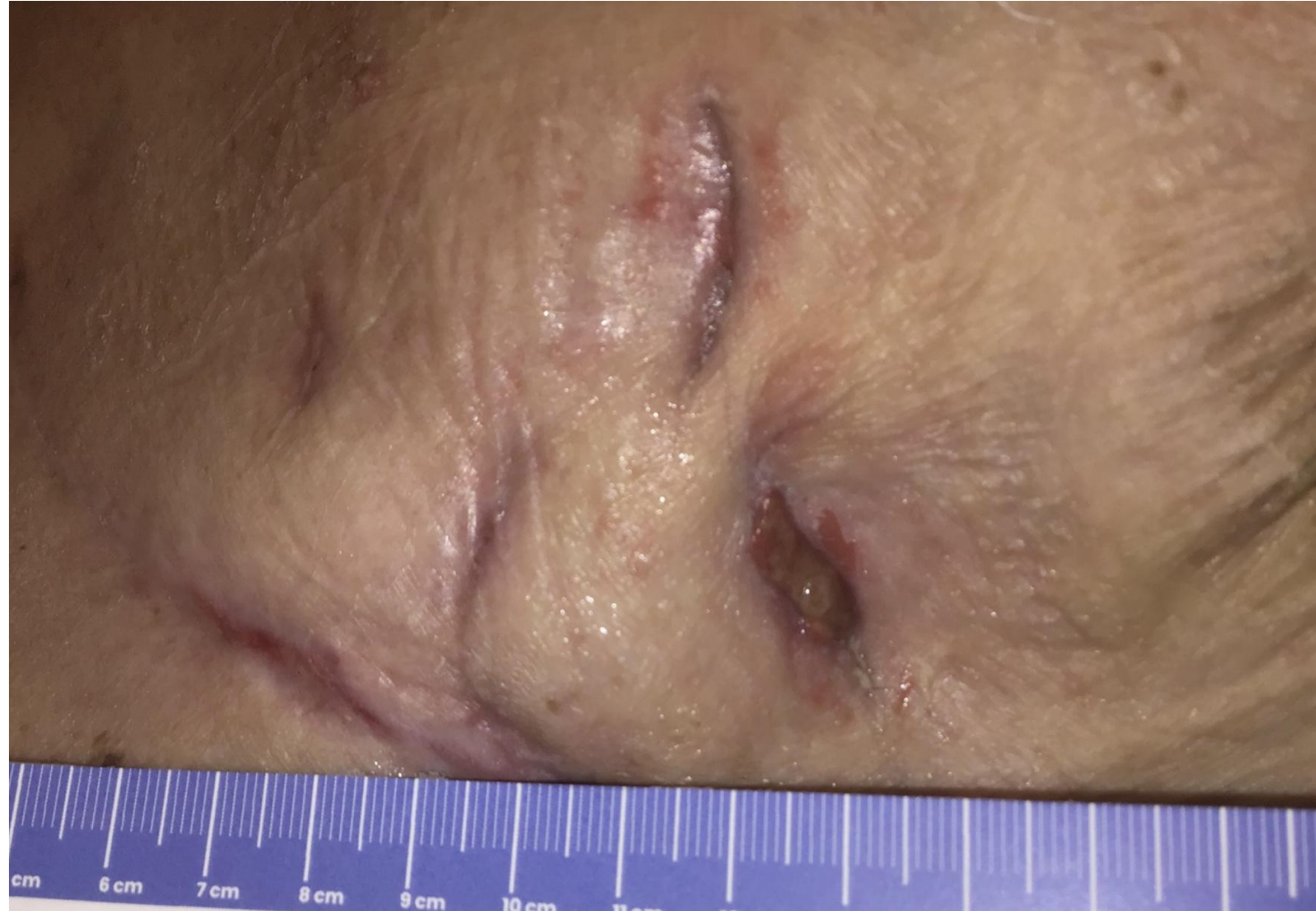
1-Wk FU and Application of Third Fish Skin Graft



1-Wk FU and Application of Third Fish Skin Graft



1-Wk FU and Application of Fourth Fish Skin Graft



Healed 6 Wks Post First Application Fish Skin Graft



- Open wounds 5/2025 to 11/5/2025
- Weekly debridement visits to wound center 9/25/2025 to 11/5/2025
- Healed 12/17/25 6 weeks (4 applications of fish skin graft)

Venous Leg Ulcer

- 80-yo female
- Past medical history
 - Chronic kidney disease
 - Coronary artery disease
 - Insulin dependent, diabetic
 - Asthma
- Presented with wound to right leg x 2 weeks, treated with silver sulfadiazine and xeroform

Initial Presentation



Starting Debridement



Debridement



Application of Fish Skin Graft



First Wound Vac Change 1 Week Post Application



Wound Vac Change 2 Weeks Post Application



3-Month Follow Up



1-Year Follow Up



Questions?

Thank You!