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COMPLEX WOUND MANAGEMENT

# A Multi-Specialty, Case-Based Exploration of Biodegradable Temporizing Matrix in Practice

# Faculty

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# Faculty Disclosures

- **Sigrid Blome-Eberwein, MD, FABA**: Advisory Board—PolyNovo, Avita
- **Paul J Kim, DPM, MS**: Consultant—PolyNovo
- **Shaun Mendenhall, MD**: Consultant—PolyNovo

*This CME activity includes brand names for participant clarity purposes only.*
*No product promotion or recommendation should be inferred.*

# Program Information

- This program is provided by HMP Education, an HMP Global company
- Supported by an educational grant from PolyNovo

# Learning Objectives

- Assess the clinical and economic burden of complex wound care and apply strategies to manage complications and optimize patient factors
- Evaluate the impact of timely debridement and early grafting on healing, recovery trajectories, and long-term outcomes in complex wound management
- Examine the underlying science, emerging research, and clinical applications of Biodegradable Temporizing Matrix in the treatment of complex wounds
- Analyze case-based examples from a multi-specialty perspective to illustrate the practical application of Biodegradable Temporizing Matrix in complex wound management

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# The Clinical and Economic Burden of Wound Care

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# Statement

- We do not, against common perception, function in a protected space
- We are not, against common perception, unaware of health care costs
- We are, against common perception, at the mercy of insurers and administrators (including hospital and political)
- We are all, against common perception, not objective
- We do not, against common perception, have a well-validated body of evidence to base our decisions upon

# Biological Skin Substitutes Market Summary

**The global biological skin substitutes market size was estimated at USD 347.6 million in 2024 and is projected to reach USD 579.08 million by 2030, growing at a CAGR of 8.88% from 2025 to 2030. The market is driven by the rising prevalence of chronic wounds, such as ulcers and burn injuries, medical technology advancements, the geriatric population, and surgical procedures.**

**Key Market Trends and Insights**

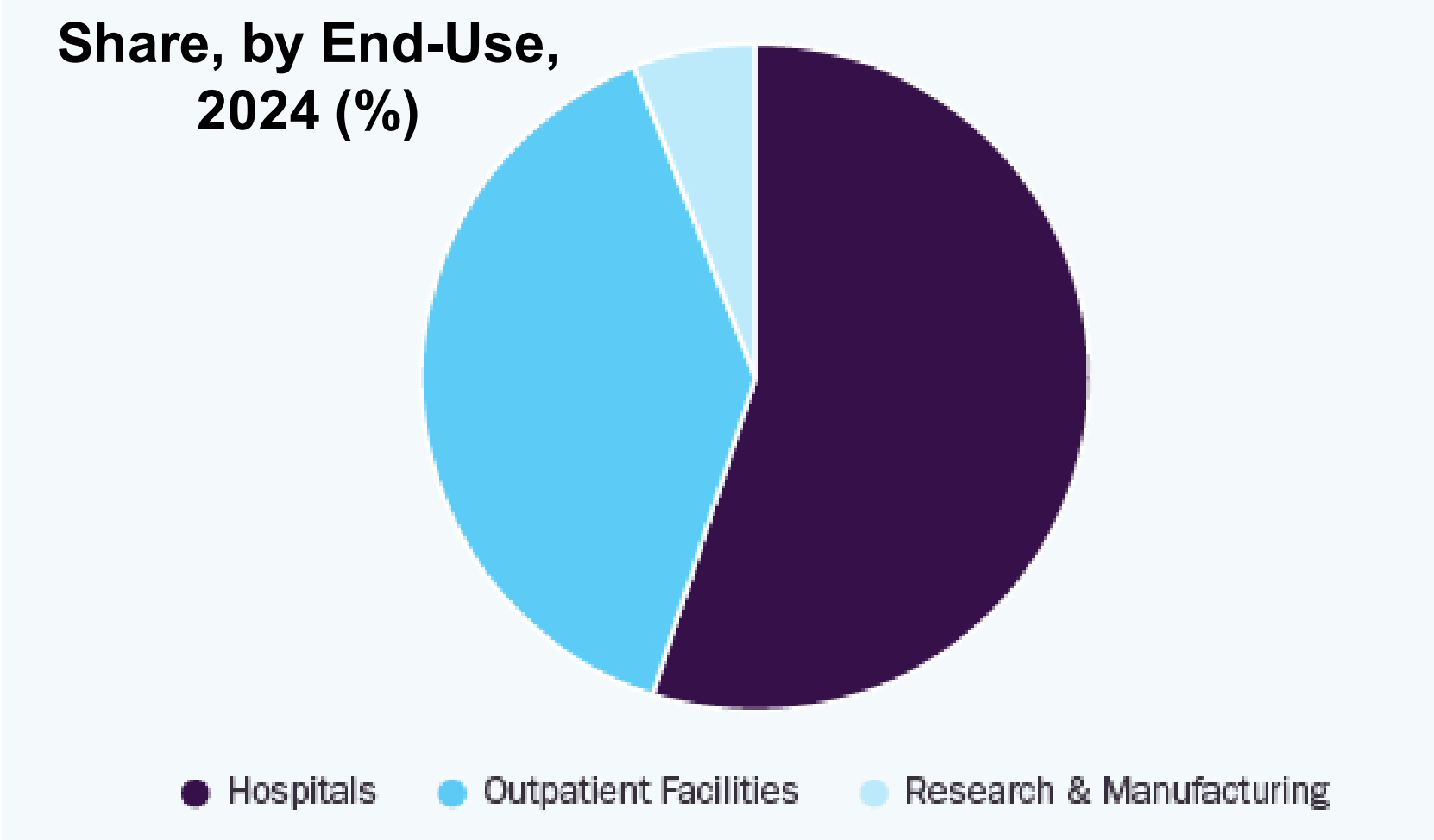
- North America's biological skin substitute market dominated the global market with a revenue share of 41.25% in 2024
- The U.S. biological skin substitute market held the largest share of the North American region in 2024
- By type, human donor tissue-derived products held the largest revenue share of around 67.42% in 2024
- By application, the acute wounds segment dominated the market in 2024
- By end use, hospitals held the largest revenue share of around 54.97% in 2024

**Market Size and Forecast**

- 2024 Market Size: USD 347.6 million
- 2030 Projected Market Size: USD 579.08 million
- CAGR (2025-2030): 8.88%
- North America: Largest market in 2024

**USD = U.S. dollar; CAGR = compound annual growth rate.**
**Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.**

# Biological Skin Substitutes Market




**$347.6M**

Global Market Size, 2024

**Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.**

# Biological Skin Substitutes Market


Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.

# Wound Care Market Summary

**The global wound care market size was estimated at USD 23.15 billion in 2024 and is projected to reach USD 29.57 billion by 2030, growing at a CAGR of 4.19% from 2025 to 2030. The demand for wound care products is rising owing to the growing number of surgical cases and the increasing prevalence of chronic disorders across the globe.**

**Key Market Trends and Insights**

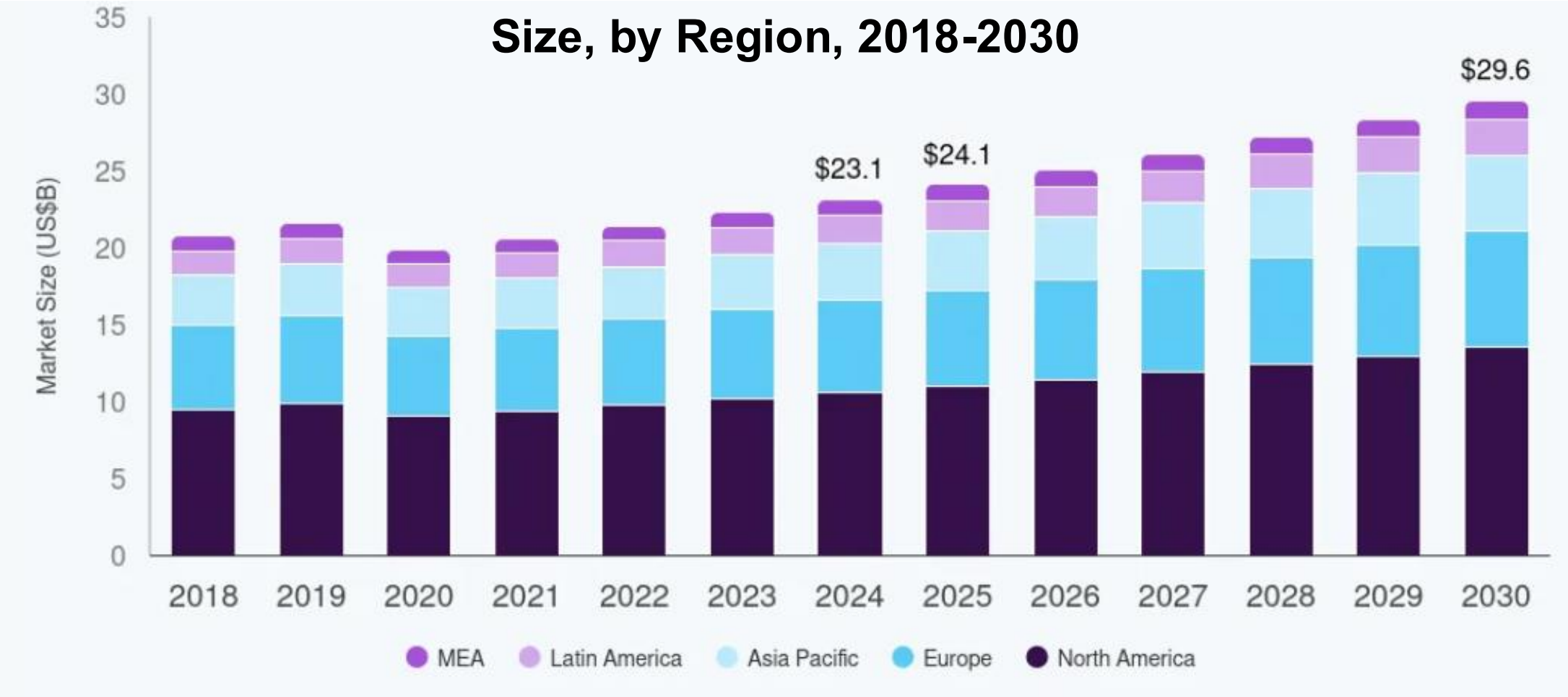
- North America's wound care market held the largest revenue share of more than 45.47% in 2024
- The wound care market in the U.S. is expected to dominate the North American region over the forecast period
- By product, the advanced wound dressing segment dominated the market with a revenue share of over 34.96% in 2024
- By application, the chronic wounds segment held the largest share of 59.84% in 2024
- By end-use, the hospital segment held the largest share of 36.30% in 2024

**Market Size and Forecast**

- • 2024 Market Size: USD 23.15 billion
- • 2030 Projected Market Size: USD 29.57 billion
- • CAGR (2025-2030): 4.19%
- North America: Largest market in 2024

**Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.**

# Wound Care Market




**MEA = Middle East and Africa.**

**Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.**

# Base of Predictions

Furthermore, the increasing number of traumatic injuries across the world is anticipated to drive the industry. For instance, according to a World Health Organization (WHO) report (published in December 2023), around 1.19 million individuals die every year as a result of road traffic accidents. Moreover, in February 2024, BPS-Statistics Indonesia reported approximately 139,258 traffic accidents, with 13,364 resulting in severe injuries and 160,449 causing slight injuries. These accidents usually lead to severe blood loss and other injuries. Thus, such cases are expected to increase the demand for wound care products.

**Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.**

# Wound Care Market

## Share, by Distribution Channel, 2024 (%)


**$23.2B**

Global Market Size, 2024

Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.

# Wound Care Market

## Trends, by Region, 2025-2030


**45.5%**

North America Market Revenue Share, 2024

**Grand View Research. Accessed November 10, 2025. https://www.grandviewresearch.com/industry-analysis/biological-skin-substitutes-market-report.**

# CMS finalizes major crackdown on skin substitutes

The agency finalized a major change to reimbursement for the skin substitutes despite heavy lobbying from the wound care industry.

BY: **ROBERT KING** | 10/31/2025 07:03 PM EDT

The Trump administration is cutting Medicare reimbursement for pricey skin substitutes from more than $1,000 to $125 per treatment.

The change, outlined in a final physician payment rule from the Centers for Medicare and Medicaid Services released Friday,comes as spending on the skin substitutes, which mimic human skin and are used to treat ulcers and other conditions, has surged to an estimated $15 billion this year, according to data from the National Association of Accountable Care Organizations, health care providers who work with Medicare to cut costs. Medicare spending on the skin substitutes increased from $256 million in 2019 to more than $10 billion last year, according to CMS data.

**CMS = Centers for Medicare and Medicaid Services.**

**King R. Politico. Published October 31, 2025. Accessed November 10, 2025. https://subscriber.politicopro.com/article/2025/10/cms-finalizes-major-crackdown-on-skin-substitutes-00632438.**

## Key statistics and trends

- **2019-2024 Growth:** Spending surged from approximately $256 million in 2019 to over $10 billion by the end of 2024.
- **2025 Projection:** Spending is projected to reach $15.4 billion by the end of 2025.
- **Driving factors:**
  - Increased utilization and higher product prices.
  - A rise in the number of new skin substitute products on the market.
  - Concerns about non-compliant pricing practices by manufacturers.
  - A shift to higher-cost products, especially in home care settings where costs per patient are significantly higher than in office settings.
- **High-cost products:** Some new products can cost as much as $5,948 per square inch, or over $2,000 per square centimeter.

## CMS response and future changes

- **Payment shift:** For 2026, the Centers for Medicare & Medicaid Services (CMS) will reclassify skin substitutes as "incident-to supplies" instead of biologicals.
- **Projected savings:** This change is expected to reduce Medicare spending on these products by up to 90%, with an estimated savings of nearly $20 billion in the next year.
- **Increased scrutiny:** The Health and Human Services Office of Inspector General (HHS-OIG) has increased its focus on potential fraud, waste, and abuse in this area and has flagged noncompliance with pricing requirements.
- **Proactive compliance:** CMS and other agencies are intensifying their review of billing practices, and providers are being advised to review documentation and strengthen compliance programs.

**Medicare.gov. Accessed November 10, 2025. https://www.medicare.gov/publications/10050-medicare-and-you.pdf.**

# Medicare Changes 2026

Medicare is reclassifying skin substitutes to be treated as "incident-to" supplies, a significant policy change that moves away from the current "biologicals" category and aims to reduce spending and control costs. This shift, proposed to start in 2026, will involve a single payment rate for most skin substitutes instead of individual rates for each product and is a response to the dramatic growth in Medicare spending on these products. The change is intended to incentivize the use of products with greater clinical evidence and is anticipated to significantly cut Part B spending.

## What the change means

- **Shift in payment category:** Skin substitutes will no longer be billed as separate "biologicals" but as "incident-to" supplies.
- **Single national payment rate:** A single, group-based payment rate will be established, intended to replace the current product-specific reimbursement rates based on Average Sales Price (ASP).
- **Reduced spending:** The Centers for Medicare & Medicaid Services (CMS) projects this change could reduce Medicare Part B spending on skin substitutes by approximately $9.4 billion in 2026.
- **Shift in incentives:** The new policy is designed to incentivize the use of products that have more clinical evidence of success and may reduce overuse and upcoding.
- **Impact on providers:** This will alter how wound care providers are reimbursed for these products, potentially impacting billing, documentation, and
- **Spending growth:** Medicare spending on skin substitutes has grown exponentially, from $256 million in 2019 to over $10 billion in 2024.
- **Abuse and waste:** CMS cites concerns about abusive pricing, upcoding, and the use of products with limited clinical evidence as reasons for the overhaul.
- **Enforcement actions:** The Office of Inspector General (OIG) has flagged increased fraud and abuse risk, including instances where providers billed for skin substitutes almost exclusively.
- **Pricing differentials:** The wide gap between the Wholesale Acquisition Cost (WAC) and Average Sales Price (ASP) of some products has been noted as a potential driver for overuse.

**Medicare.gov. Accessed November 10, 2025. https://www.medicare.gov/publications/10050-medicare-and-you.pdf.**

# Pricing – List? Or Imagination? Or Negotiation?

Medicare's Role

- **Initial pricing**: Under current Medicare rules, companies can set a high reimbursement rate for new skin substitutes for the first six months
  - After that, the rate adjusts to reflect actual prices paid after discounts
- **Proposed changes**: Starting in 2026, CMS is proposing a cap of $806 per square inch for certain skin substitutes to control costs
- **Payment methodology**: CMS announced a new payment methodology for 2026 that will set a single payment rate for all skin substitute categories at approximately $127.28 per square centimeter
  - This is intended to streamline the payment process and may help to moderate the average cost of skin substitutes

# Evidence

Original Research-Clinical Science | Open Access

## A clinical trial of Integra Template for diabetic foot ulcer treatment

Vickie R. Driver MS, DPM, Lawrence A. Lavery MPH, DPM, Alexander M. Reyzelman DPM, Timothy G. Dutra MS, DPM, Cyaandi R. Dove DPM, Sandra V. Kotsis MPH ... See all authors

First published: 22 August 2015 | https://doi.org/10.1111/wrr.12357 | Citations: 206

Trial Registration: clinicaltrials.gov Identifier: NCT01060670.

## A systematic review of the Novosorb® Biodegradable Temporizing Matrix in the treatment of complex wounds

Olivia Fruergaard, Mathias Ørholt, Christian Lyngsaa Lang, Jennifer Berg Drejøe, Mikkel Herly, Peter Vester-Glowinski, David Hebbelstrup Jensen

## Comparing Amniotic Membranes to Other Bioengineered Skin Substitutes in Wound Healing: A Propensity Score-Matched Analysis

by Micaela J. Tobin, Audrey K. Mustoe, Sasha Nickman, Tricia Mae Raquepo, Mohammed Yamin, Agustin N. Posso, Sarah J. Karinja, Bernard T. Lee and Ryan P. Cauley *

## Porcine Xenograft and Epidermal Fully Synthetic Skin Substitutes in the Treatment of Partial-Thickness Burns: A Literature Review

Herbert L Haller [1], Sigrid E Blome-Eberwein [2], Ludwik K Branski [3], Joshua S Carson [4], Roselle E Crombie [5], William L Hickerson [6], Lars Peter Kamolz [7], Booker T King [8], Sebastian P Nischwitz [7], Daniel Popp [7], Jeffrey W Shupp [9], Steven E Wolf [2]

Haller HL, Blome-Eberwein SE, et al. *Medicina*. 2021;57(5):432. Tobin MJ, et al. *J Clin Med*. 2025;14(12):4272. Driver VR, et al. *Wound Repair Regen*. 2015;23(6):891-900. Fruergaard O, et al. *Burns Open*. 2025;9:100378.

# So, What Did We Learn?

- Faced with a complex patient with a complex wound
  - Decisions need to be made based on patient specifics
  - Decisions need to be made based on available resources
  - Decisions need to be made on geography
  - Decisions need to be made based on impact on cost for individual
  - Decisions need to be made based on cost for healthcare system
  - Decisions need to be made based on cost for national/global healthcare

  - SORRY, WAY above my paygrade!!!!

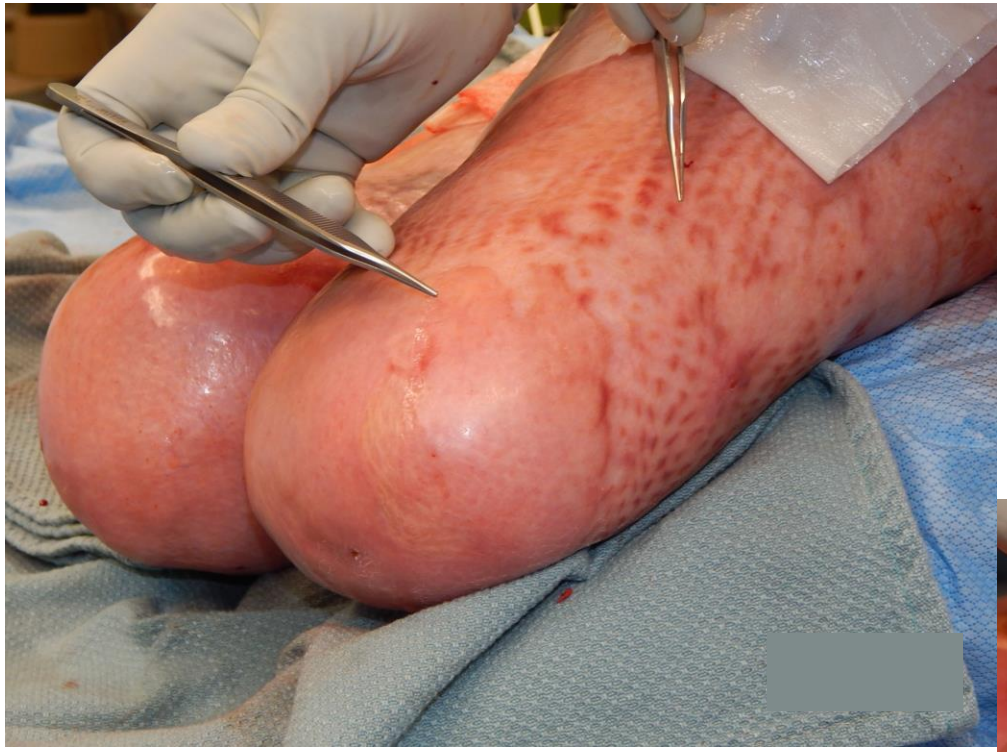
# How to Optimize Complex Wound Care?

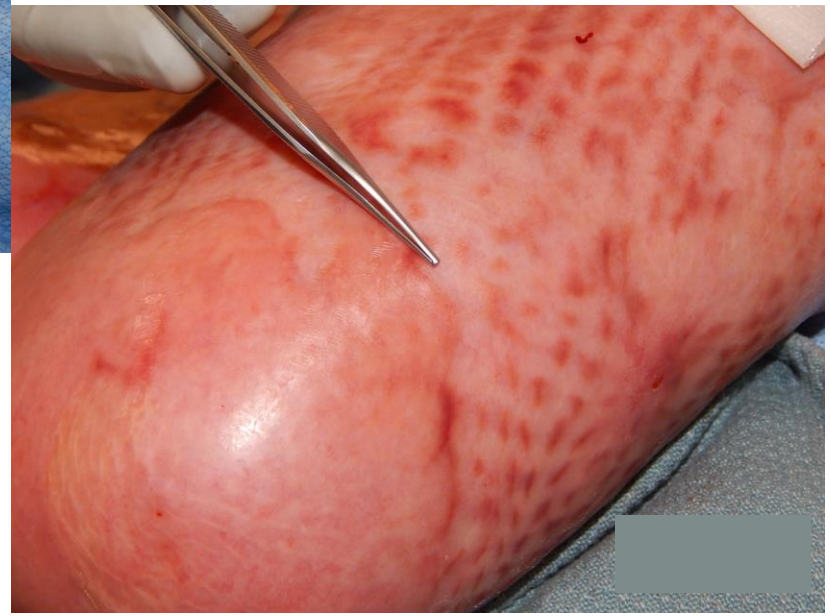
- Patient optimization first (nutrition, infection, smoking cessation, vascularization, etc.)
- Patient compliance optimization (assistive devices, home care, clinic or office visits, physical therapy, etc.)
- Decrease in-hospital stay
- Choose the right product and/or procedure for the right indication (evidence-based)
- Prepare the wound bed optimally
- Limit the use of multiple products for the same wound
- Timing of definitive wound closure

# Some Considerations

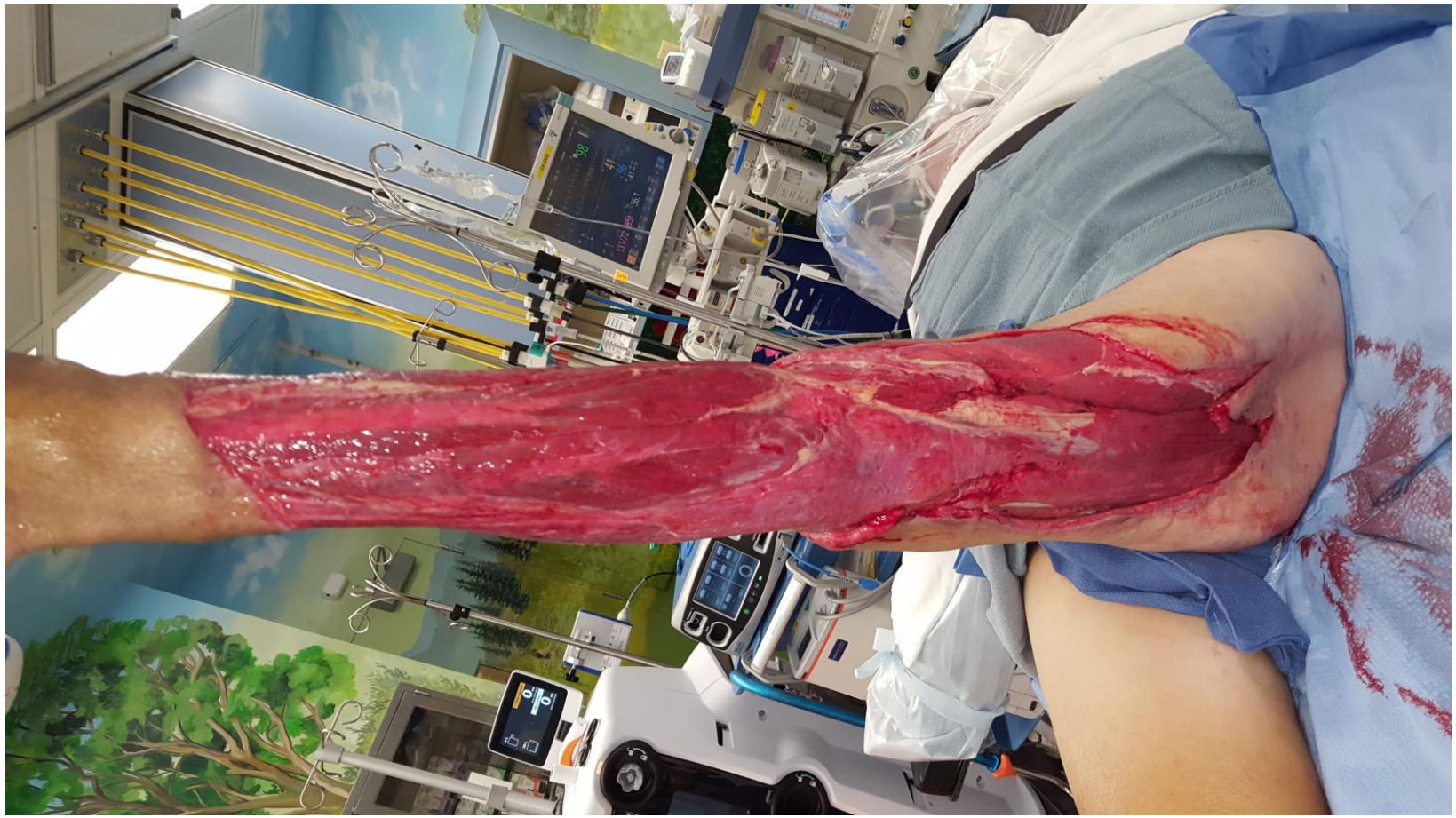
- Synthetics are less expensive???? (production, natural resources, degradation, long-term sensitization, immune modulation…)
- Biologic is expensive???? (sourcing, preservation, sterilization, reaction, long-term sensitization, immune modulation, religious considerations…)
- What convinces me?
  - Decreased overall pain and burden for the patient
  - Better outcomes
  - Fewer secondary procedures

# With and Without BTM

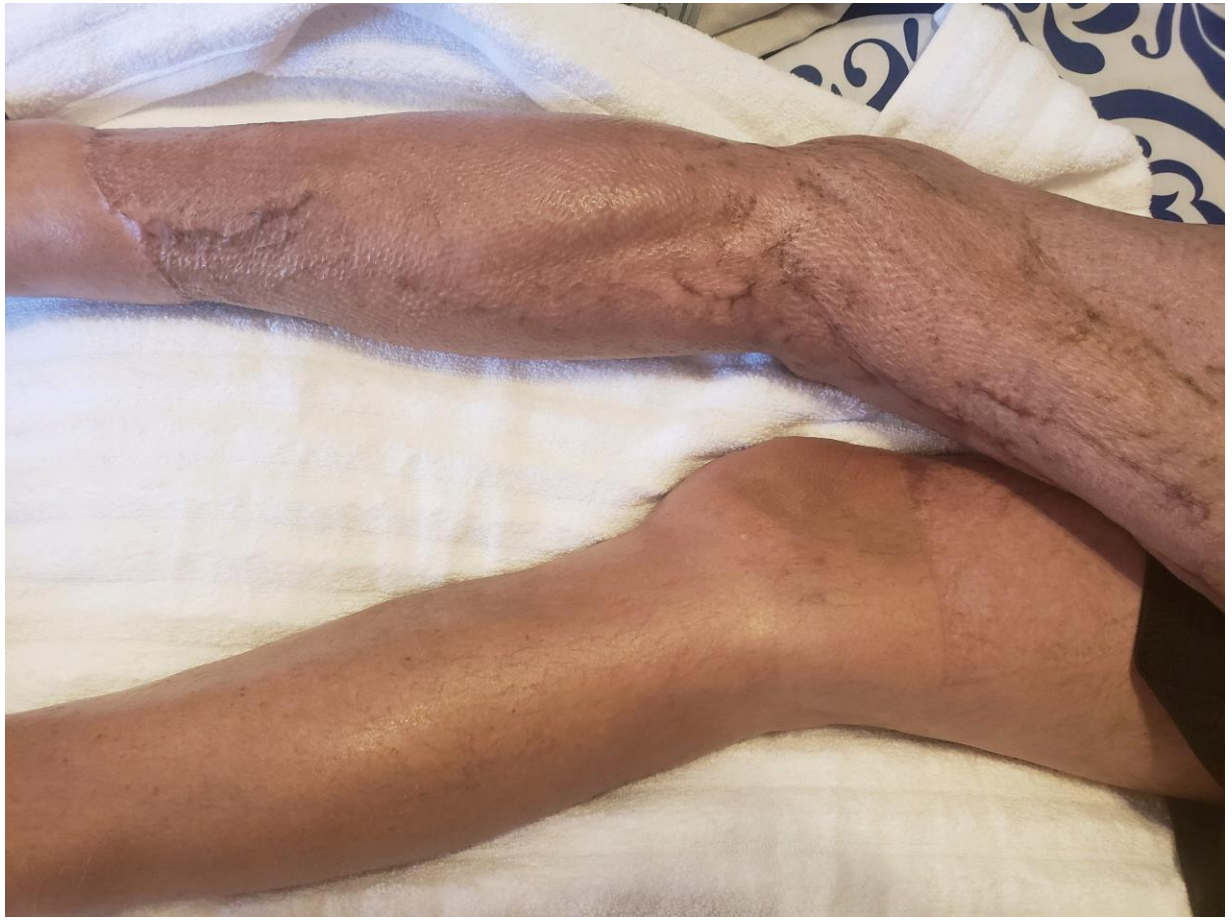




# Necrotizing Fasciitis, Marathon Runner



# ~7 Months Later, No Knee Contracture



# Why a Matrix?

- Complex burns and wounds need a vascularized wound bed
- Granulation often takes a long time and then leads to severe contracture or disfiguring scarring
- Exposed tendons, joints, or bones get attached or fixed to the scar skin when the granulation tissue functions as a vascularized wound bed—this prevents tendon glide and joint motion in the long run and leads to functional disability
- We are talking about situations where flap coverage is “out of the question” for multiple, above-mentioned, reasons
- We are talking about better outcomes
- We are talking about fewer secondary procedures

# Conclusion

- From a global economic health care perspective, using a matrix makes sense
- The matrix should
  - Be of the shelf
  - Reliably integrate
  - Produce a dermis-like structure
  - Cause few adverse events
  - Be sensitive to global economic constraints

# Post-DVA Reconstruction Cases

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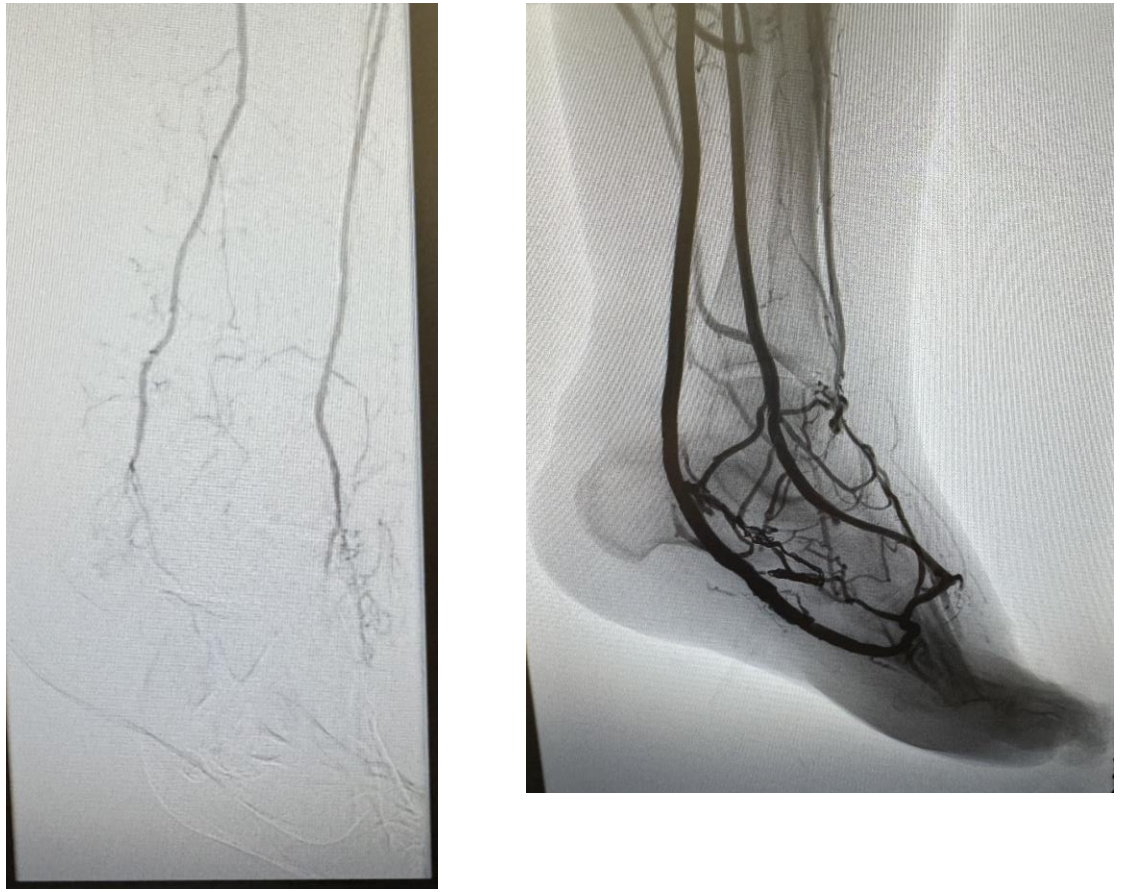
Medical Director, Wound Program
University of Texas Southwestern
Dallas, Texas

# Deep Venous Arterialization (DVA)

- No-option revascularization
- Creation of a fistula from PT, peroneal, or PT/peroneal trunk artery to PT or peroneal vein
- Typically conducted endovascularly, but can be done open

Pre- and post-DVA 3 months



**PT = posterior tibial.**

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

# Transcatheter Arterialization of Deep Veins in Chronic Limb-Threatening Ischemia

Mehdi H. Shishehbor, D.O., M.P.H., Ph.D., Richard J. Powell, M.D., Miguel F. Montero-Baker, M.D., Anahita Dua, M.D., Jorge L. Martínez-Trabal, M.D., Matthew C. Bunte, M.D., Arthur C. Lee, M.D., Andrew S. Mugglin, Ph.D., Joseph L. Mills, M.D., Alik Farber, M.D., and Daniel G. Clair, M.D., for the PROMISE II Investigators*

ABSTRACT

**BACKGROUND**

Approximately 20% of patients with chronic limb-threatening ischemia have no revascularization options, leading to above-ankle amputation. Transcatheter arterialization of the deep veins is a percutaneous approach that creates an artery-to-vein connection for delivery of oxygenated blood by means of the venous system to the ischemic foot to prevent amputation.

**METHODS**

We conducted a prospective, single-group, multicenter study to evaluate the effect of transcatheter arterialization of the deep veins in patients with nonhealing ulcers and no surgical or endovascular revascularization treatment options. The composite primary end point was amputation-free survival (defined as freedom from above-ankle amputation or death from any cause) at 6 months, as compared with a performance goal of 54%. Secondary end points included limb salvage, wound healing, and technical success of the procedure.

**RESULTS**

We enrolled 105 patients who had chronic limb-threatening ischemia and were of a median age of 70 years (interquartile range, 38 to 89). Of the patients enrolled, 33 (31.4%) were women and 45 (42.8%) were Black, Hispanic, or Latino. Transcatheter arterialization of the deep veins was performed successfully in 104 patients (99.0%). At 6 months, 66.1% of the patients had amputation-free survival. According to Bayesian analysis, the posterior probability that amputation-free survival at 6 months exceeded a performance goal of 54% was 0.993, which exceeded the prespecified threshold of 0.977. Limb salvage (avoidance of above-ankle amputation) was attained in 67 patients (76.0% by Kaplan–Meier analysis). Wounds were completely healed in 16 of 63 patients (25%) and were in the process of healing in 32 of 63 patients (51%). No unanticipated device-related adverse events were reported.

**CONCLUSIONS**

We found that transcatheter arterialization of the deep veins was safe and could be performed successfully in patients with chronic limb-threatening ischemia and no conventional surgical or endovascular revascularization treatment options. (Funded by LimFlow; PROMISE II study ClinicalTrials.gov number, NCT03970538.)

From University Hospitals Harrington Heart and Vascular Institute, Cleveland (M.H.S.); the Division of Vascular Surgery, Dartmouth–Hitchcock Medical Center, Lebanon, NH (R.J.P.); the Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston (M.F.M.-B., J.L.M.); the Division of Vascular Surgery, Massachusetts General Hospital, Harvard Medical School (A.D.), and the Division of Vascular and Endovascular Surgery, Boston Medical Center, Boston University School of Medicine (A.F.) — both in Boston; the Division of Vascular Surgery, Ponce Health Sciences University, St. Luke's Episcopal Hospital, Ponce, Puerto Rico (J.L.M.-T.); Saint Luke's Mid America Heart Institute, Kansas City, MO (M.C.B.); HCA Florida North Florida Hospital, the Cardiac and Vascular Institute, Gainesville (A.C.L.); Paradigm Biostatistics, Anoka, MN (A.S.M.); and the Department of Vascular Surgery, Vanderbilt School of Medicine, Nashville (D.G.C.). Dr. Shishehbor can be contacted at mehdi.shishehbor@uhhospitals.org or at University Hospitals Harrington Heart and Vascular Institute, 11100 Euclid Ave., Lakeside 3rd Fl., Cleveland, OH 44106.

*A complete list of the PROMISE II trial investigators is provided in the Supplementary Appendix, available at NEJM.org.

N Engl J Med 2023;388:1171-80.
DOI: 10.1056/NEJMoa2212754


CME at NEJM.org





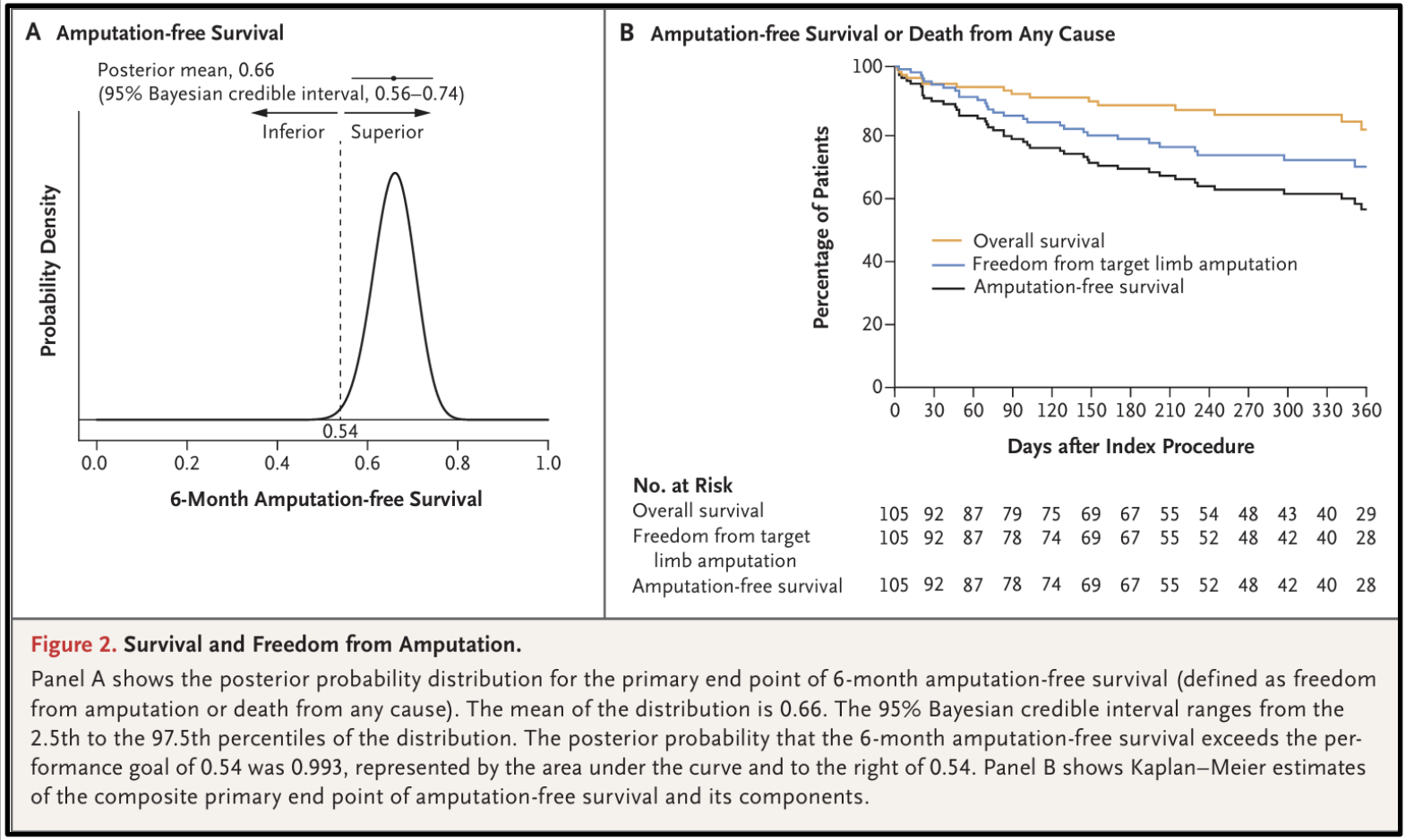



**Figure 2. Survival and Freedom from Amputation.**

Panel A shows the posterior probability distribution for the primary end point of 6-month amputation-free survival (defined as freedom from amputation or death from any cause). The mean of the distribution is 0.66. The 95% Bayesian credible interval ranges from the 2.5th to the 97.5th percentiles of the distribution. The posterior probability that the 6-month amputation-free survival exceeds the performance goal of 0.54 was 0.993, represented by the area under the curve and to the right of 0.54. Panel B shows Kaplan–Meier estimates of the composite primary end point of amputation-free survival and its components.

**Shishehbor MH, et al. *N Engl J Med*. 2023;388(13):1171-1180.**

# Peri-DVA Adjunctive Foot Surgery

- At the time of DVA (joint case or sometime after DVA)
  - Amputation/removal of all nonviable tissue
    - Minimal dissection, delicate tissue handling
    - No primary closure
    - Leave bone embedded in soft tissue
    - Remove all cartilage
  - Application of synthetic graft
    - Place MTX deep (can fold and stack prn) and BTM over the top
    - Staple in place
    - No deep sutures
- Follow-up
  - Close weekly follow-up for first 3 weeks (both vascular and podiatric)
    - Watch for infection
    - Antibiotics and topical antimicrobials
    - Further tissue demarcation
    - Ultrasound
    - Pain control

**MTX = matrix; BTM = biodegradable temporizing matrix.**

# Peri-DVA Adjunctive Foot Surgery

- Repeat Surgery
  - Vascular may have to reintervene, including shutting down of veins
  - Amputation/removal of all nonviable tissue
  - Will bleed a lot – venous ooze, use of topical anticoagulants
    - Avitene (microfibrillar collagen hemostat) powder mixed with 1 g vancomycin
  - Reapplication of synthetic graft
  - Expect hematoma
- Follow-up
  - Continue close monitoring
  - If delaminates, continue monitoring of neuvodermis formation
  - Can use NPWT
  - Secondary healing or STSG
  - Wait 3 months to conduct any additional definitive surgery or other surgery on the foot

**NPWT = negative pressure wound therapy; STSG = split-thickness skin graft.**

# Polyurethane Dermal Matrix

## Optimization of a Polyurethane Dermal Matrix and Experience With a Polymer-Based Cultured Composite Skin

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John E. Greenwood, AM, BSc(Hons), MBChB, MD, DHlthSc,
FRCS(Eng), FRCS(Plast), FRACS†

The aims were to 1) describe the in vivo studies leading to an optimized model of the biodegradable temporizing matrix (BTM), 2) describe our efforts in effecting closure over this optimized matrix after integration with a cultured composite skin (CCS), and 3) reexamine the ability of the CCS to definitively close fresh wounds (without BTM). Foam scaffolds of biodegradable polyurethane were created to allow in vivo tissue ingrowth or in vitro co-culture. Using the porcine surgical model, multiple BTM optimization studies took place before the BTM-CCS main study was conducted. For the CCS study, optimized sealed 2 mm matrices were implanted into 6-mm deep, 8 × 8 cm wounds (three per pig) and allowed to integrate for 21 days, whereas collected blood and harvested skin tissue were used to prepare autologous composite skins in similar (unsealed) 1 mm matrices. These were then applied at day 21 either over the integrated BTMs or into a freshly created fourth wound. All of the optimized matrices integrated fully, without loss, and were found to resist wound contraction effectively until the composites were ready for application at day 21. The composites demonstrated the ability to generate a bilayer repair with robust epidermis anchored by a basement membrane visible from day 7 after application. The final optimized sealed BTM delaminates easily to produce a clean, temporized wound bed and will be used in the upcoming burn clinical trial. Although the CCS is a magnitude away from human trials, it is still capable of generating a bilayer repair in both BTM-integrated and fresh wounds (onto fat), and with further refinement and optimization of foam structure, seeding densities, and timing, consistent success should be possible. (J Burn Care Res 2014;35:437–448)

Attempting to reproduce dermal and epidermal functions in deep wounds, where skin graft is not available, is a daunting prospect. In the extensive burn situation, failure to do so can result in death by sepsis or outcomes marred by delayed healing, poor or abnormal scarring, and joint contracture, deformity, and loss of function. With the creation of Integra Dermal Regeneration Template® (Integra Life-Sciences Corp., Plainsboro, NJ) by Burke and Yannas, the dermal matrix strategy for major burn care became possible. The silicone sheet sealing the matrix mimics physiological wound closure,[1] whereas the collagen matrix component becomes integrated into the wound to create a stable and robust bed for subsequent grafting, thus improving both function and cosmesis.[2–4]

Some issues with the strategy have reduced its potential globally and can be categorized into problems inherent with collagen matrices and problems related to the fact that split-skin graft is still required to effect definitive closure. Collagen-based matrices remain expensive for the end user.[5] The biological

*From the *Skin Engineering Laboratory and †Adult Burn Centre, Royal Adelaide Hospital, Adelaide, South Australia, Australia.*
*This study was supported by a grant from BioInnovation SA, a South Australian Government-affiliated grant funding body. The NovoSorb™ biodegradable polyurethane platform is produced by PolyNovo Biomaterials Pty. Ltd. based in Port Melbourne, Victoria, Australia. NovoSkin Pty. Ltd. is a joint venture company established to investigate the role of NovoSorb™ in deep burn wounds. Associate Professor Greenwood owns a 20% share in NovoSkin Pty. Ltd., and the remaining 80% is owned by PolyNovo Pty. Ltd.*
*Address correspondence to John E. Greenwood, AM, Adult Burn Service, Royal Adelaide Hospital North Terrace, Adelaide, South Australia 5000, Australia.*

*1559-047X/2014*
*DOI: 10.1097/BCR.0000000000000061*

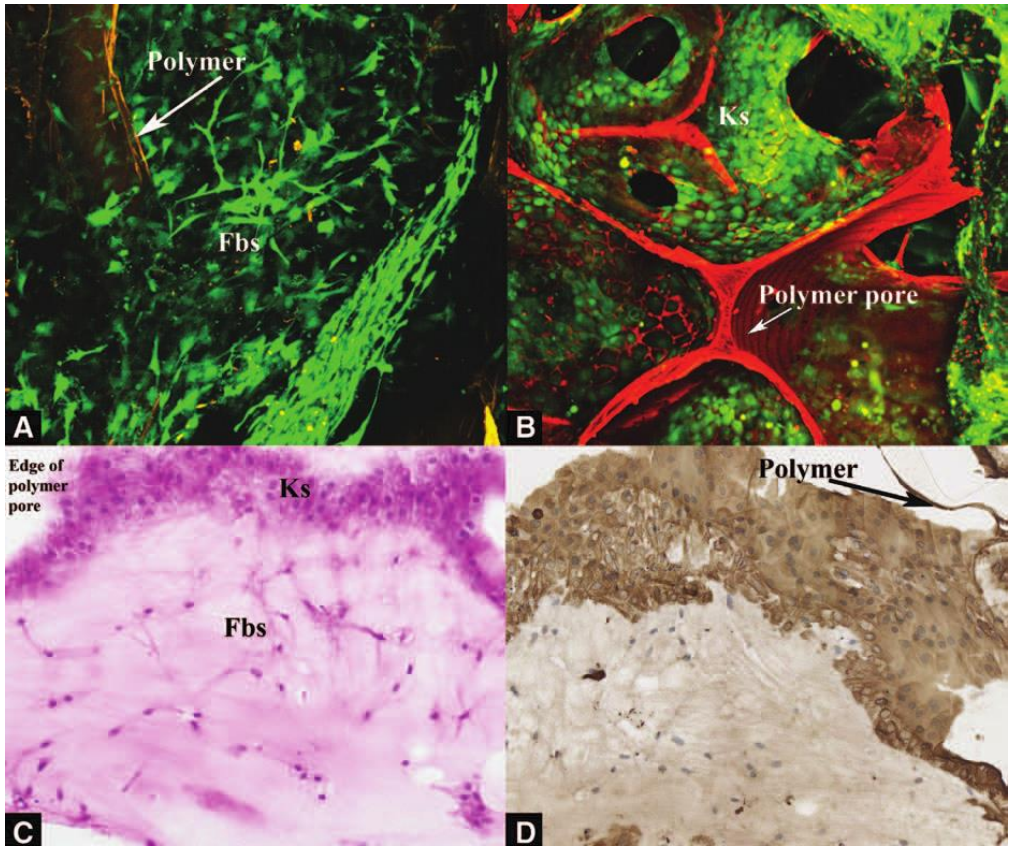



**Figure 3.** Cultured composite skin in vitro before application. A. Fibroblasts (Fbs) stained green (calcein), filling the polymer pore. B. Co-cultured fibroblasts and keratinocytes (Ks) lining the polymer wall (polymer scaffold stained red). C. Hematoxylin and eosin horizontal section demonstrates a single pore with keratinocytes bordering the polymer edge with central fibroblasts. D. Immunopositive staining (brown) for keratin (BovK).

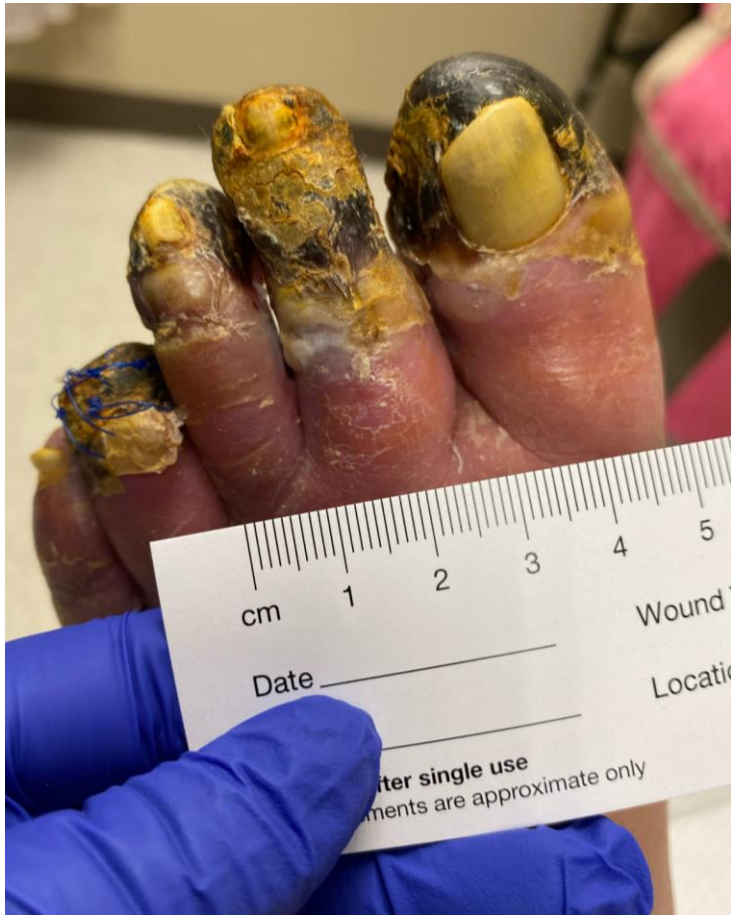
**Dearman BL, et al. *J Burn Care Res*. 2014;35(5):437-448.**

# Case 1

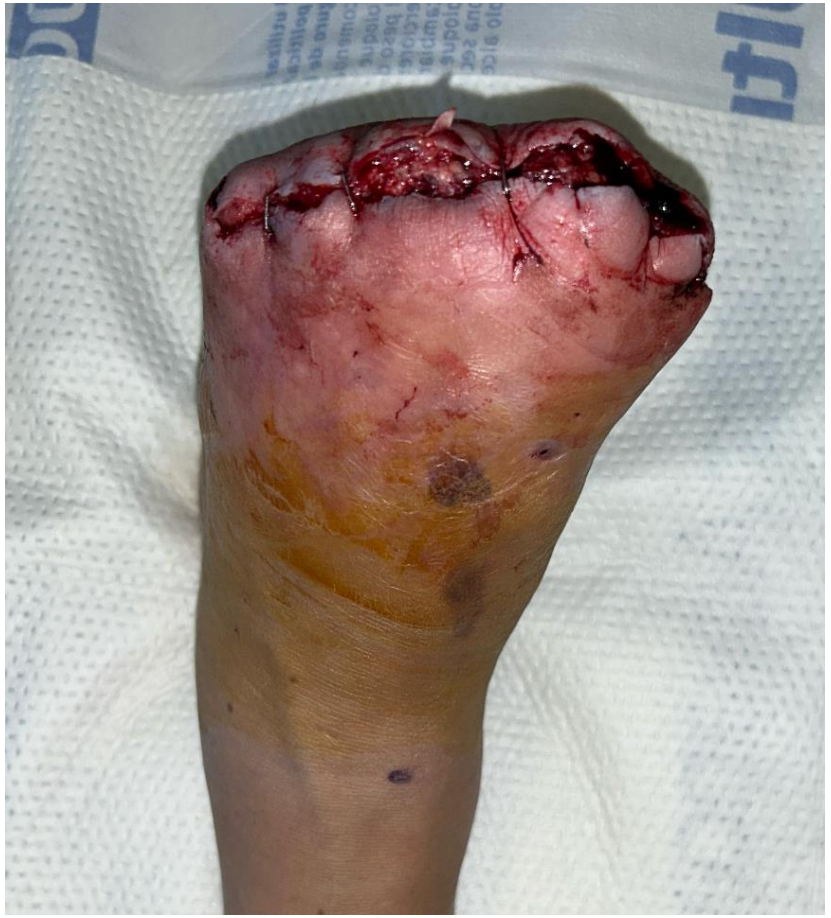
- DM, PVD, BKA on right
- Post-DVA, partial closure failure

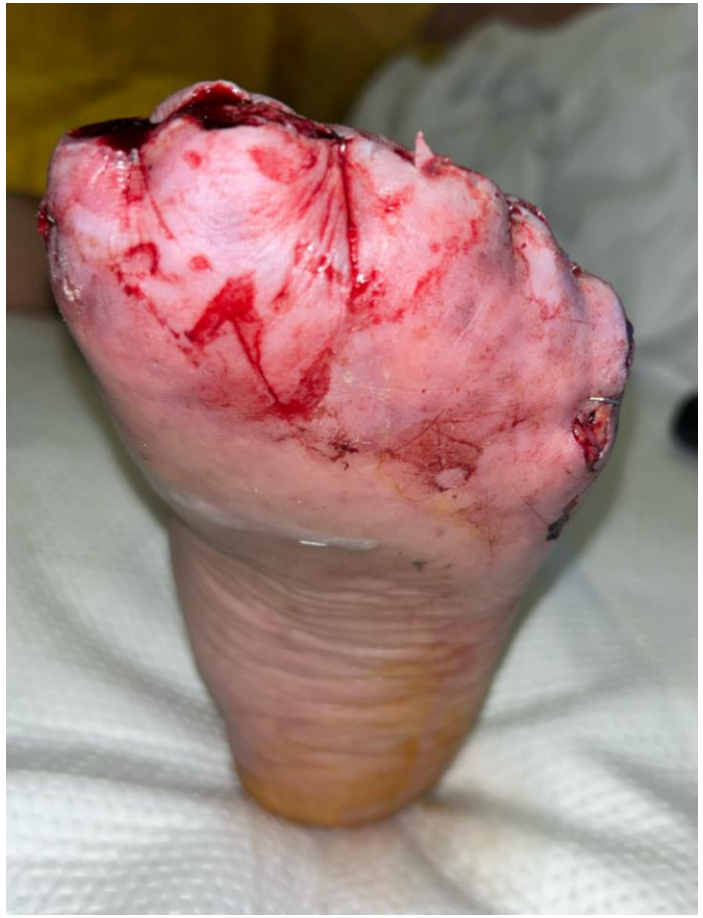
**DM = diabetes mellitus; PVD = peripheral vascular disease; BKA = below-knee amputation.**

Pre-DVA and trans digital amputation



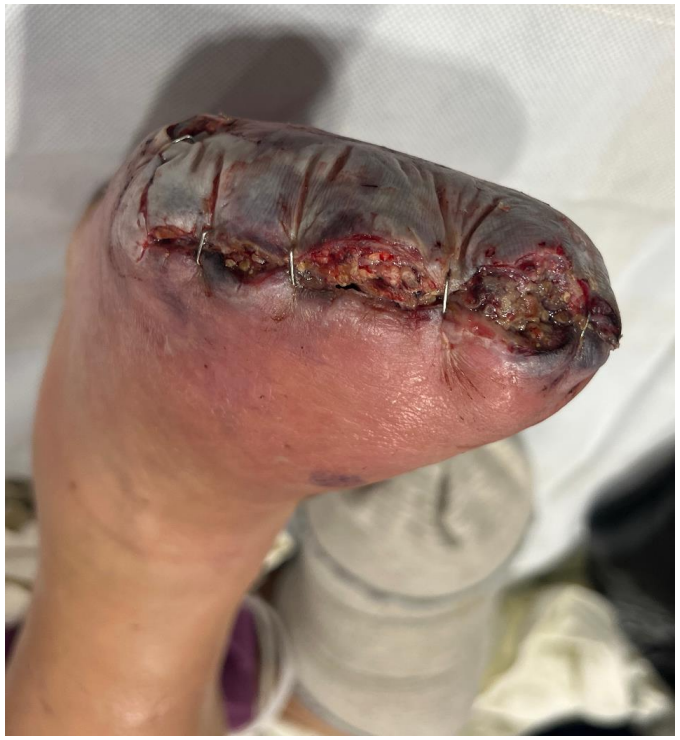

Post-DVA and POD 1 trans digital amputation with partial closure

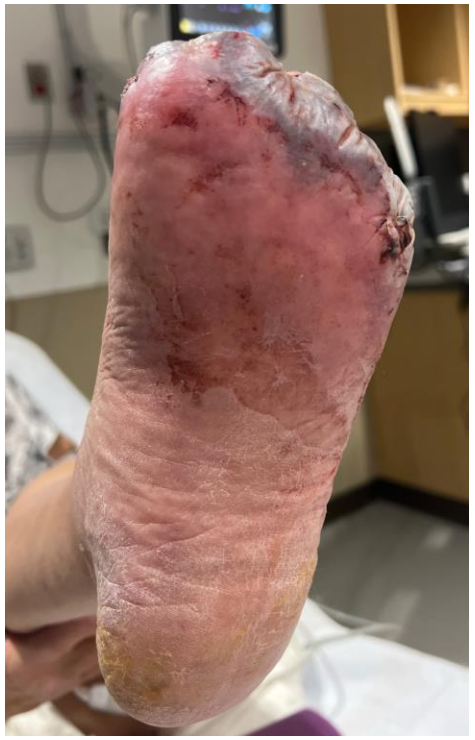




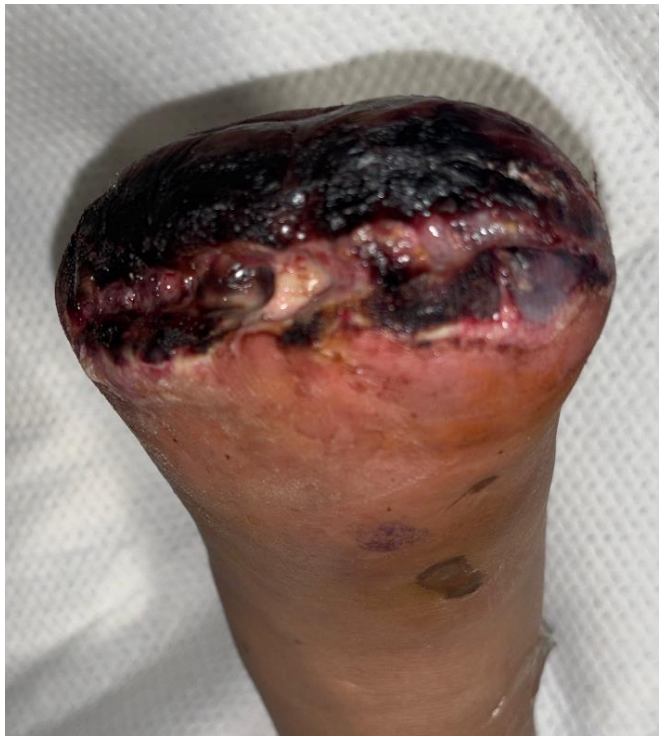
**POD = post-operative day.**

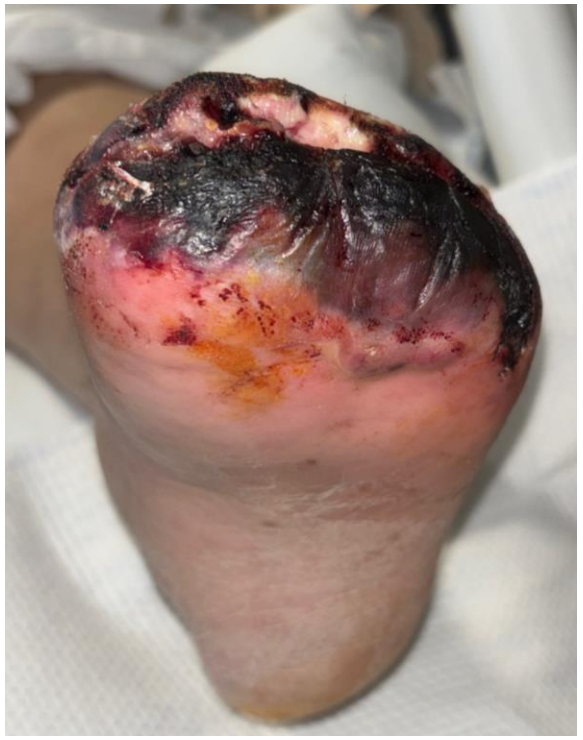
POD 3 trans digital amputation



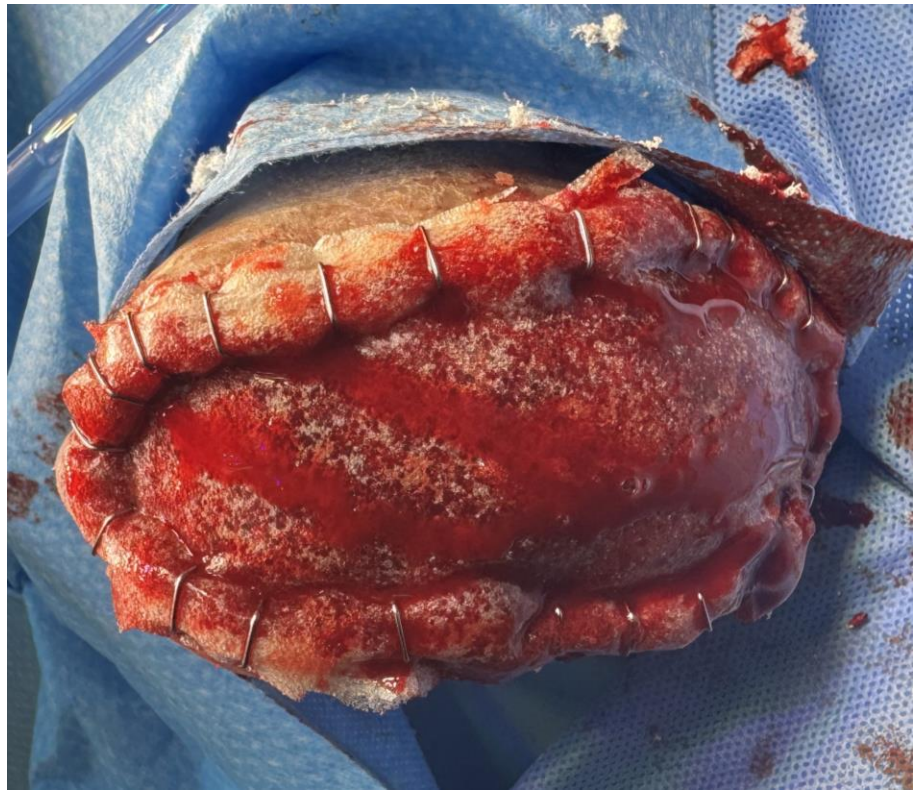


POD 5 trans digital amputation

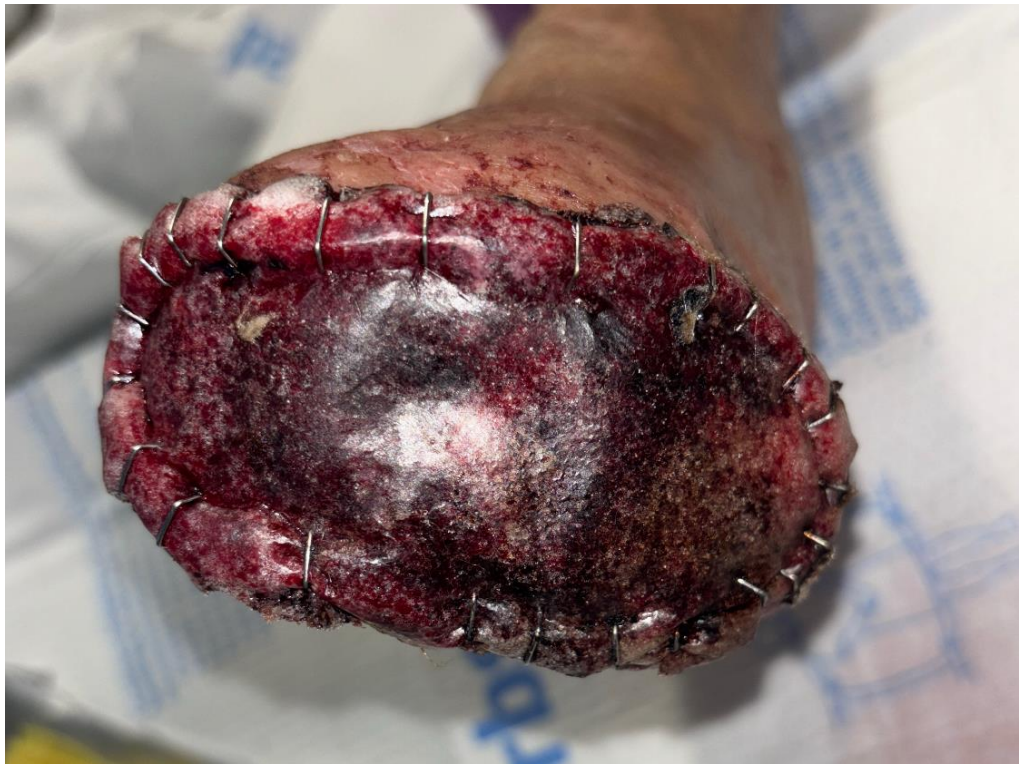




Revision to TMA
Intra-op application of BTM

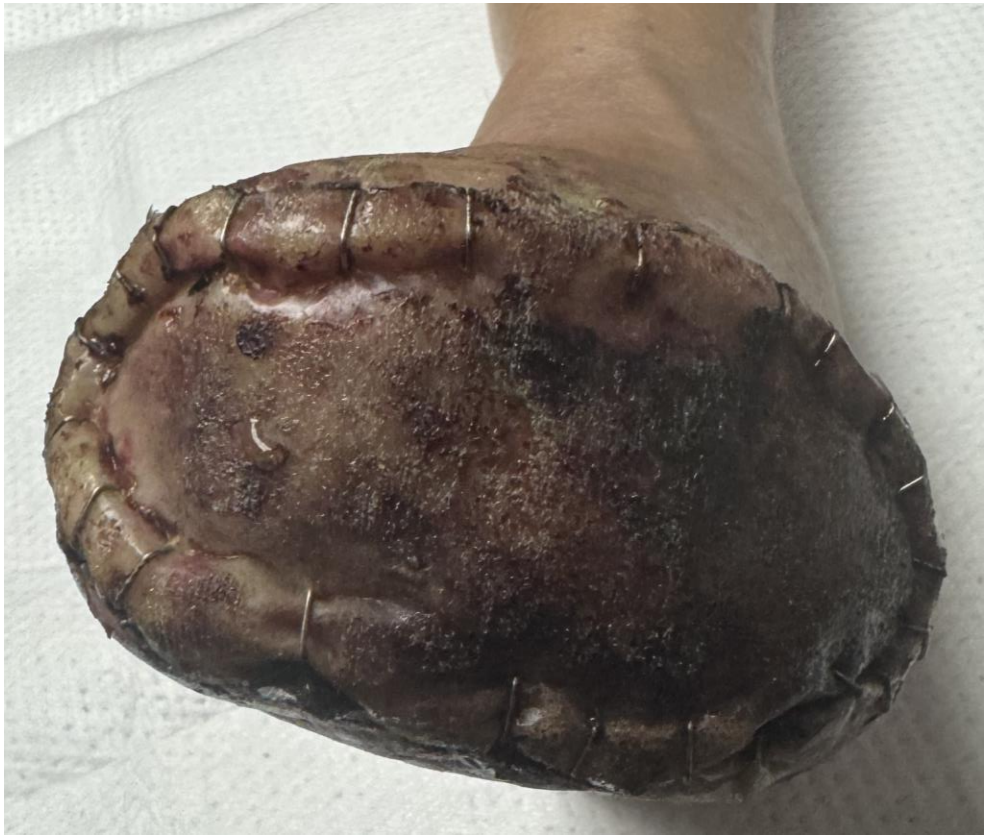


Post-op day 1

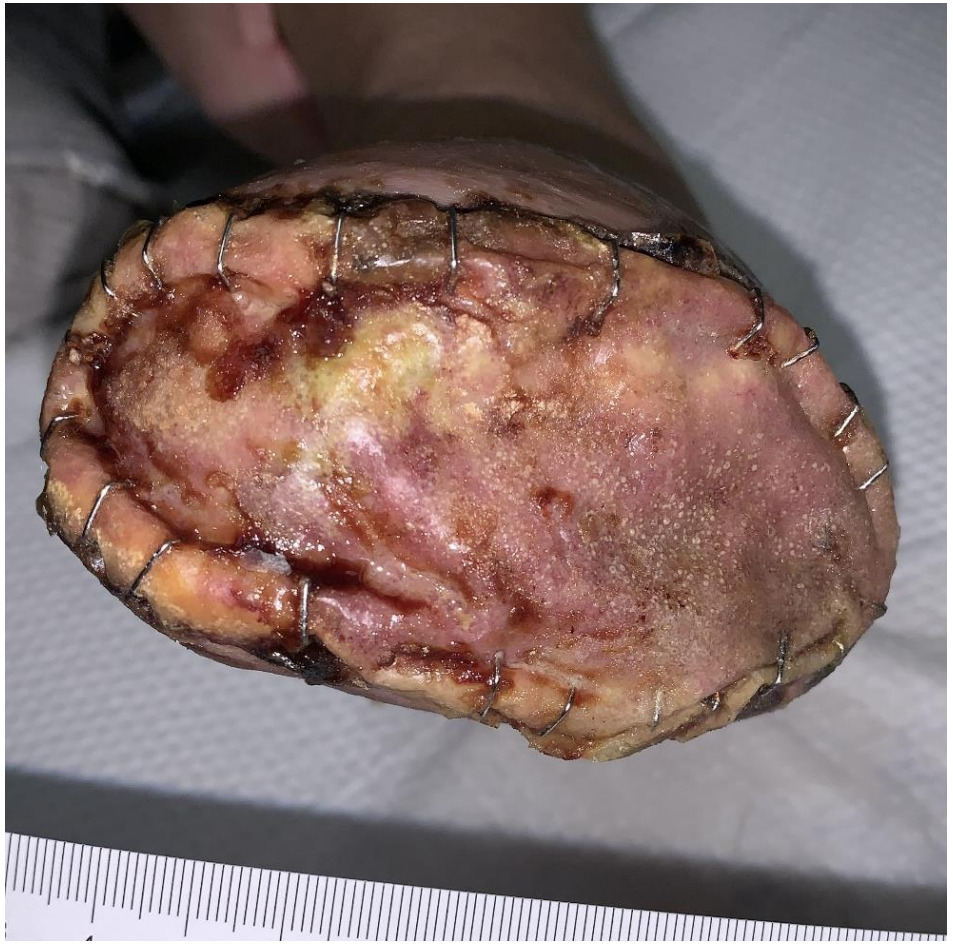


**TMA = transmetatarsal amputation.**

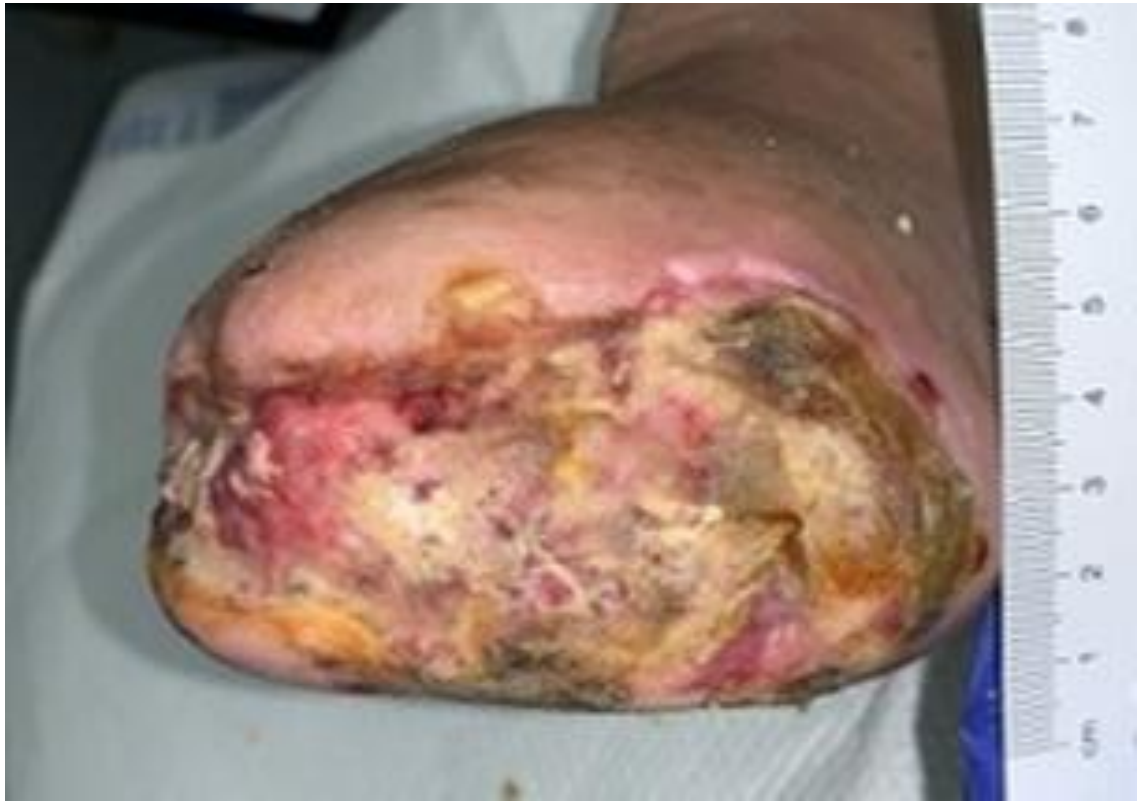
Post-op day 14



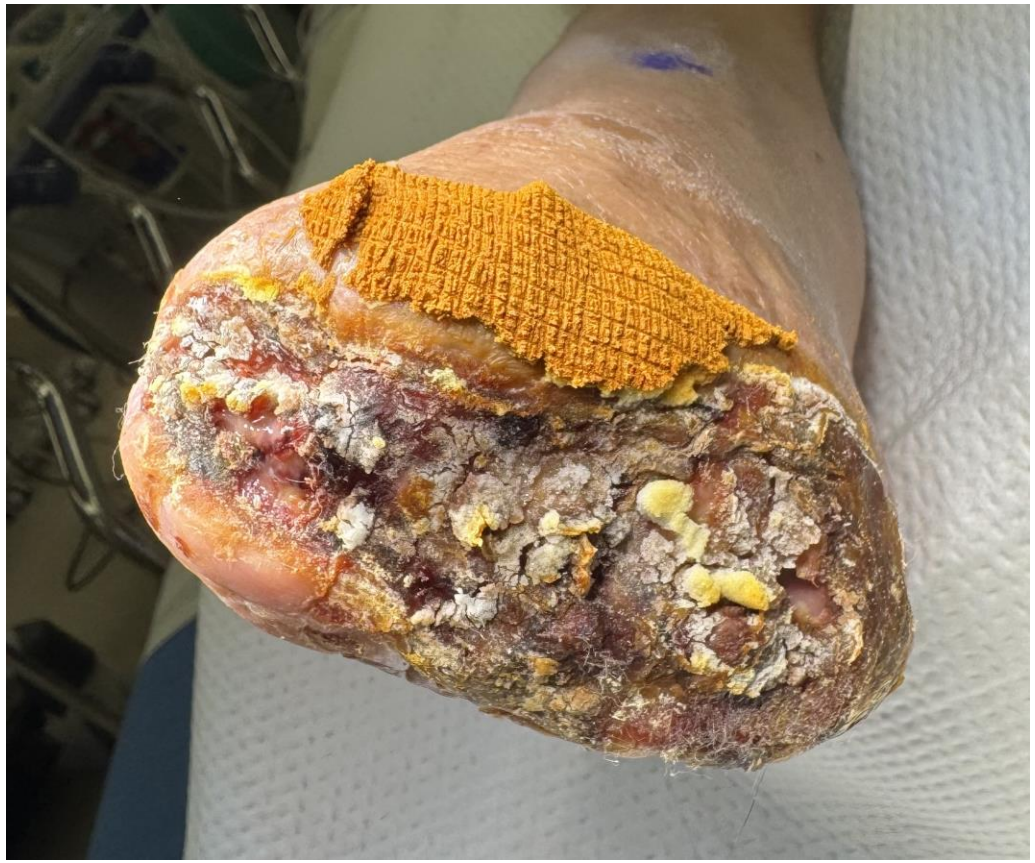
Post-op day 30

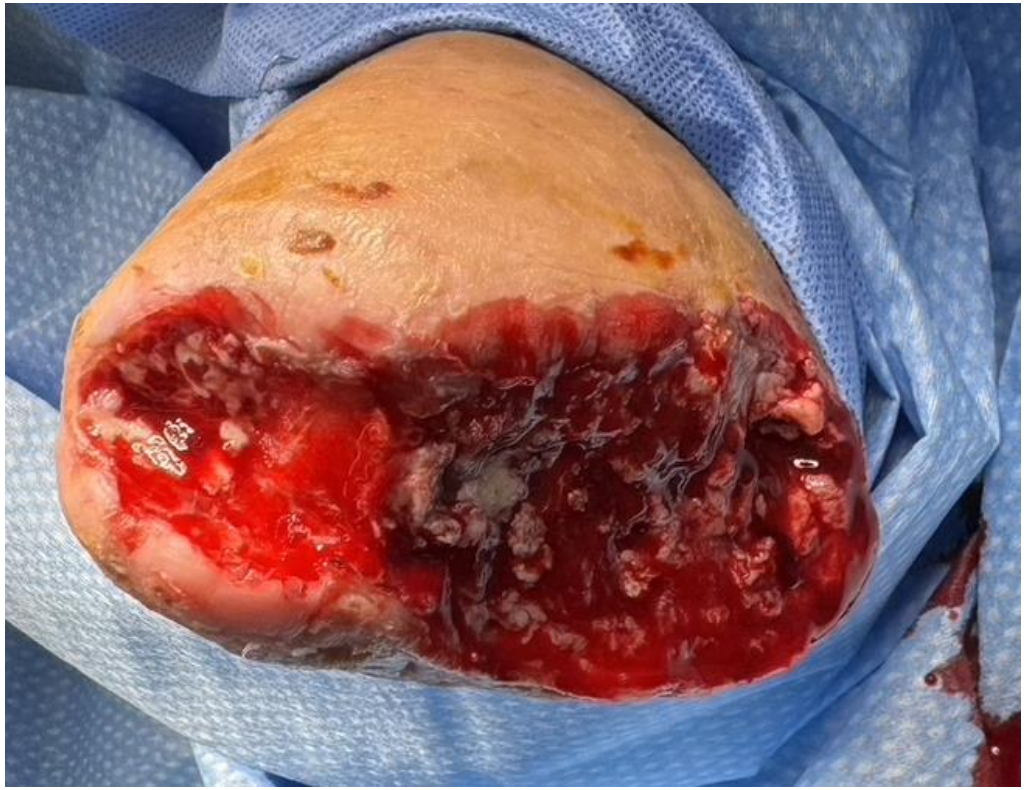


Post-op day 45



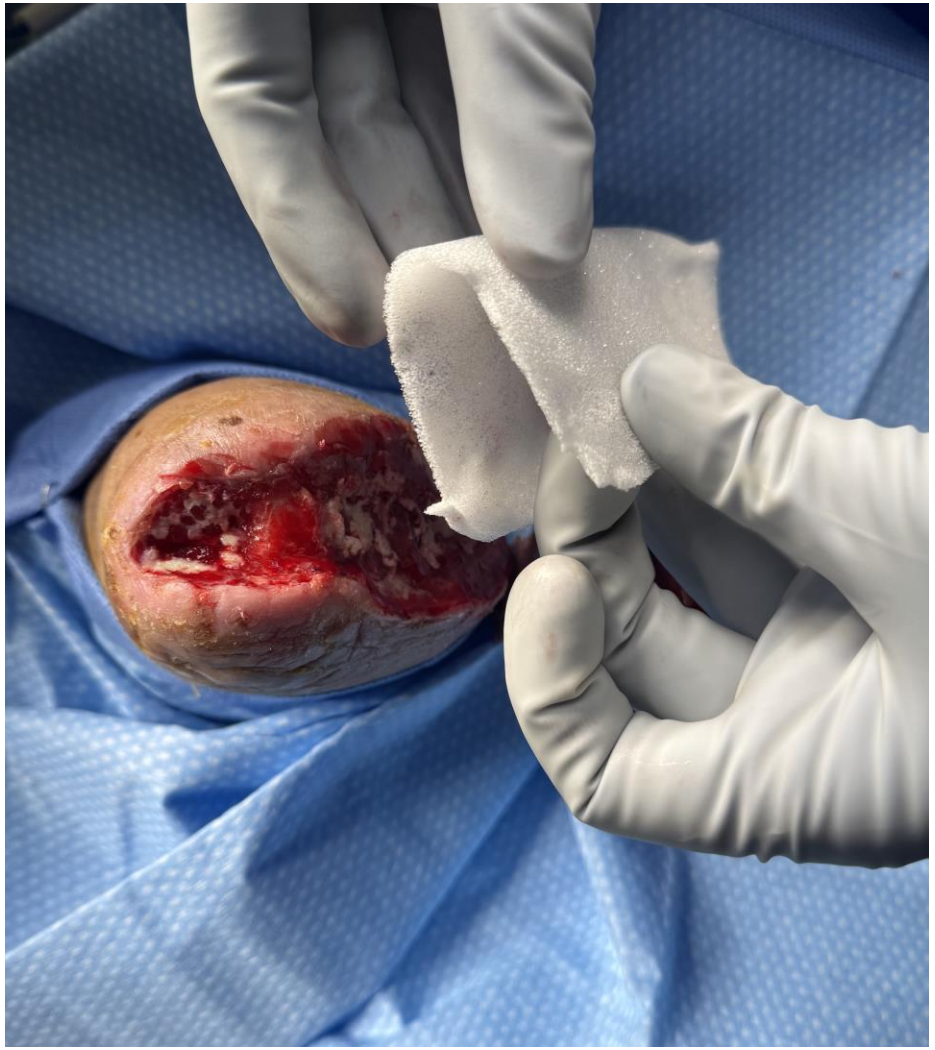
Second OR pre- and post-debridement
Resection of all metatarsal heads

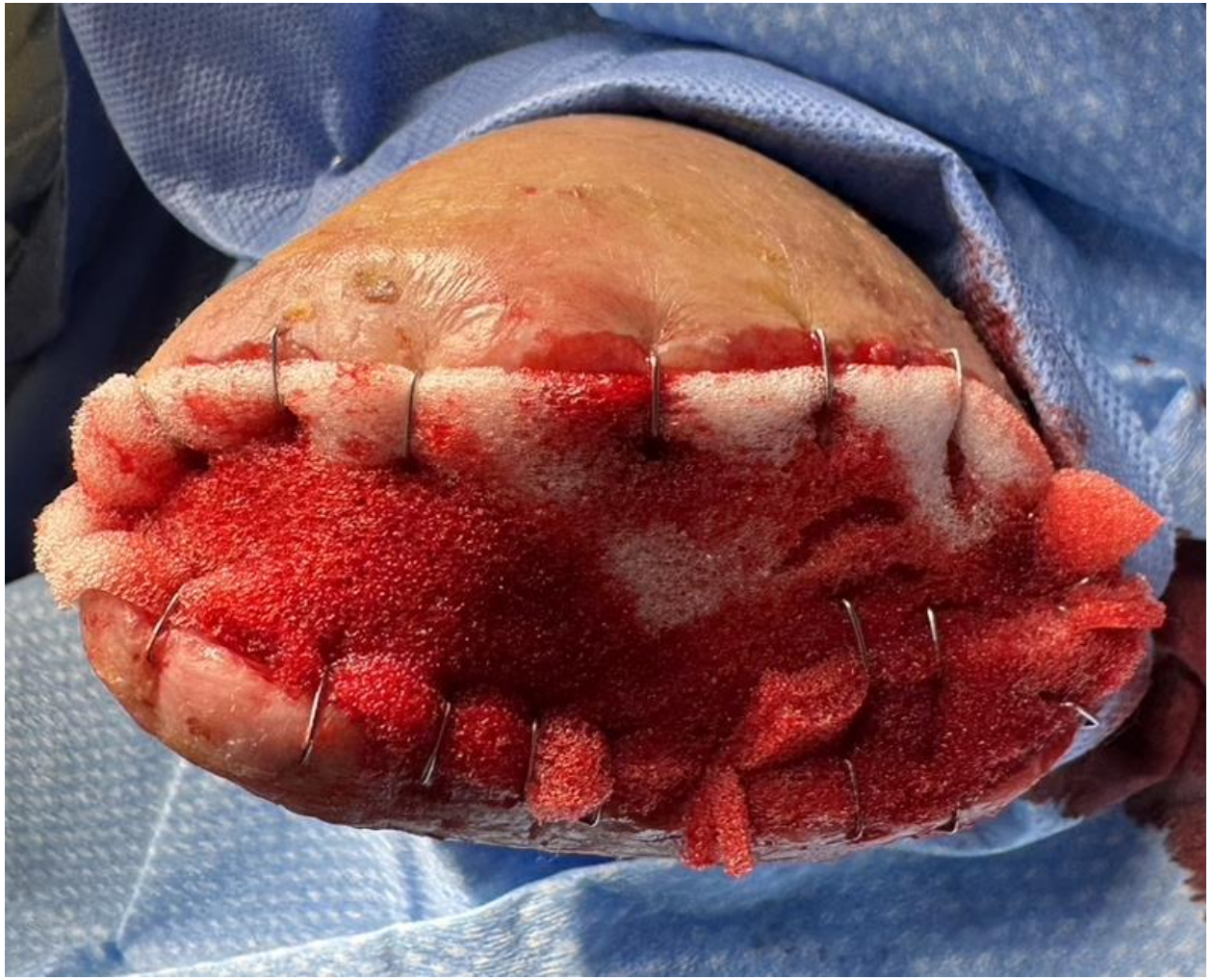




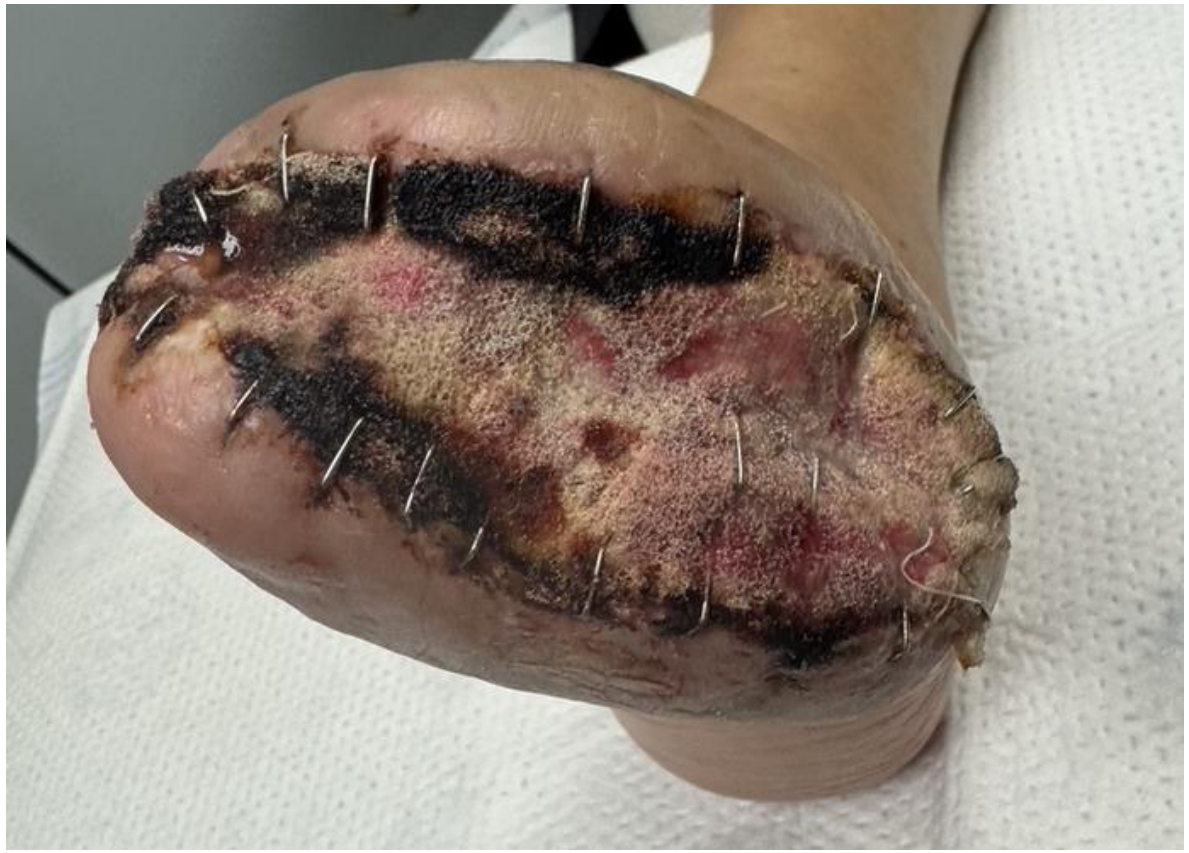
**OR = operating room.**

Intra-op
Folded MTX in half

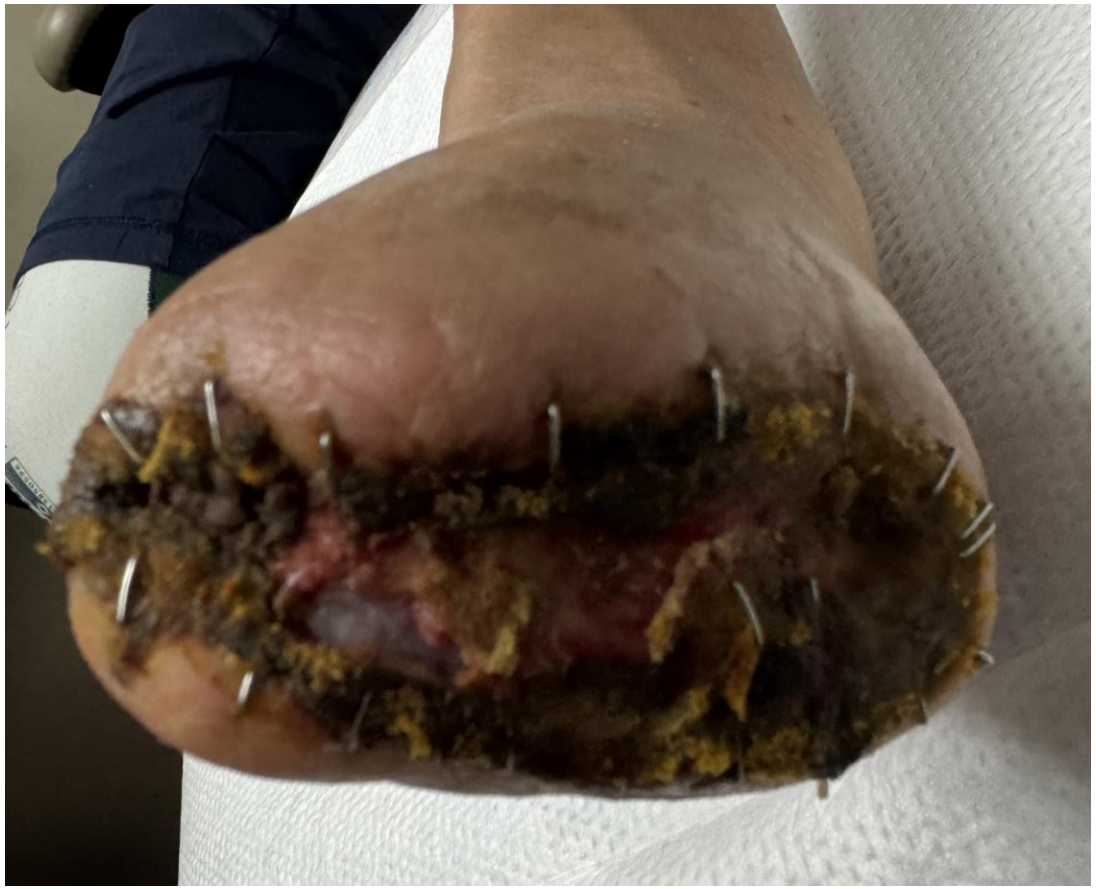




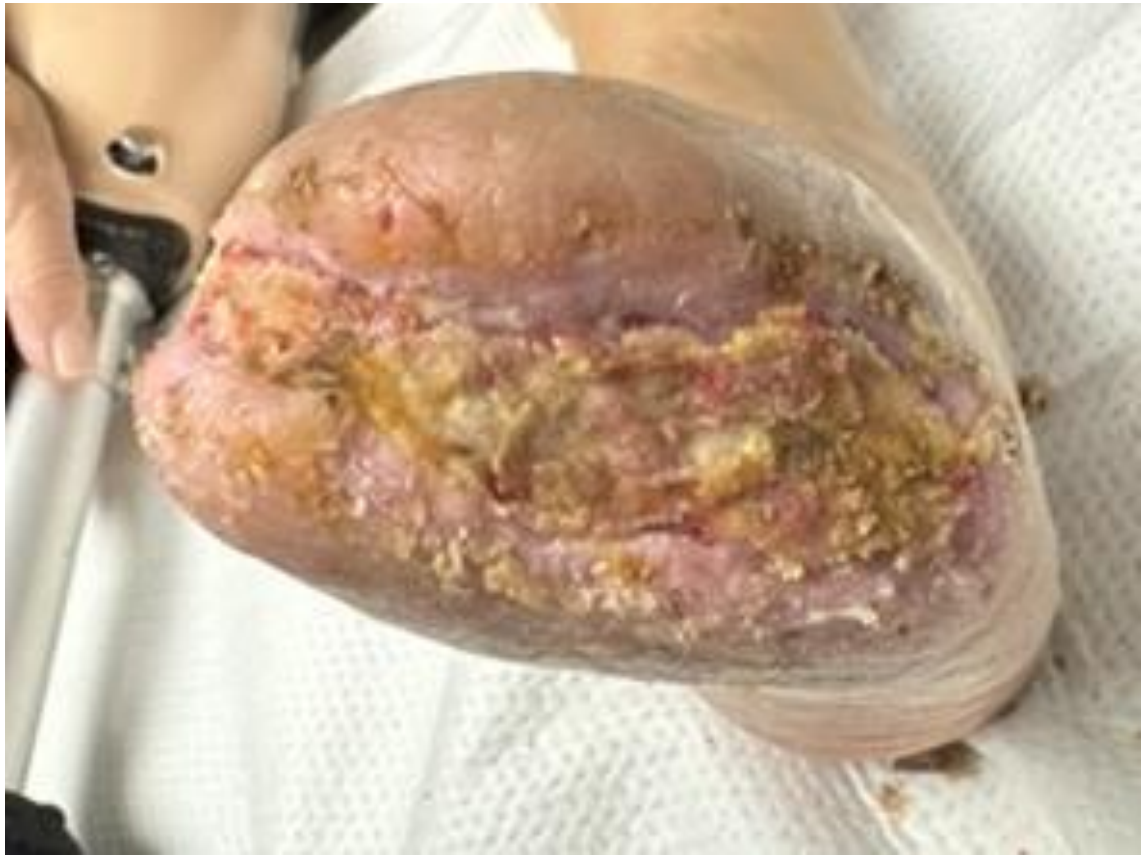
2 weeks post-op



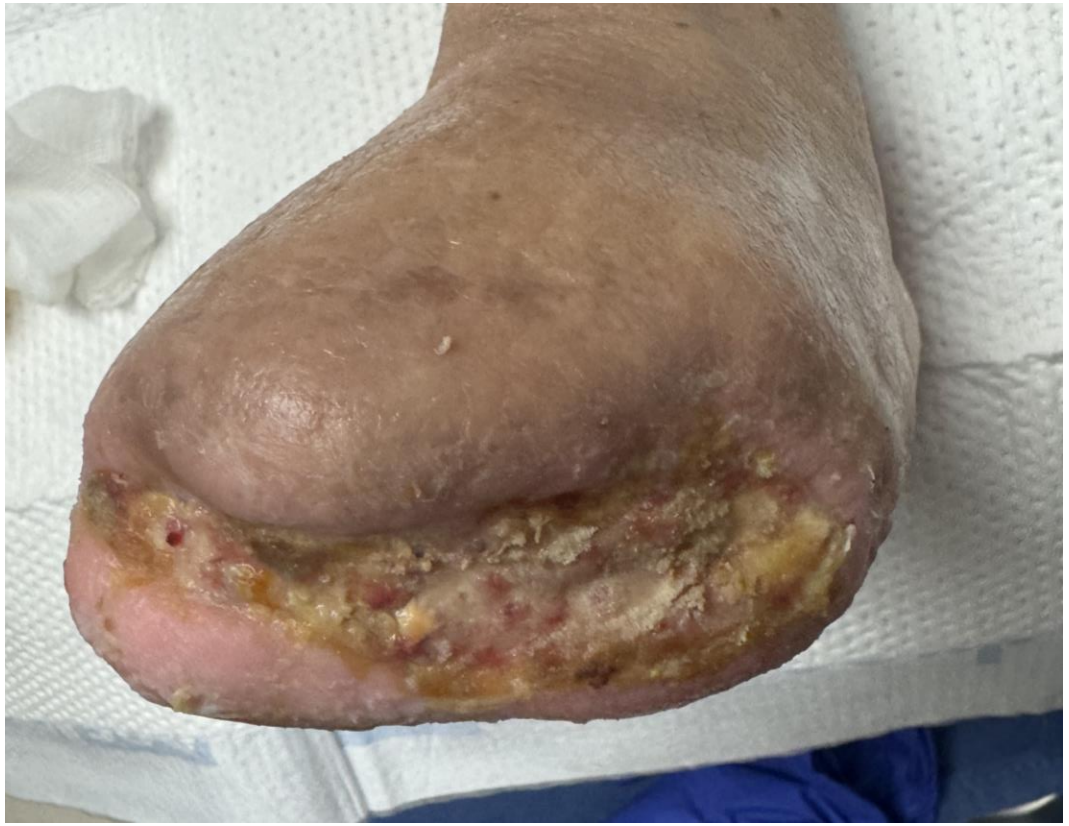
4 weeks post-op



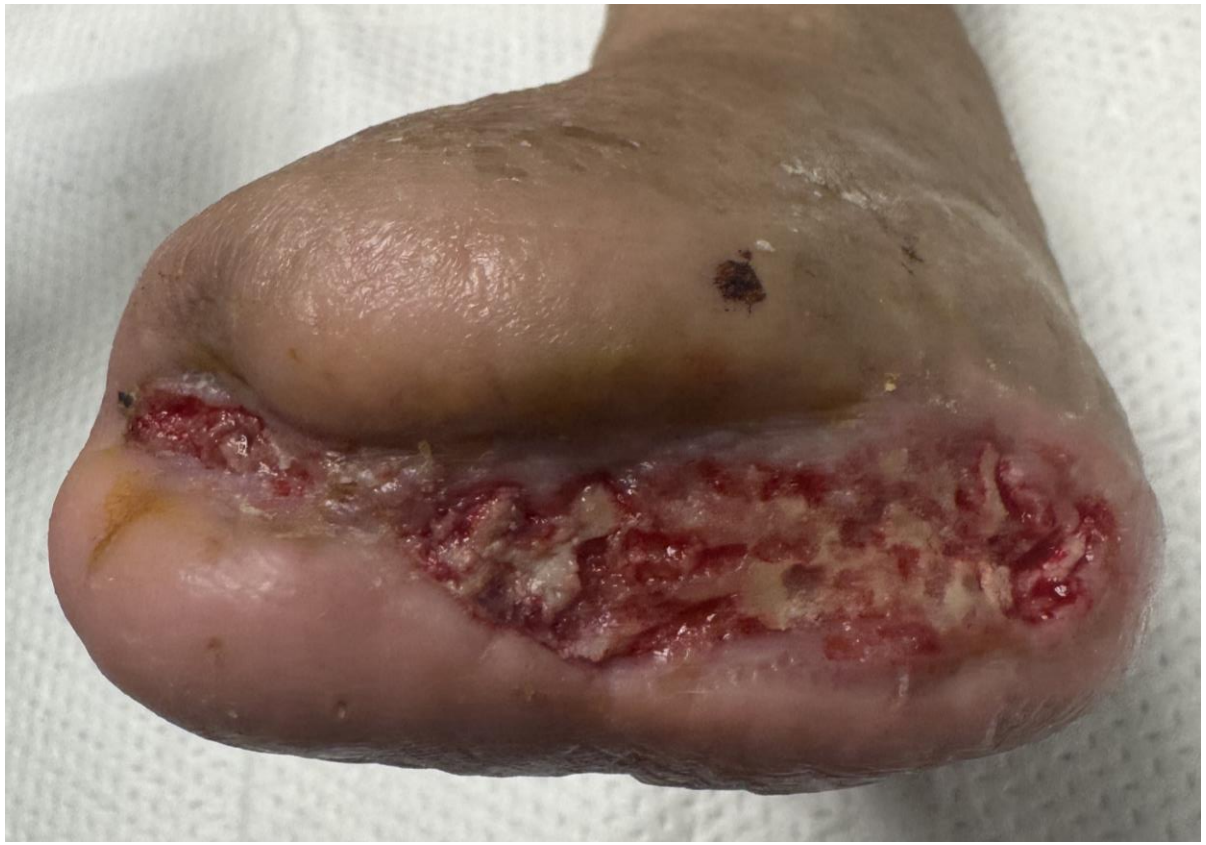
8 weeks post-op



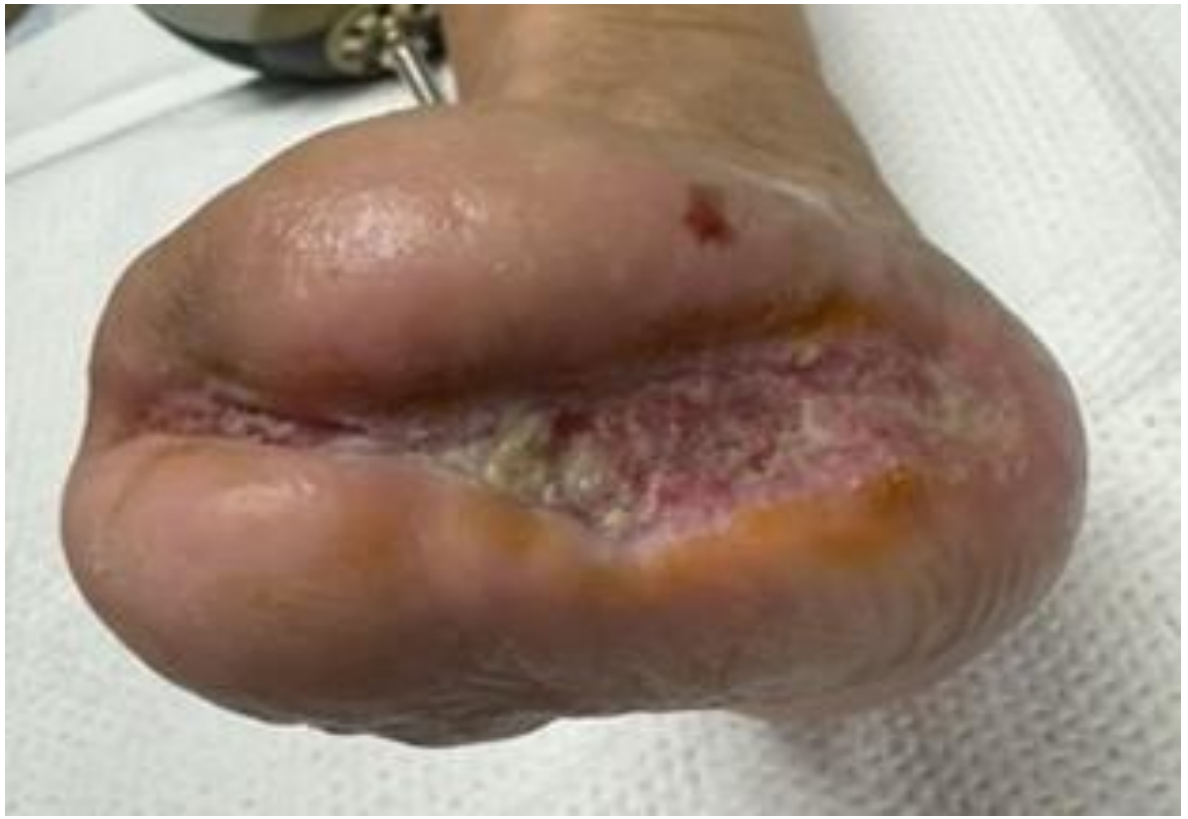
10 weeks post-op



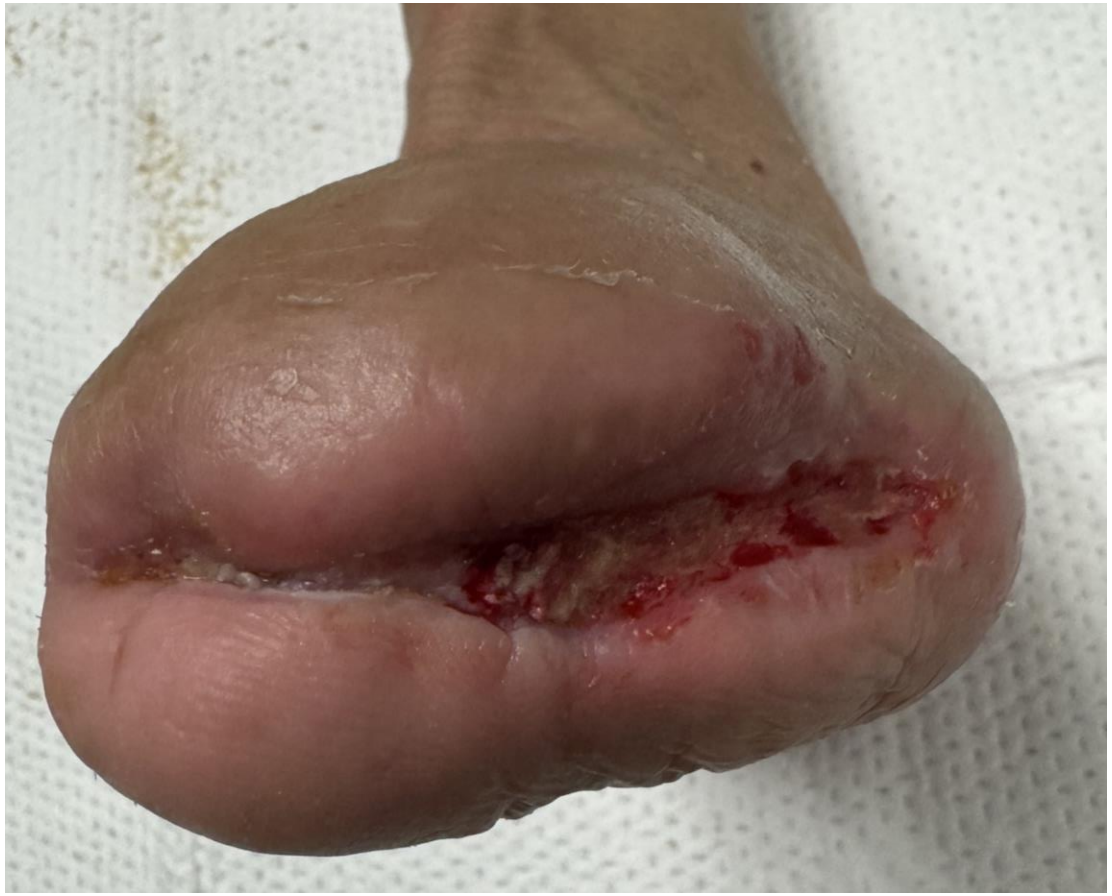
12 weeks post-op



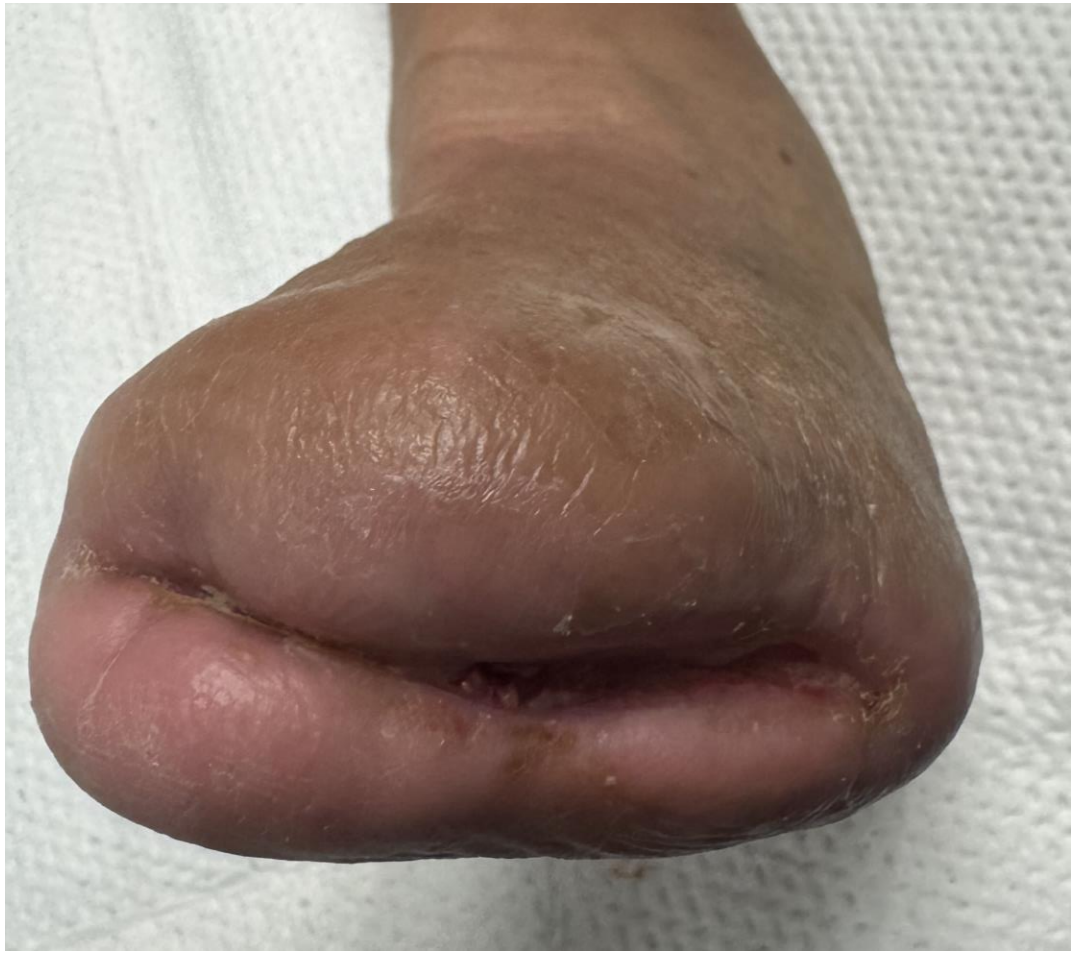
16 weeks post-op



24 weeks post-op



38 weeks post-op

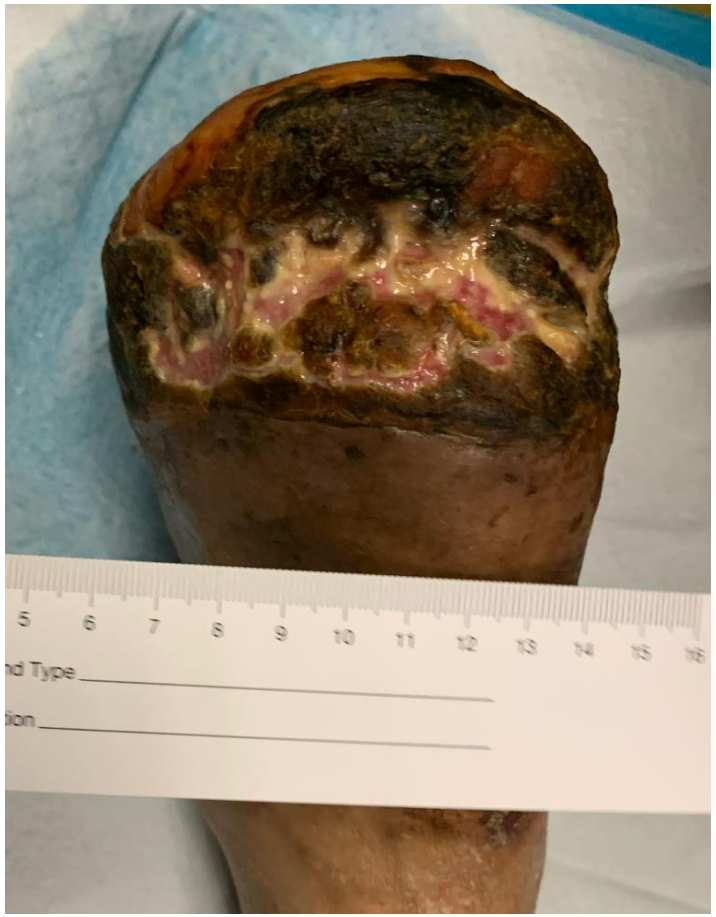


# Case 2

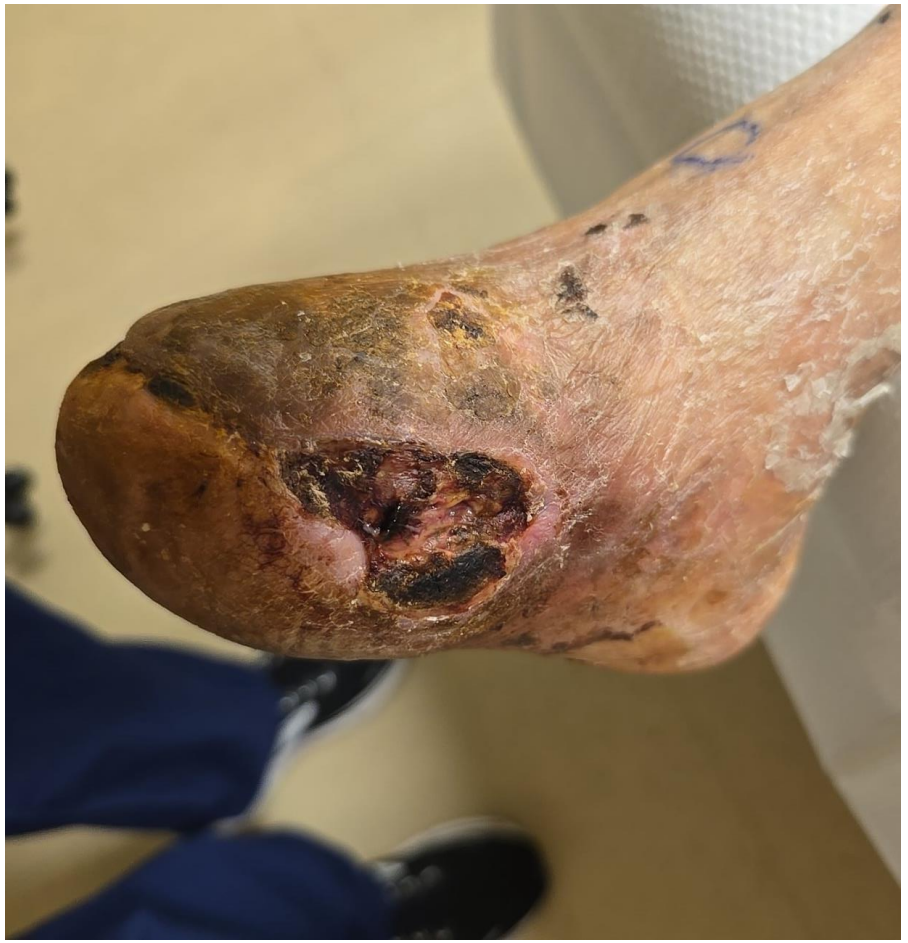
- DM, PVD, ESRD, DVA
- Bilateral TMA wounds

**ESRD = end-stage renal disease.**

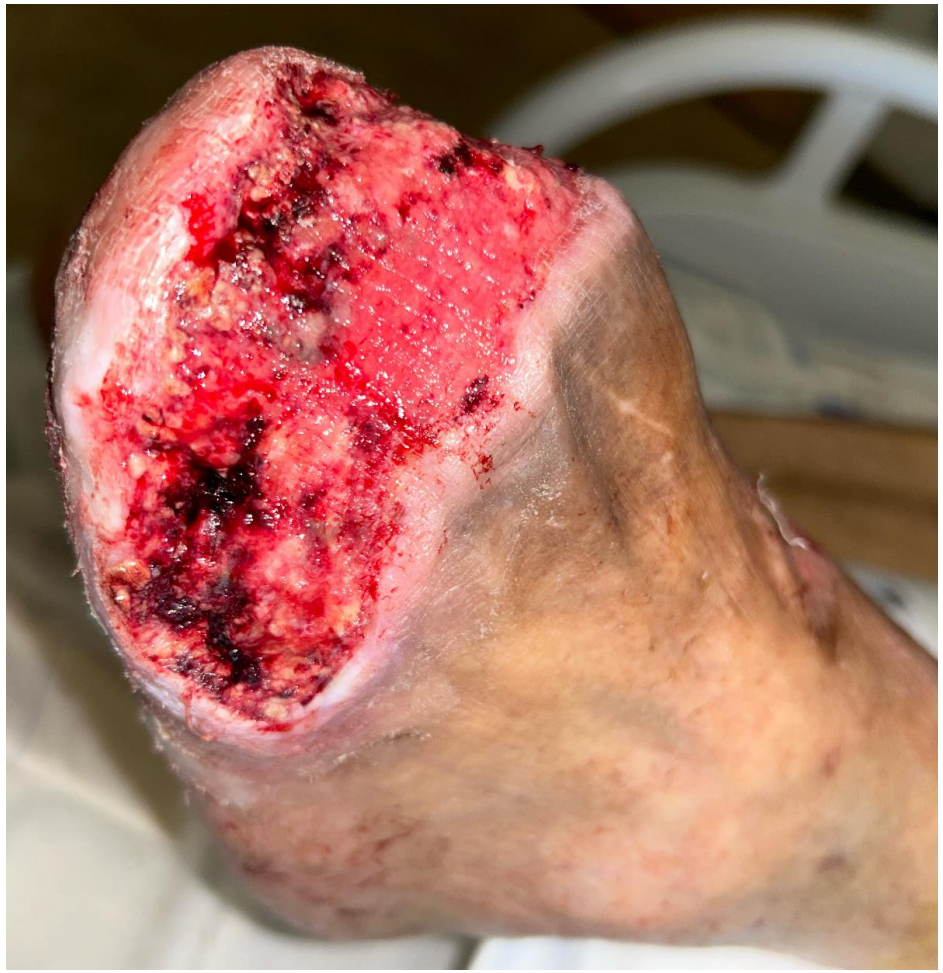
Left foot TMA dehiscence at initial presentation



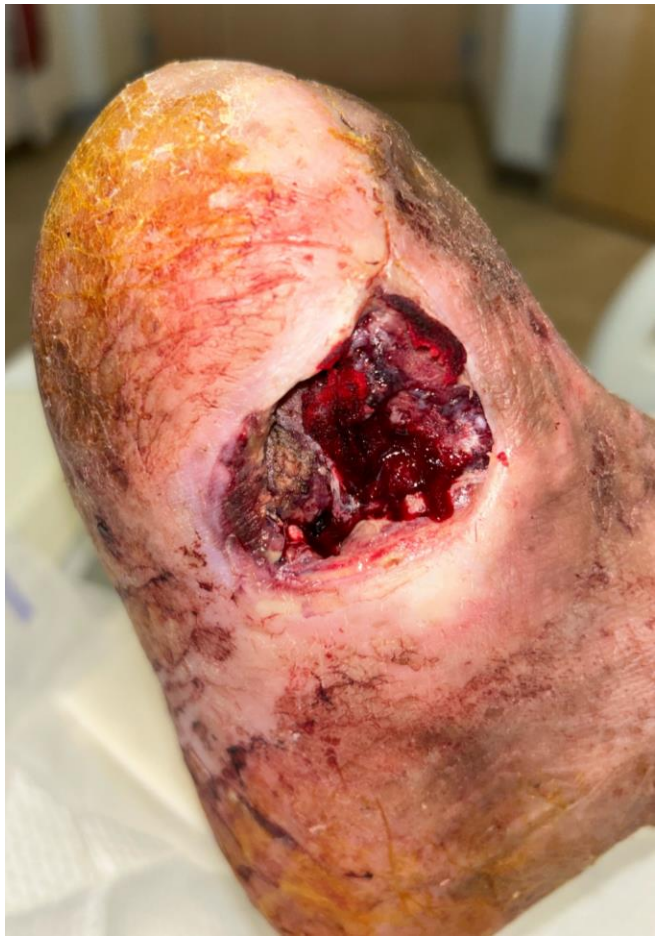
Right foot TMA dehiscence at initial presentation



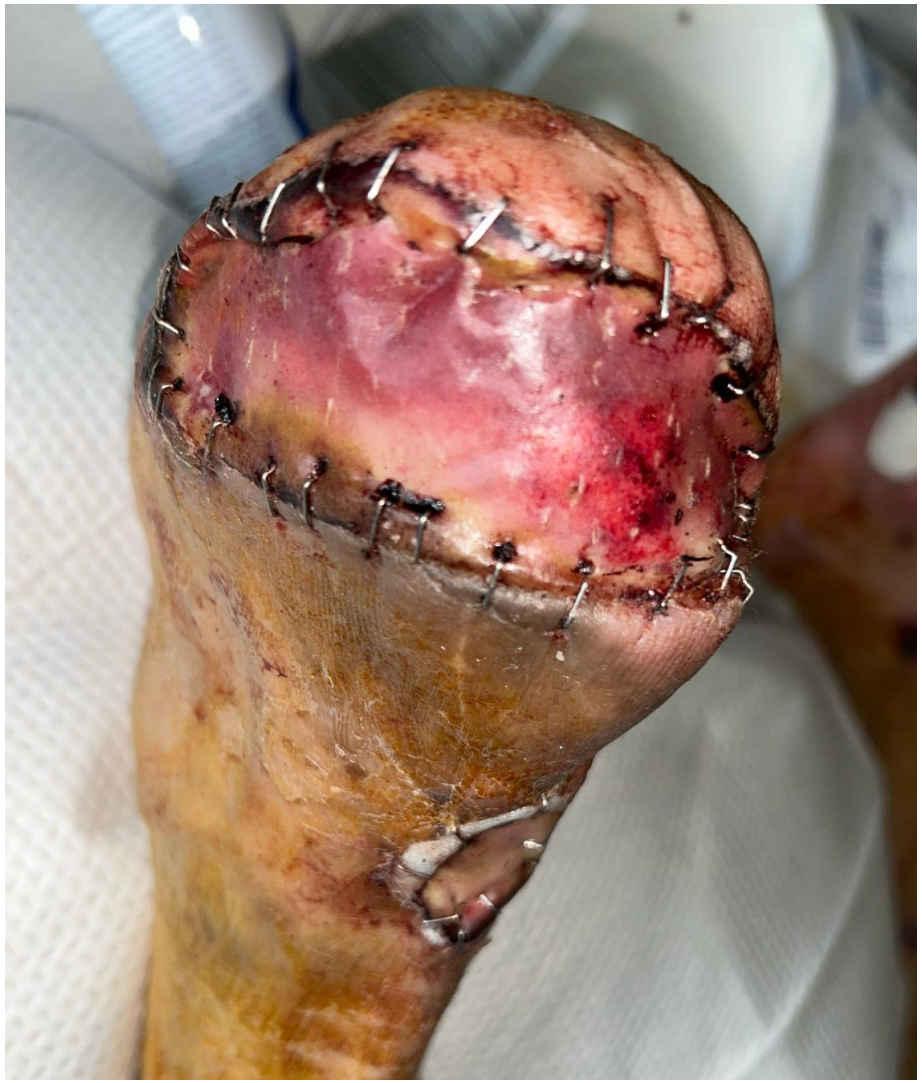
Left foot TMA dehiscence
Post-excisional debridement and DVA

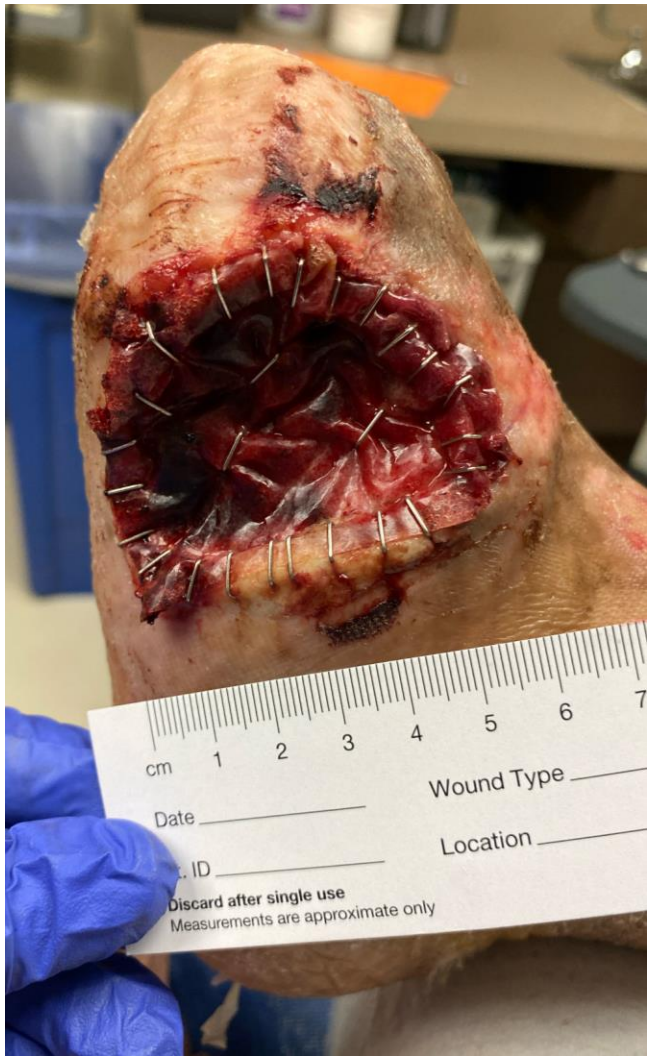


Right foot TMA dehiscence
Post-excisional debridement

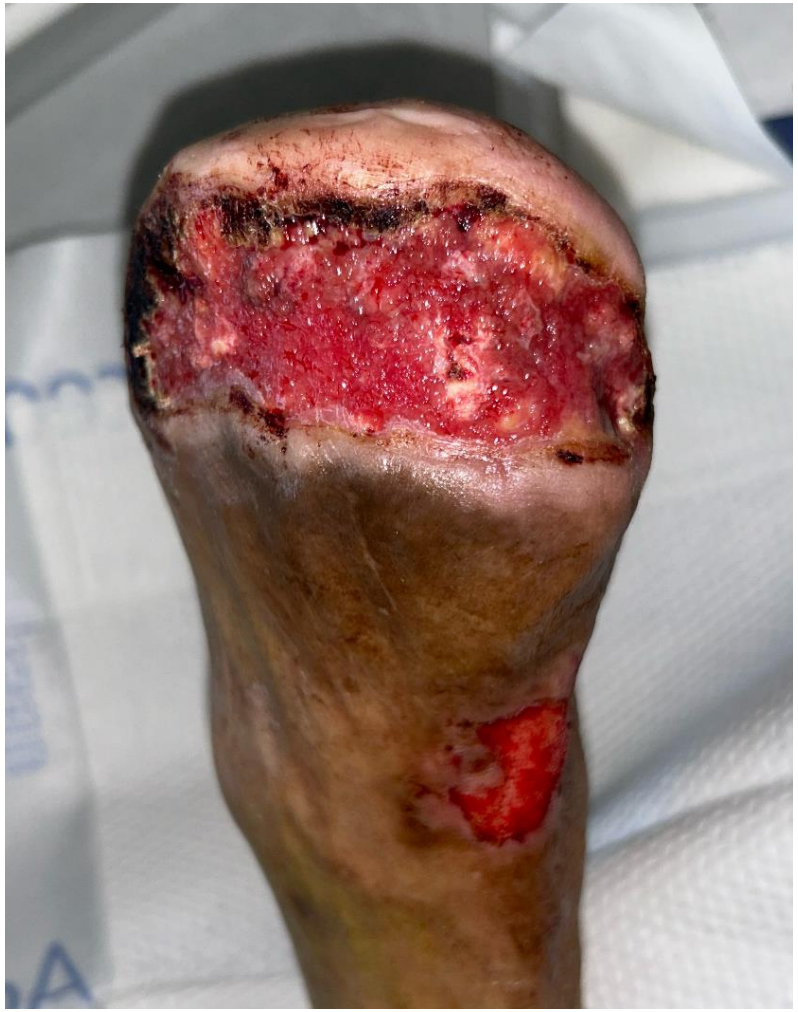


# Post-application of BTM day 3

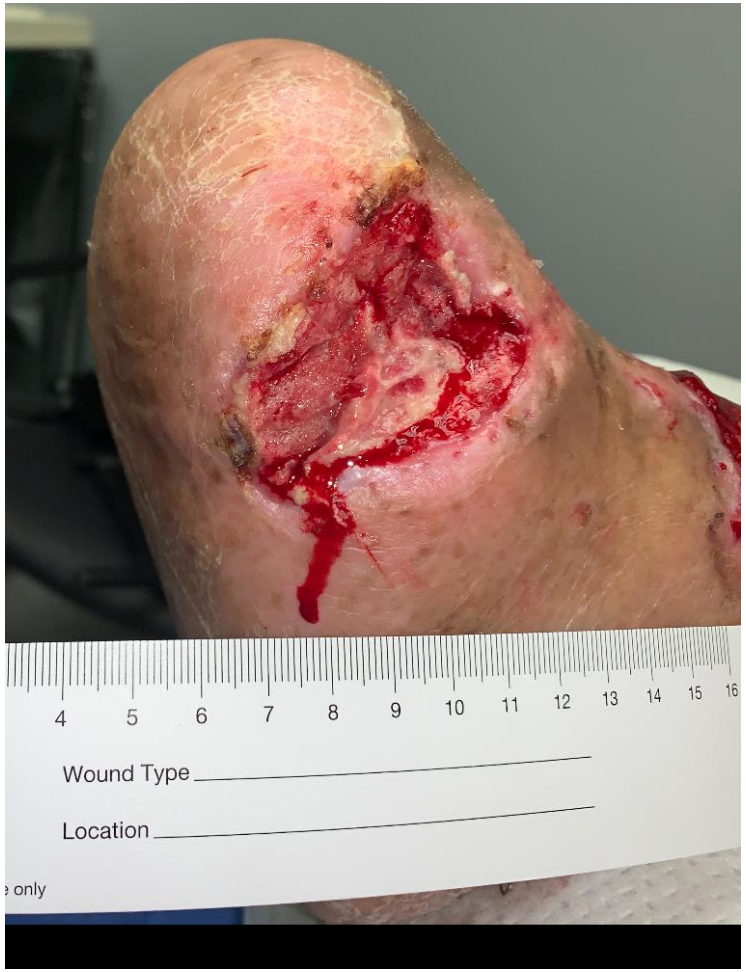




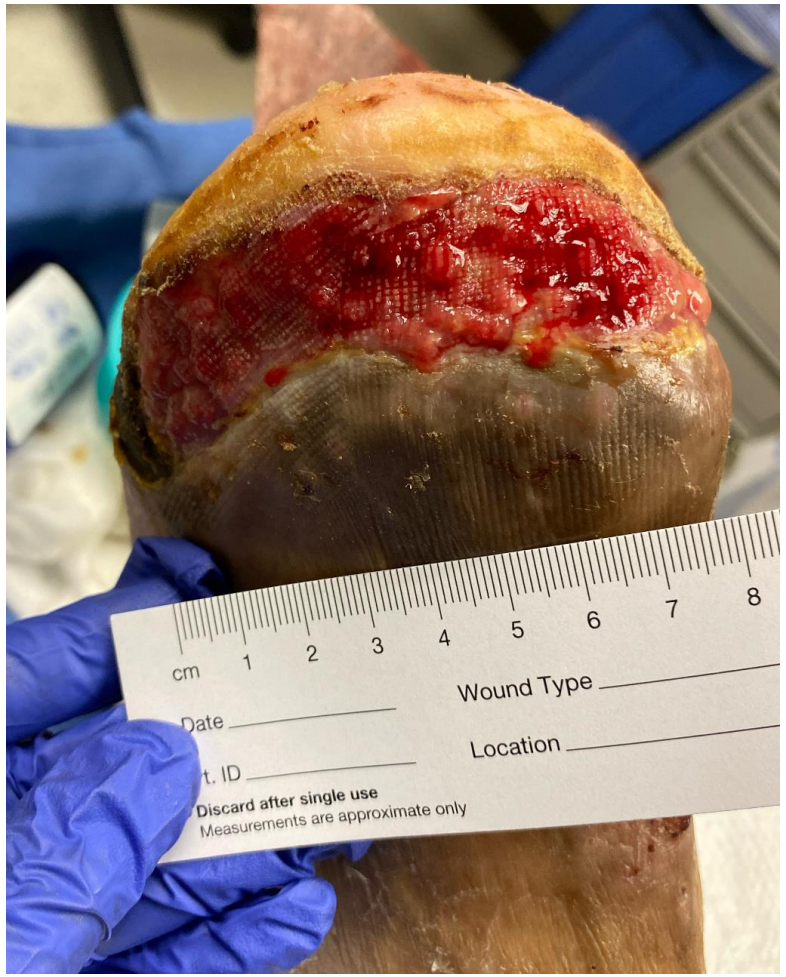
Post-application of BTM day 21

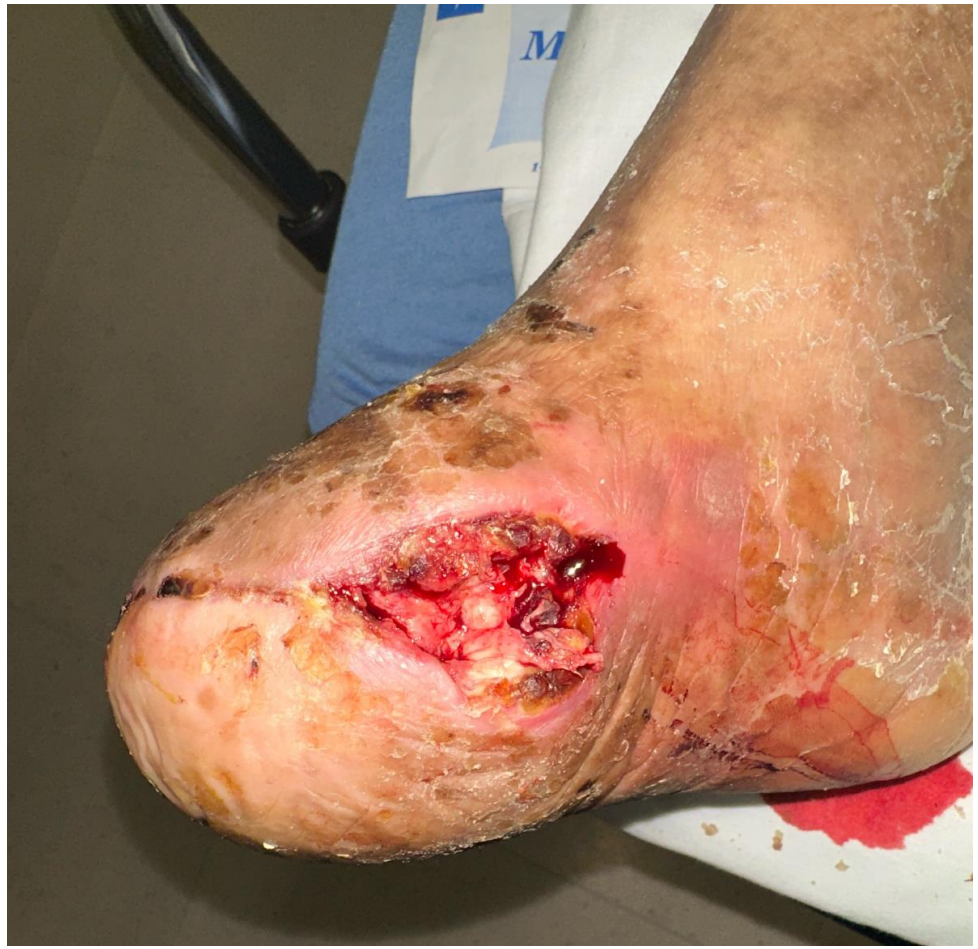


Post-application of BTM day 21

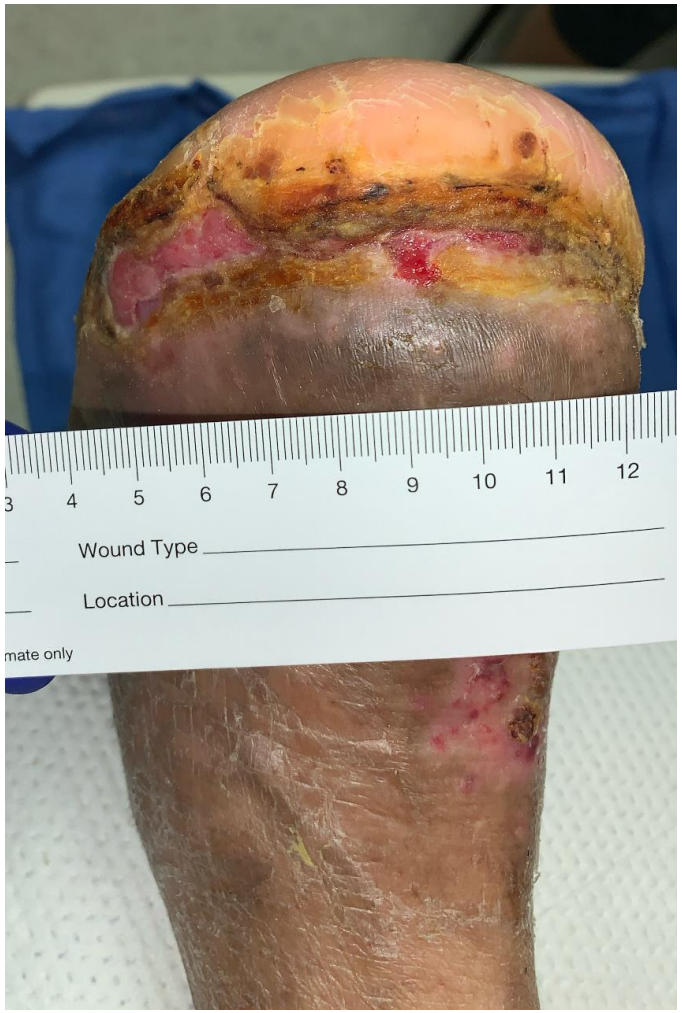


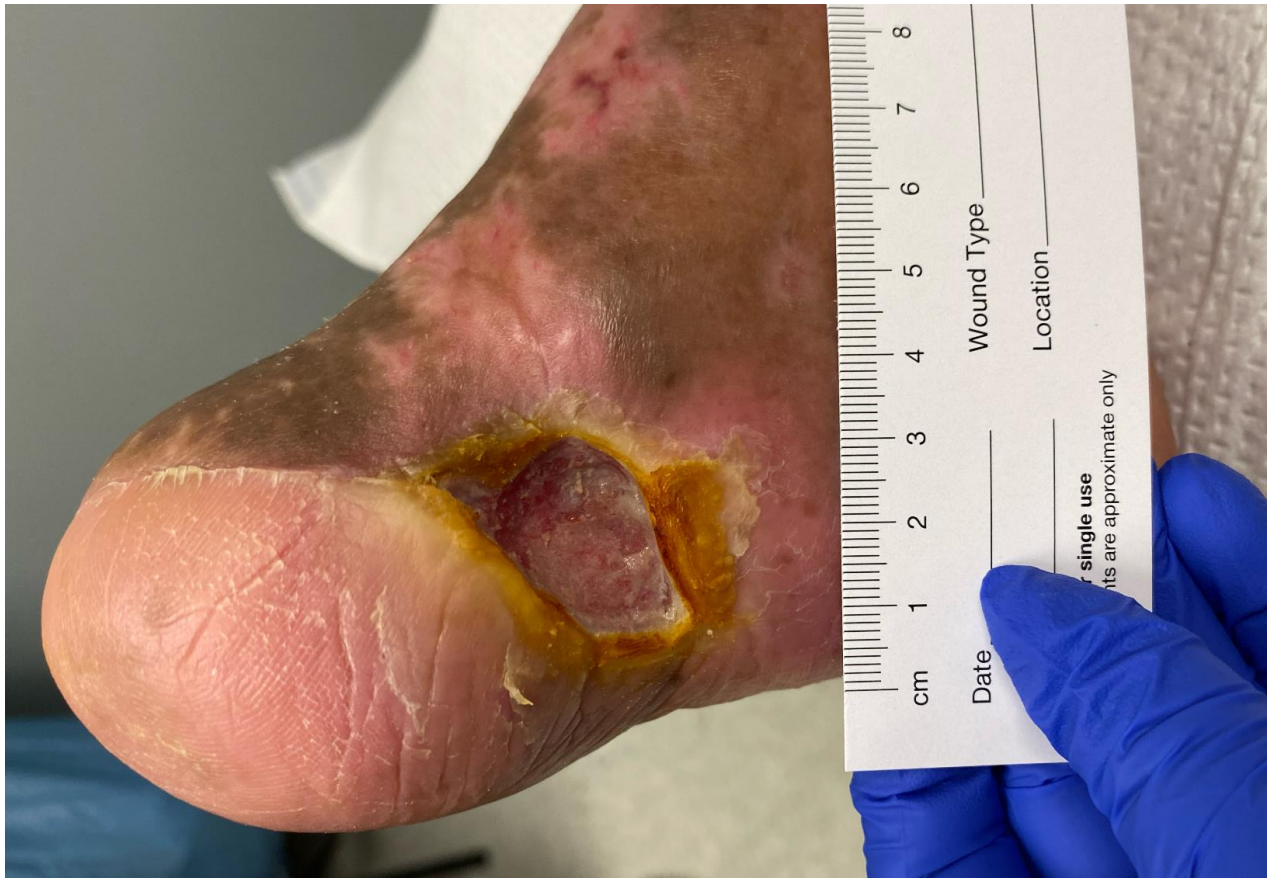
# Post-application of BTM day 45



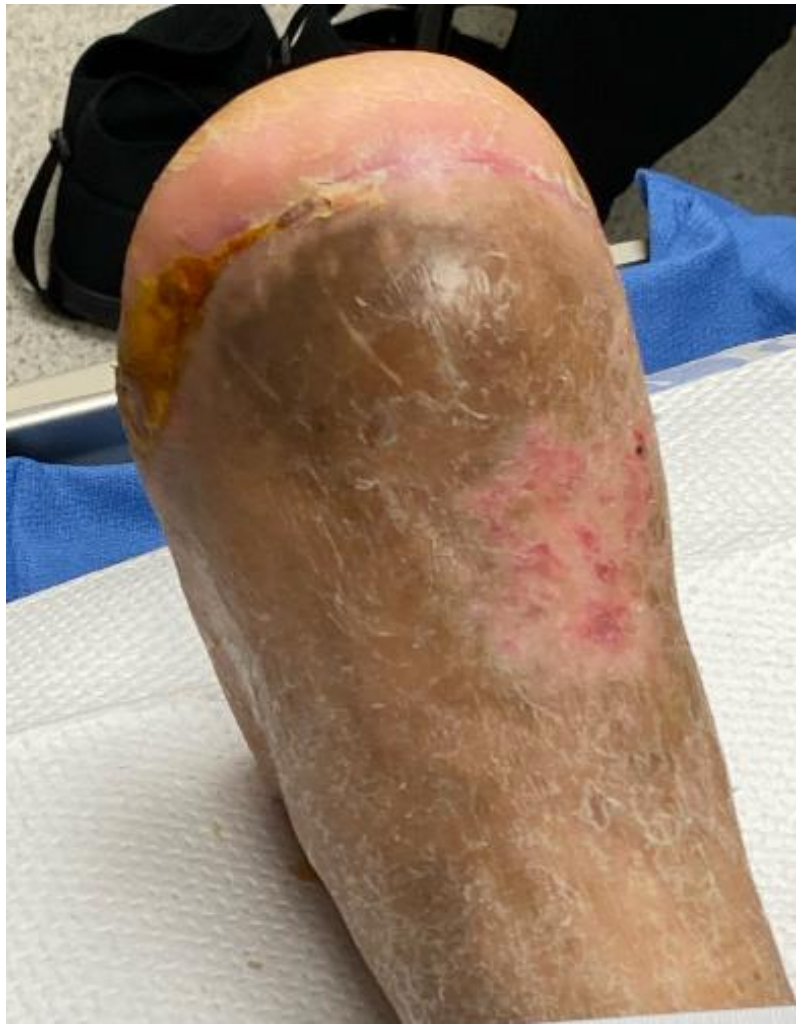



# Post-application of BTM day 60

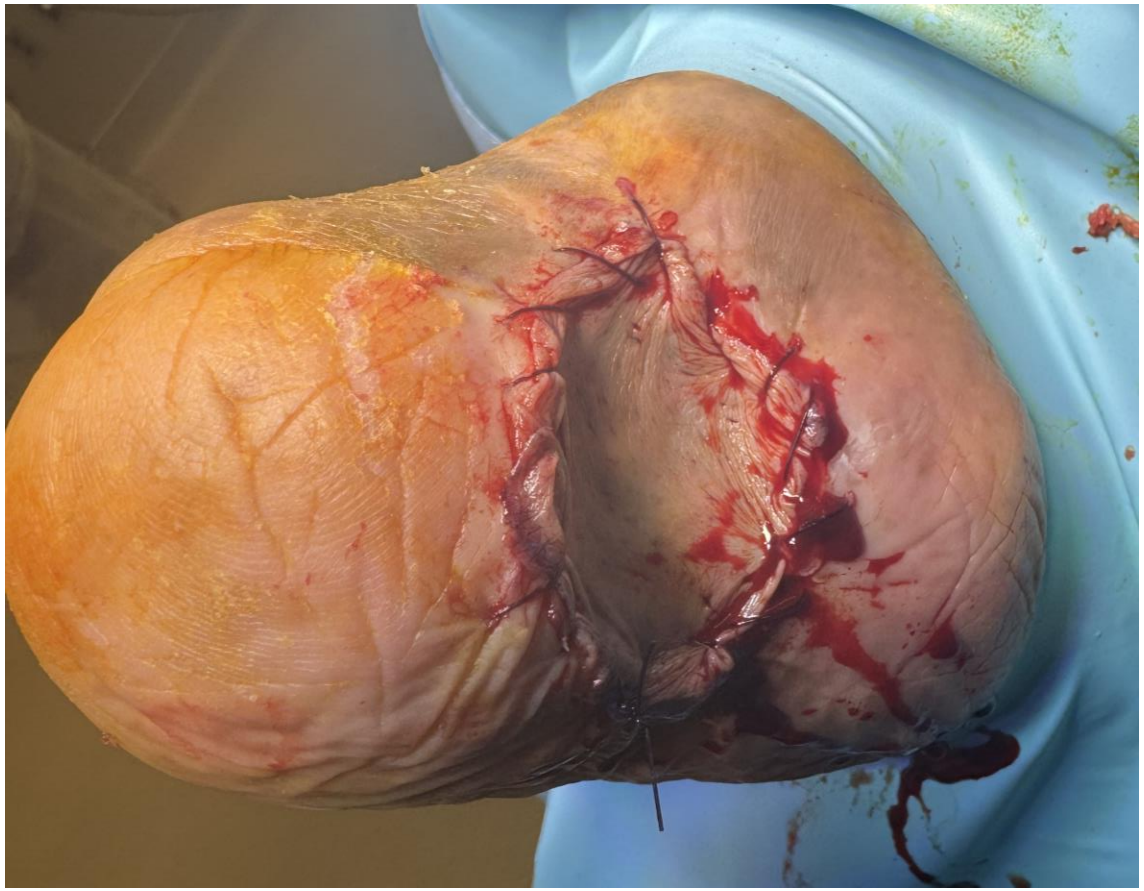


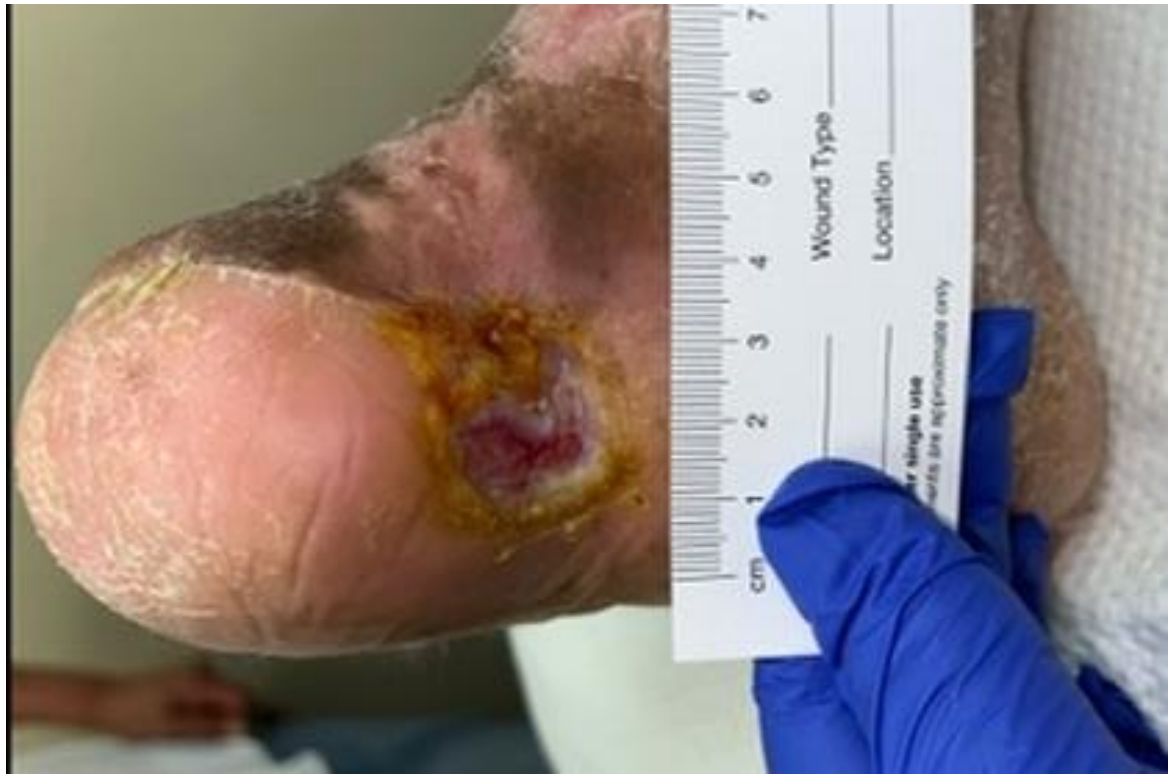
Left foot healed at 90 days



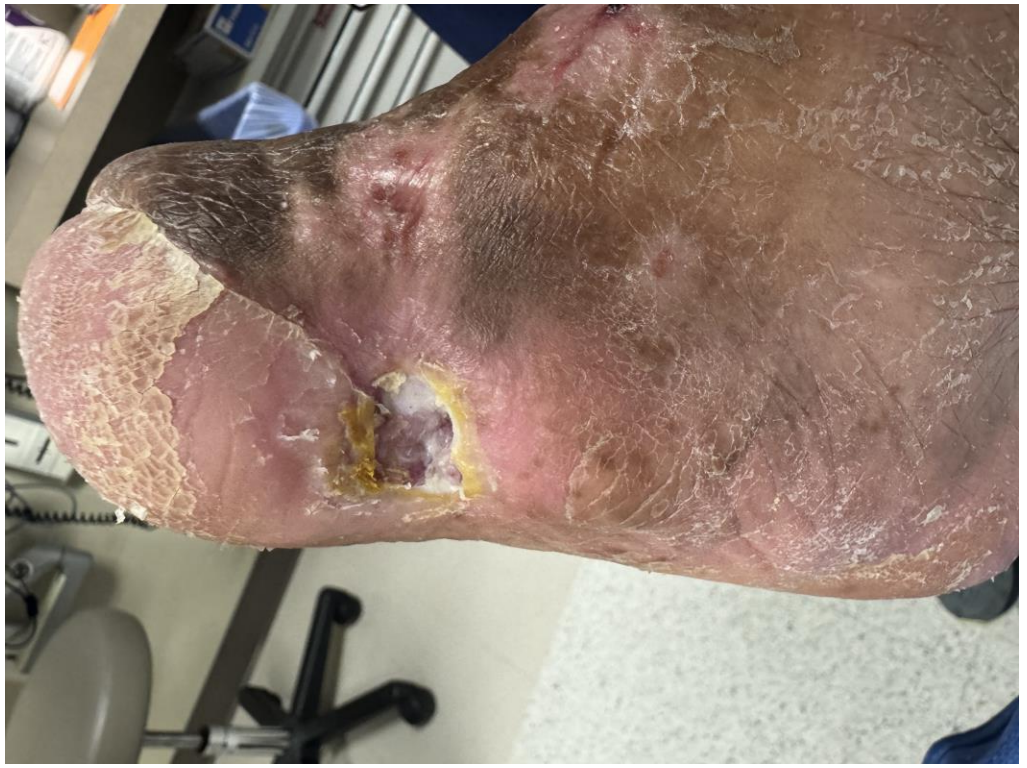
Right foot intra-op STSG application



Right foot 6 weeks post-op

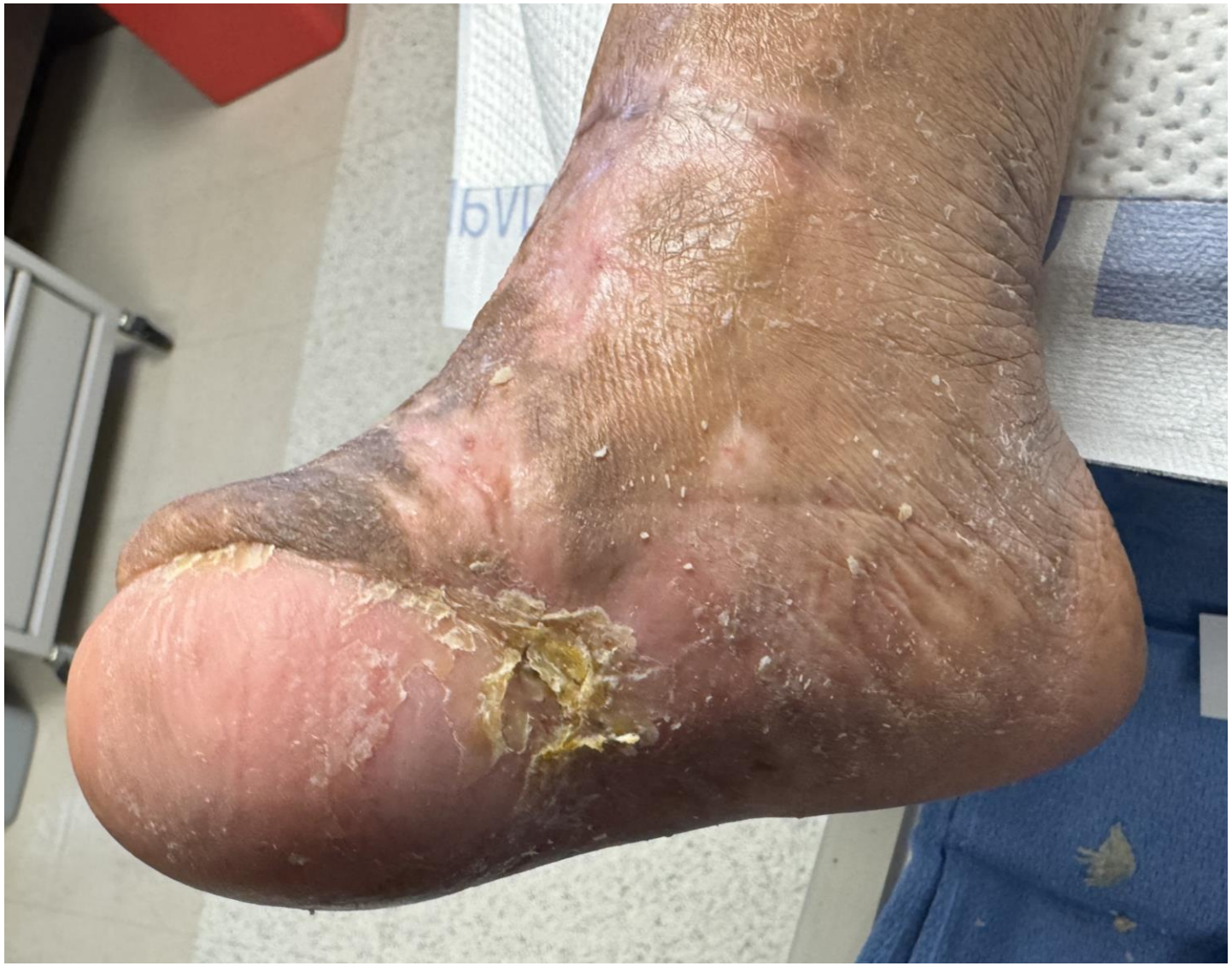



Right foot 12 weeks post-op
20 HBO dives later



**HBO = hyperbaric oxygen.**

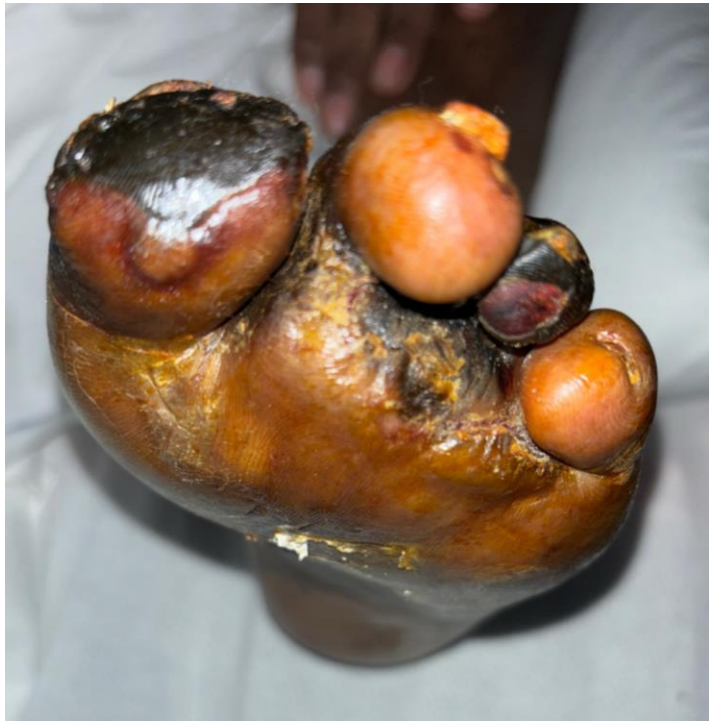
Right foot 14 weeks post-op

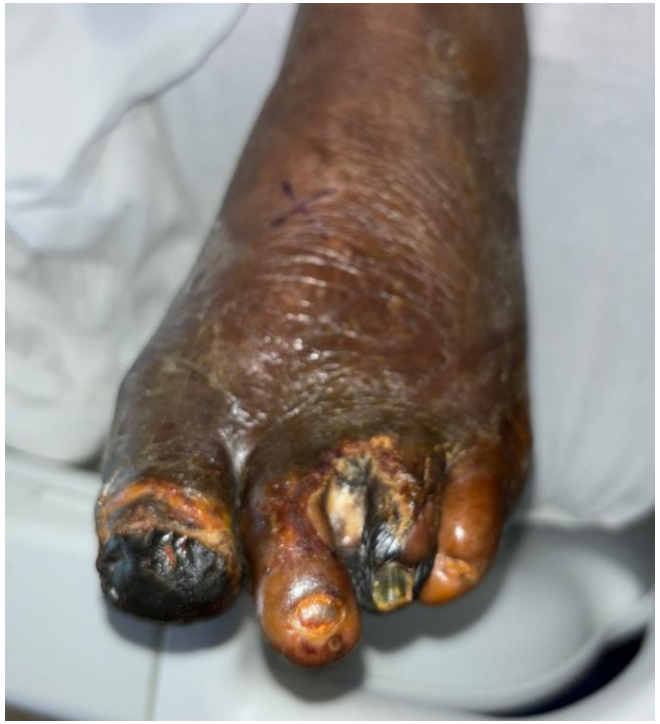


# Case 3

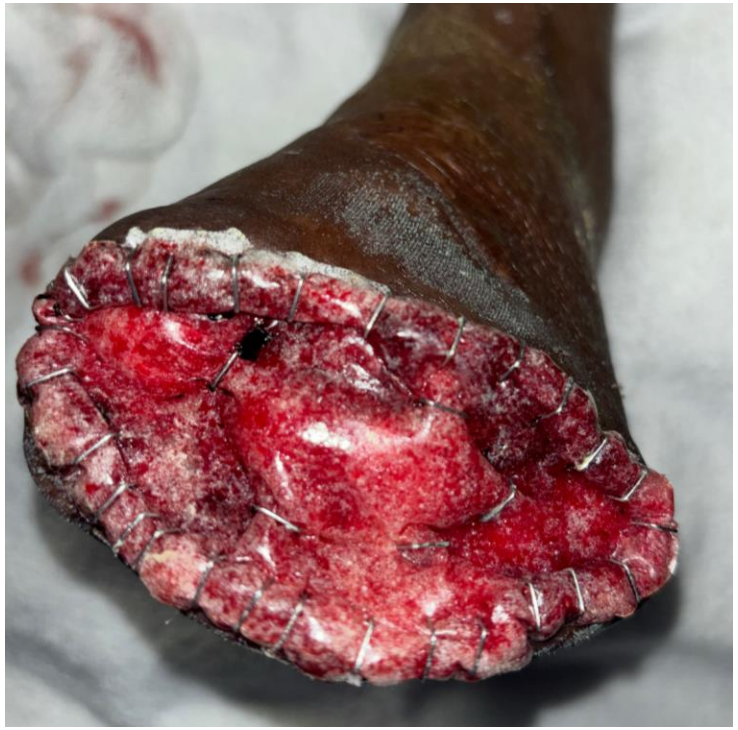
- DM, PVD
- Post-DVA

At presentation



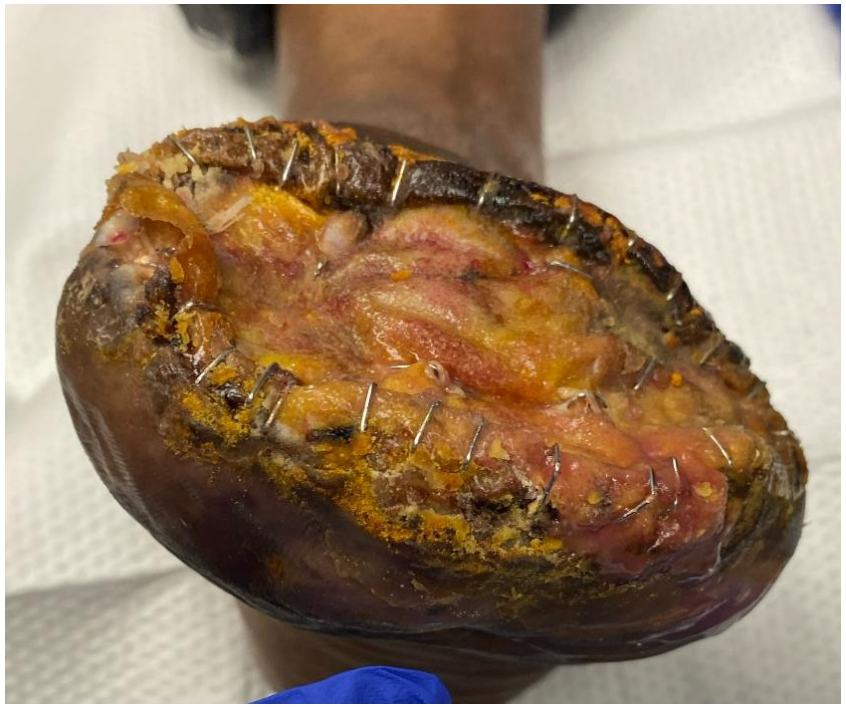


2 days post-pan digital amputation
Application of BTM

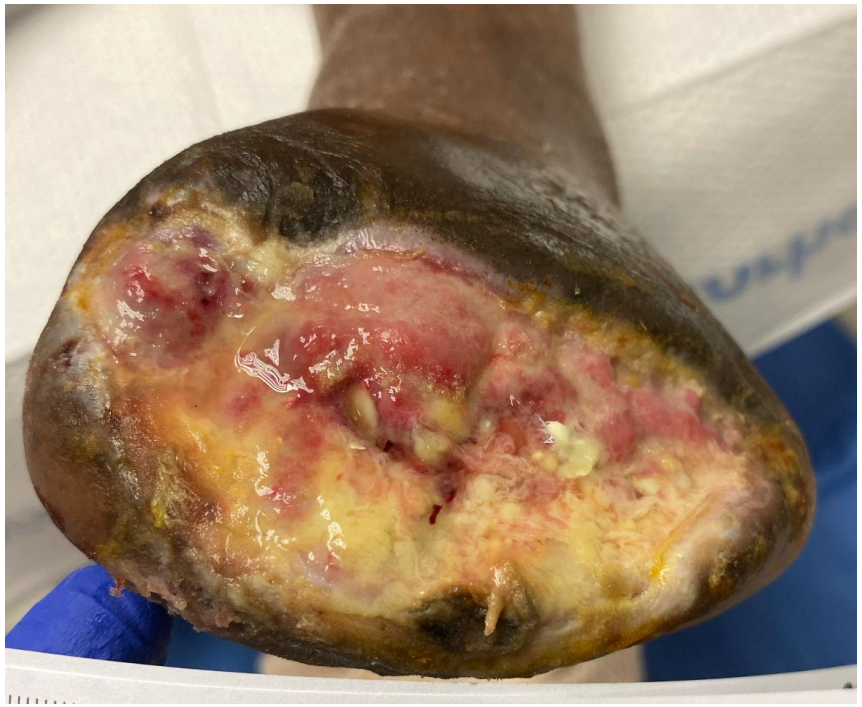


2 weeks post

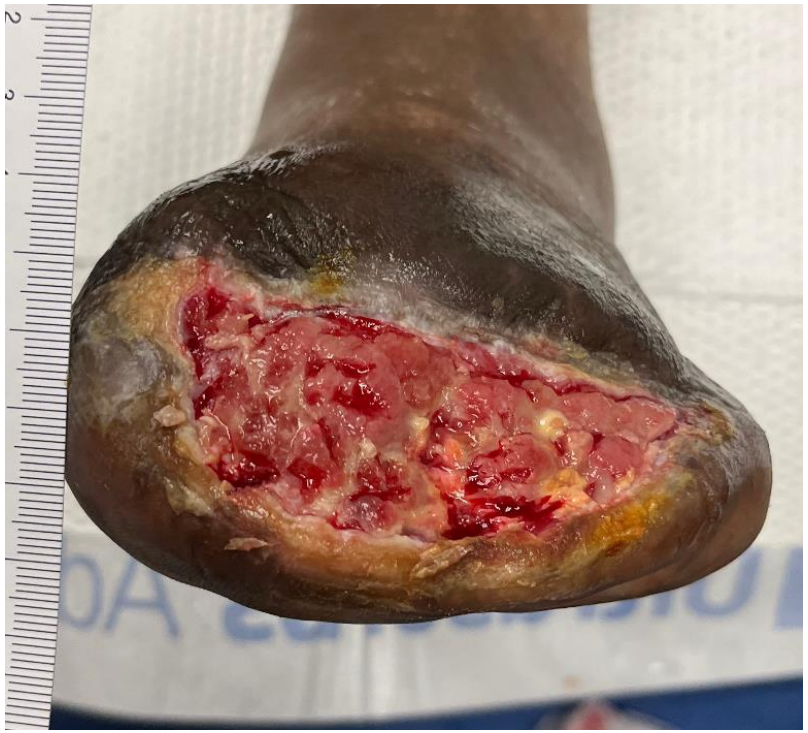
4 weeks post



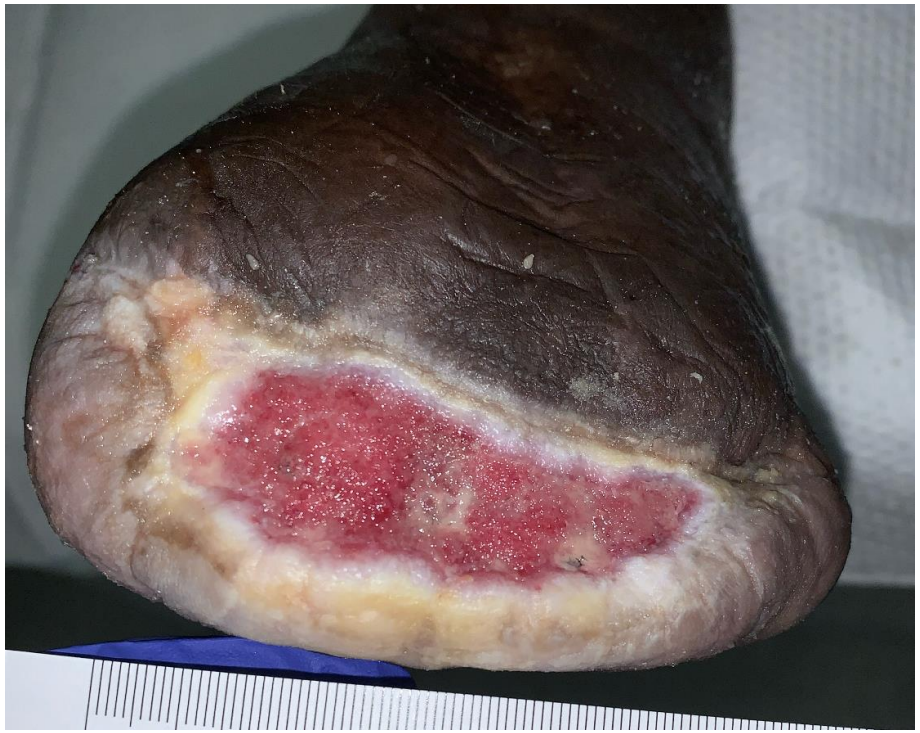
6 weeks post



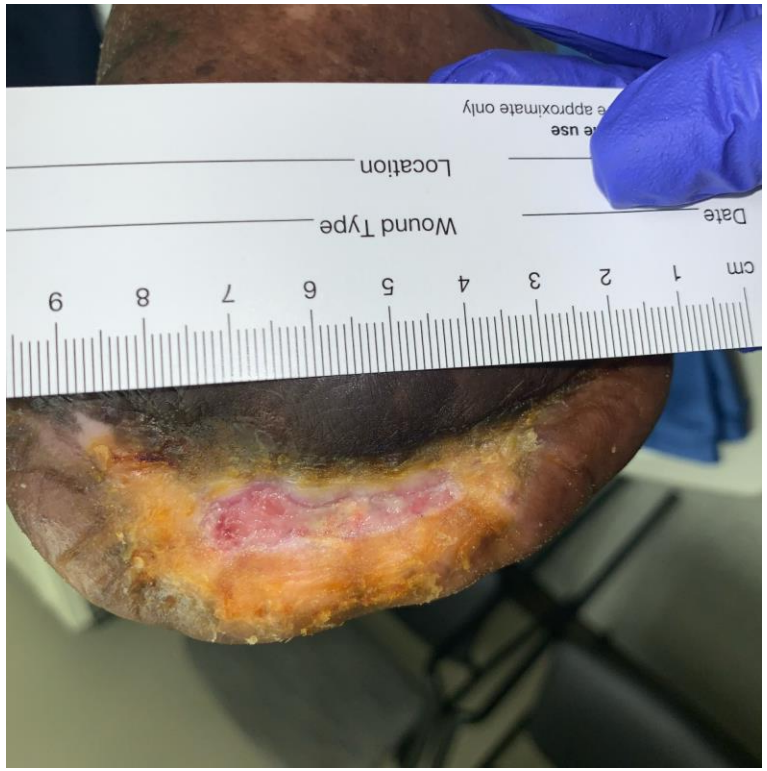
8 weeks post



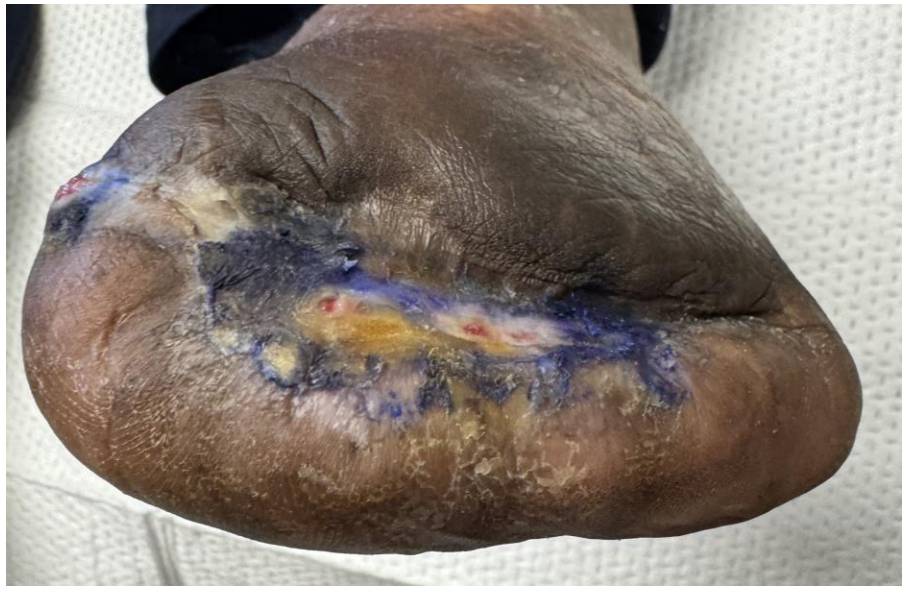
12 weeks post



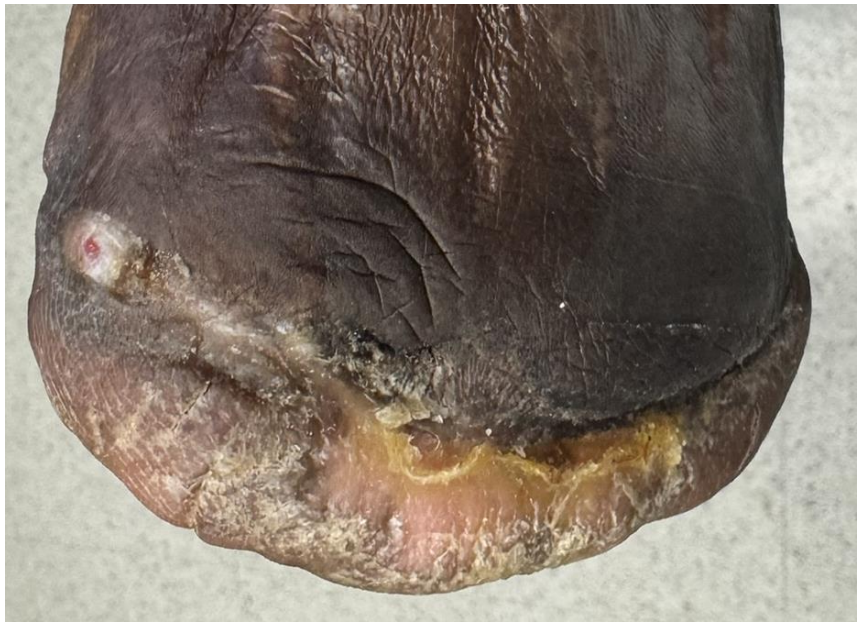
14 weeks post



18 weeks post



20 weeks post



# Important Tips

- If the remainder of the foot is not functional, it's not worth saving
  - Lisfranc's joint
  - May require repeat vascular and podiatry surgery—prepare the patient
- Infection trumps any attempt at tissue salvage
- Topical antimicrobials during dressing changes
  - Eg, cadexomer iodine or hypochlorous acid gel—smear on top of graft
  - Absorbative outer layer, alginate, or ABD
  - Resolution of pain is a good indicator of successful reperfusion; expect pain initially, even in your neuropathic patients

# Conclusions

- This is the most difficult lower extremity population
- The long-term outcomes of DVA are yet to be determined
- BTM/MTX is a viable option for soft tissue reconstruction

ePlasty

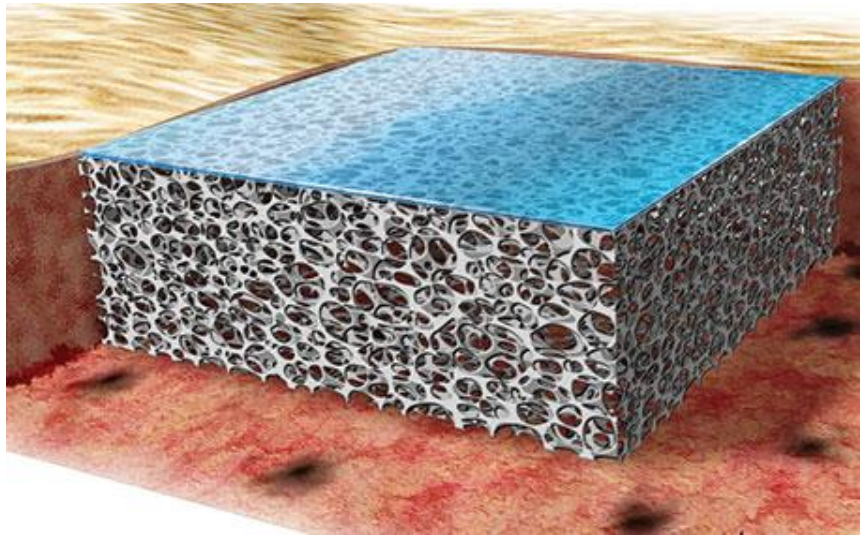
# Practical Applications of BTM and MTX for Complex Soft Tissue Reconstruction:

## A Multi-Specialty, Case-Based Analysis

**Shaun Mendenhall, MD**
Section Head of Hand Surgery
Associate Professor of Surgery
University of Utah and Intermountain Primary Children's Hospital
Salt Lake City, Utah

# BTM and MTX for Complex Reconstruction

- About me and my practice
- How BTM has helped me in my practice
- Indications and cases
- Published case series
- Q&A



**Shaun Mendenhall, MD**

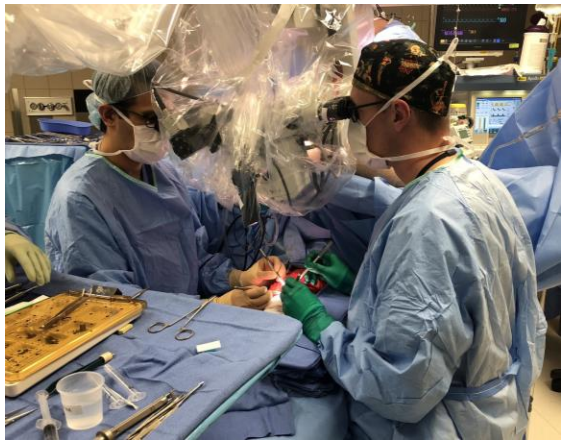
- Pediatric Hand and Plastic Surgeon at University of Utah and Primary Children's Hospital
- Focus on all aspects of hand surgery, nerve surgery, microsurgery, extremity recon, and orthoplastic surgery
- Full-time academic practice, including research and teaching
- Board-certified in plastic surgery and hand surgery

HEALTH
UNIVERSITY OF UTAH

SIU MEDICINE
INSTITUTE FOR PLASTIC SURGERY

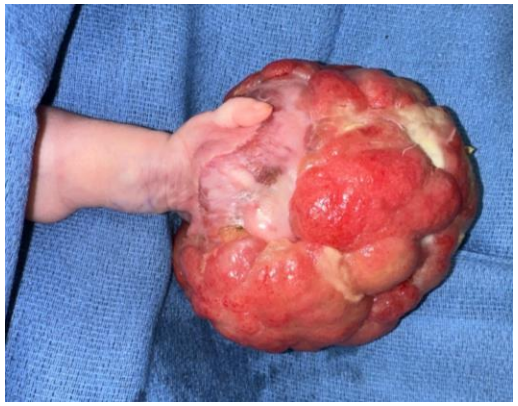
Penn Medicine

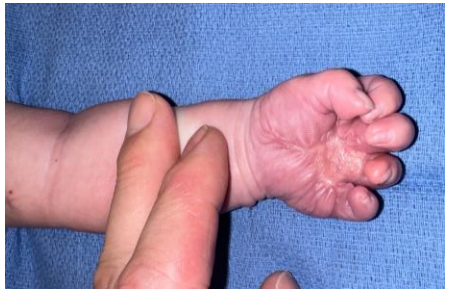
Intermountain Children's Health

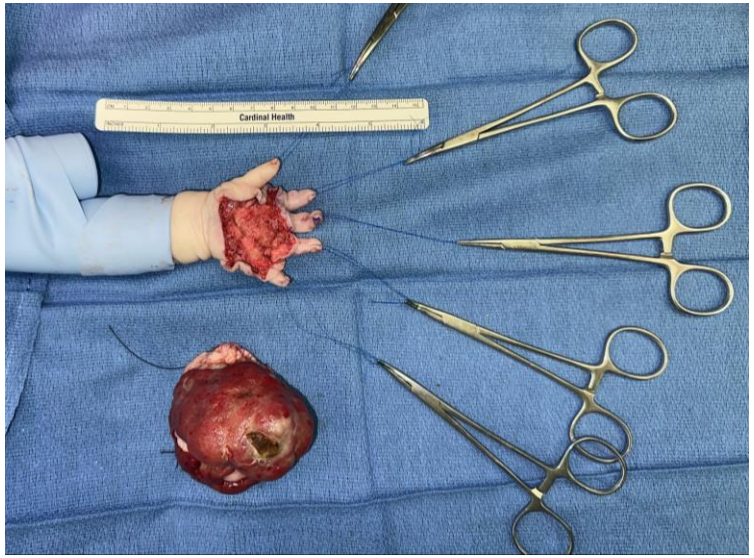


# How BTM/MTX Has Helped Me in My Practice

- Buys me time…
  - Great for temporizing wounds (cancer, infection, covering vital structures until recon possible)
- Buys me tissue thickness…
  - Cover exposed tendon, bone, small joints when flap options or patient not ideal, prevents scar contracture, less deformity, cover flap donor sites, bail out after flap failure
- Bails me out of tough situations…
  - When no other great options, seals up wounds
- Buys my patients pain relief…
  - Dressings not as painful, vac changes without anesthesia
- Buys the hospital $$$...
  - Cheaper than alternatives

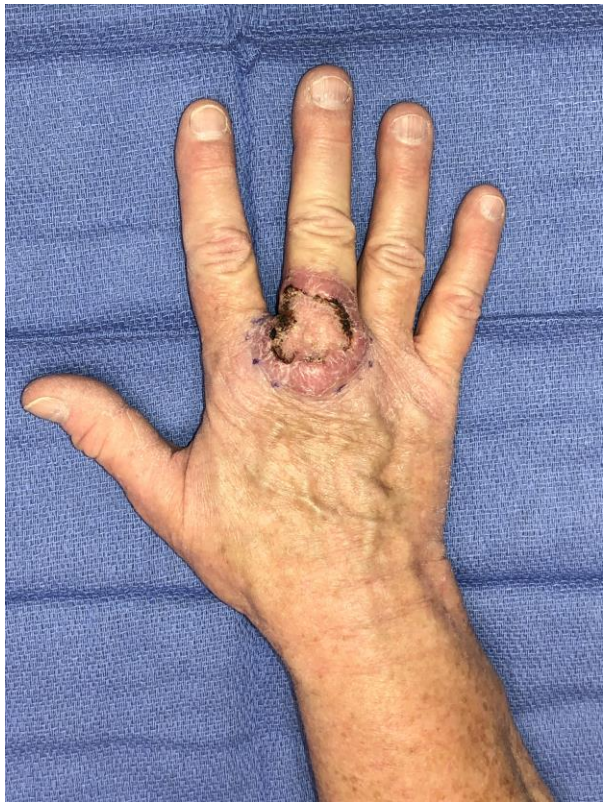
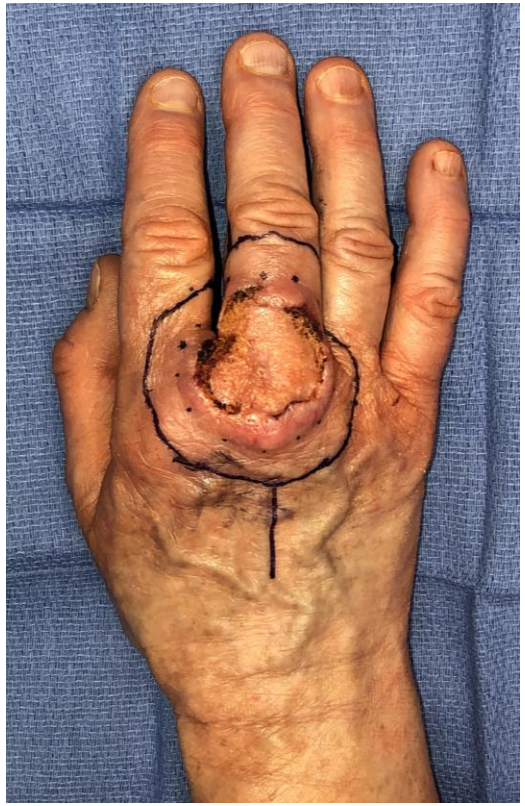
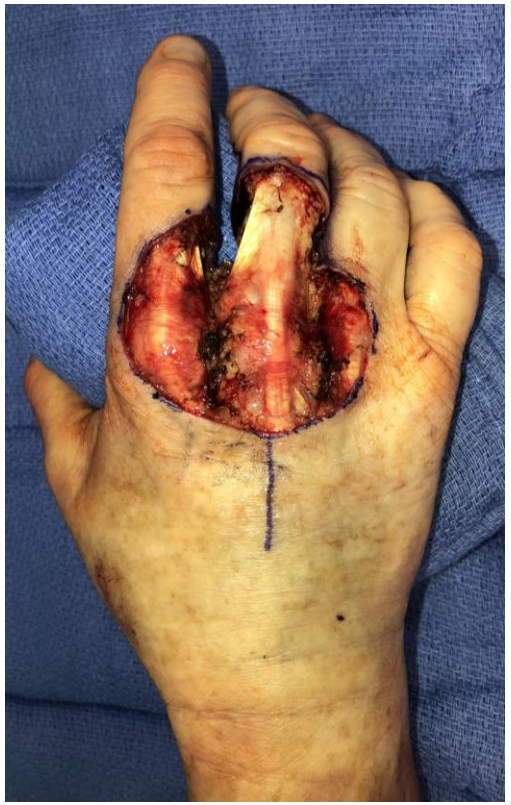
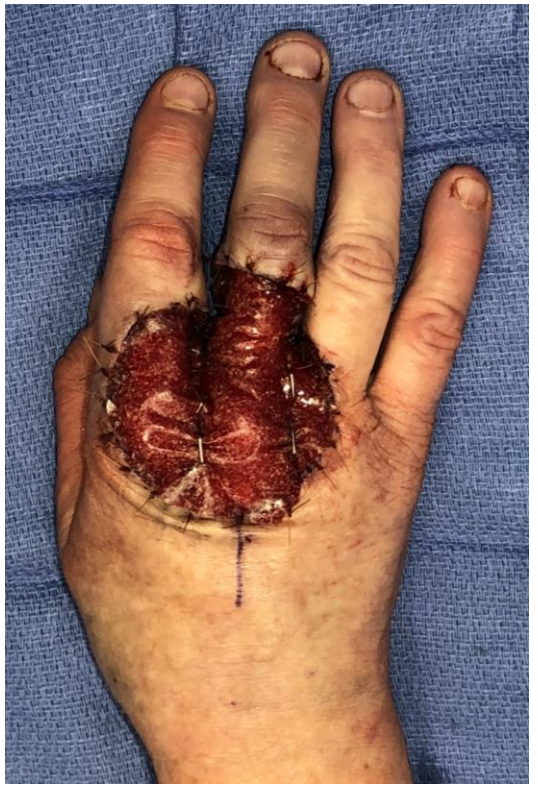






# Indication: Temporizing Wounds

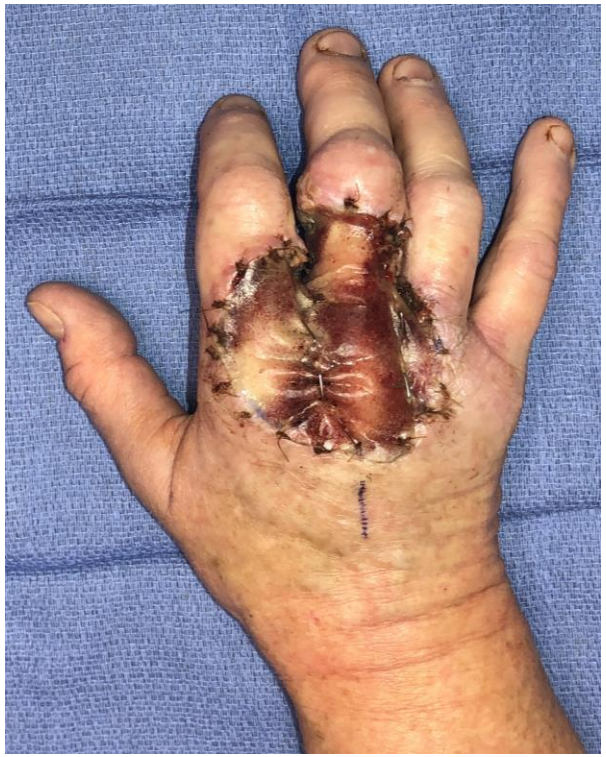
- 69-year-old with dorsal hand SCC-wide local resection

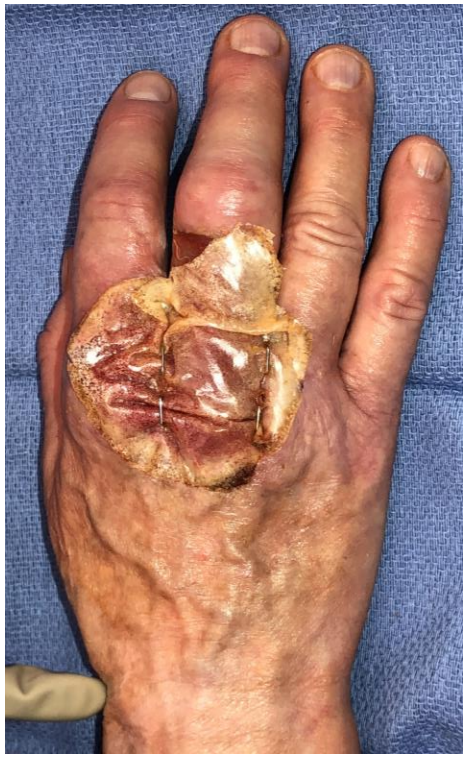
**SCC = squamous cell carcinoma.**

# Indication: Temporizing Wounds

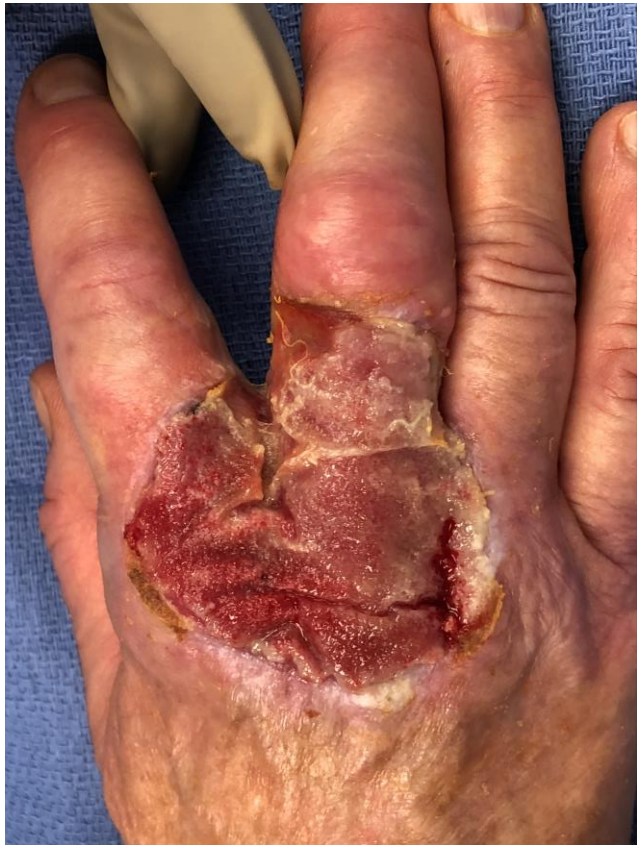
- 69-year-old with dorsal hand SCC-wide local resection



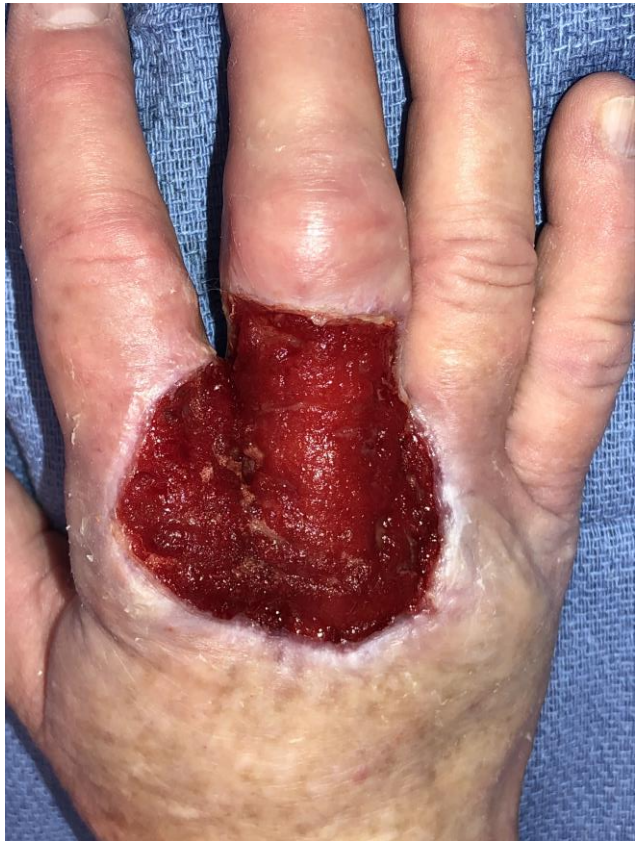
1-week post-op



4 weeks post-op



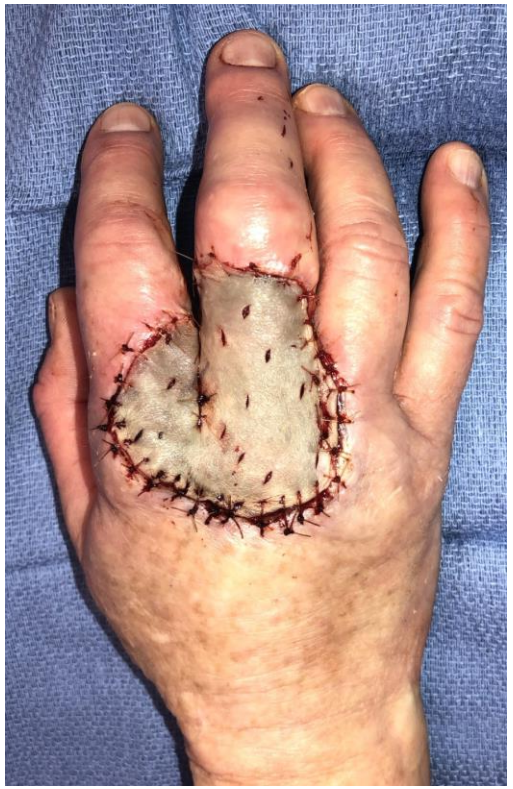
After delaminating



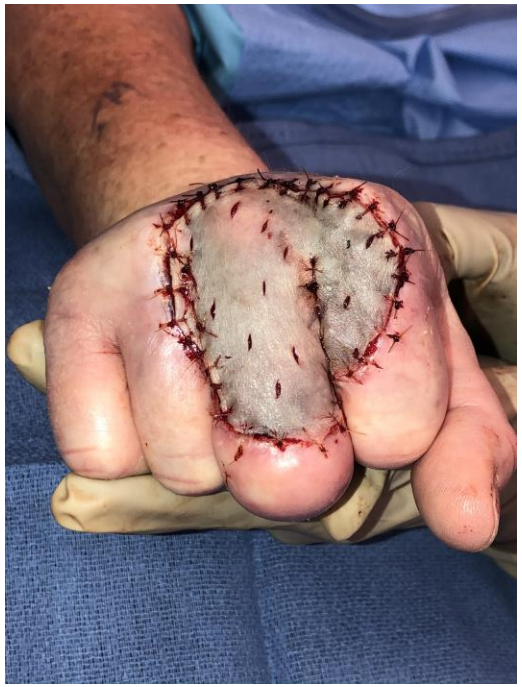
After debridement

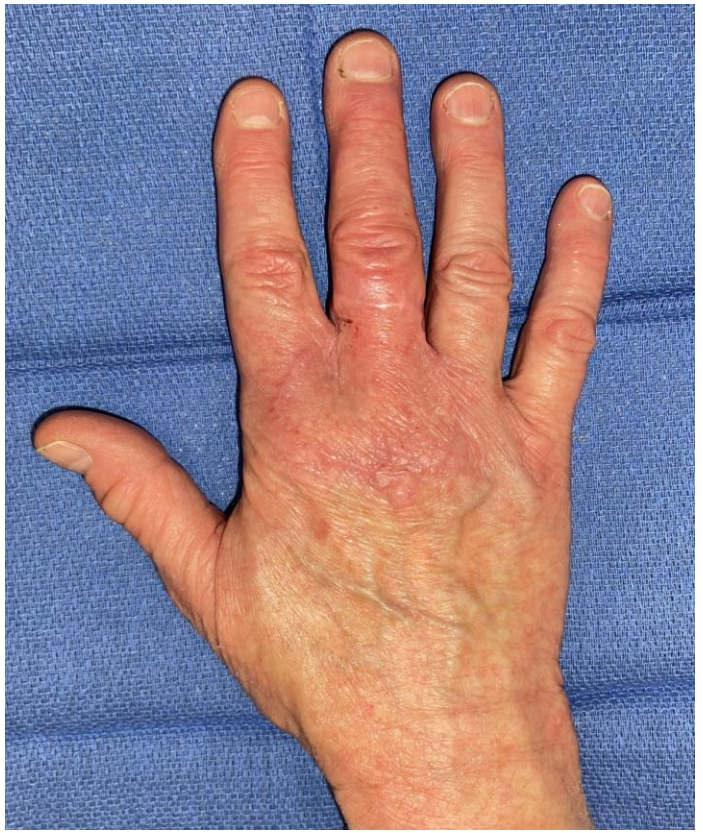
# Indication: Temporizing Wounds

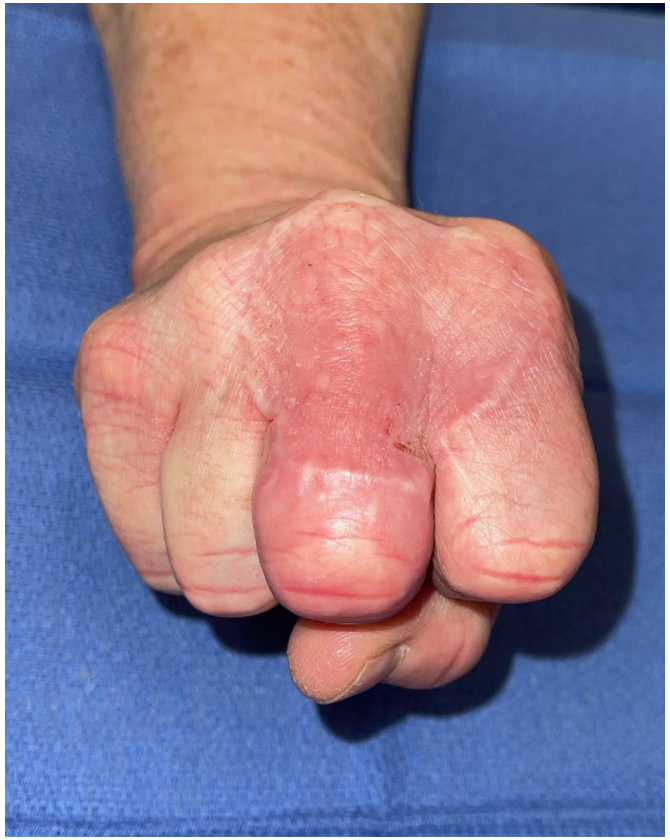
- 69-year-old with dorsal hand SCC-wide local resection



STSG



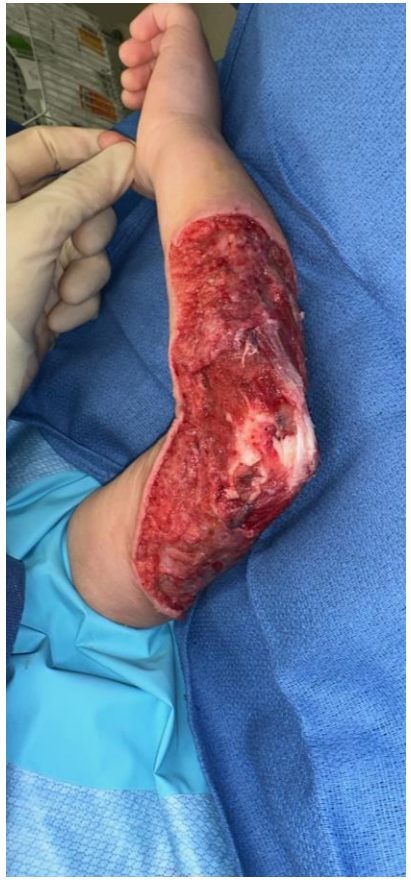


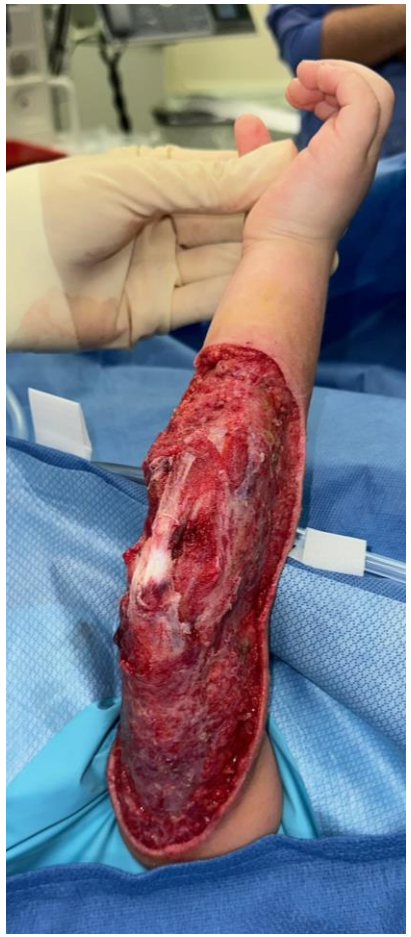


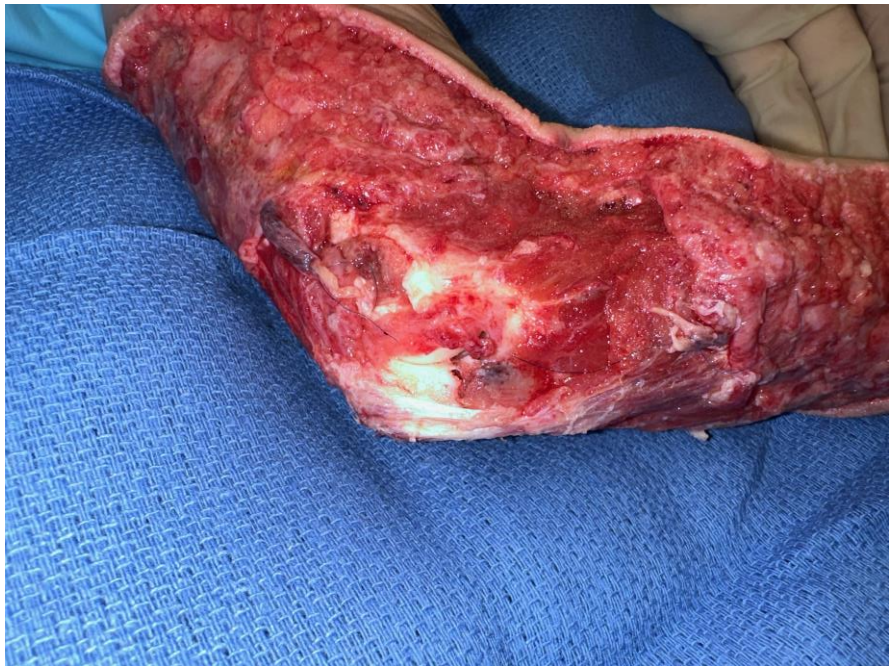
4-month post-op

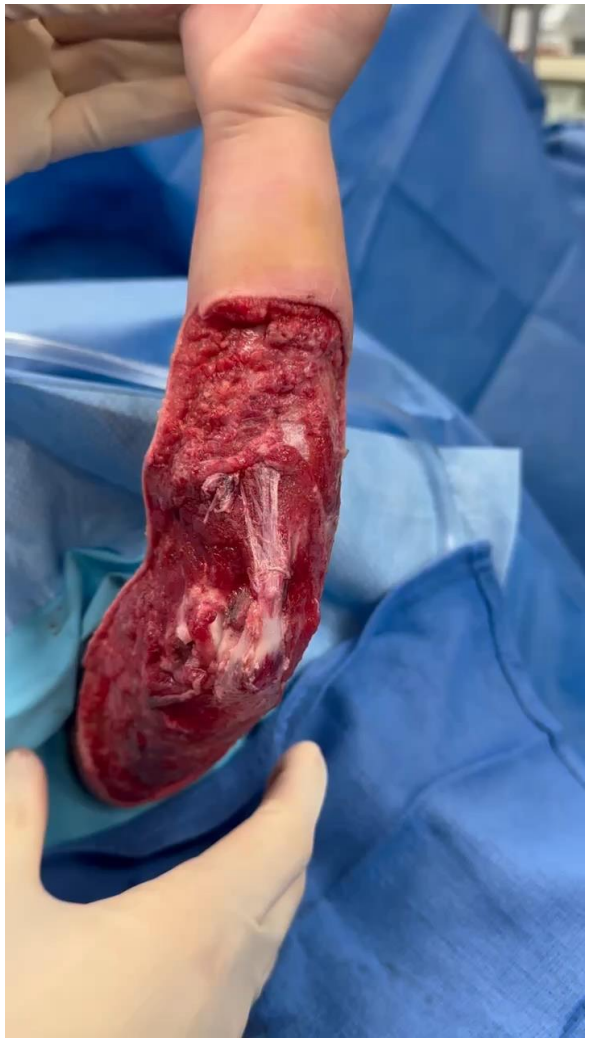
# Indication: Temporizing Wounds

- 3-year-old girl with lawnmower injury to left arm

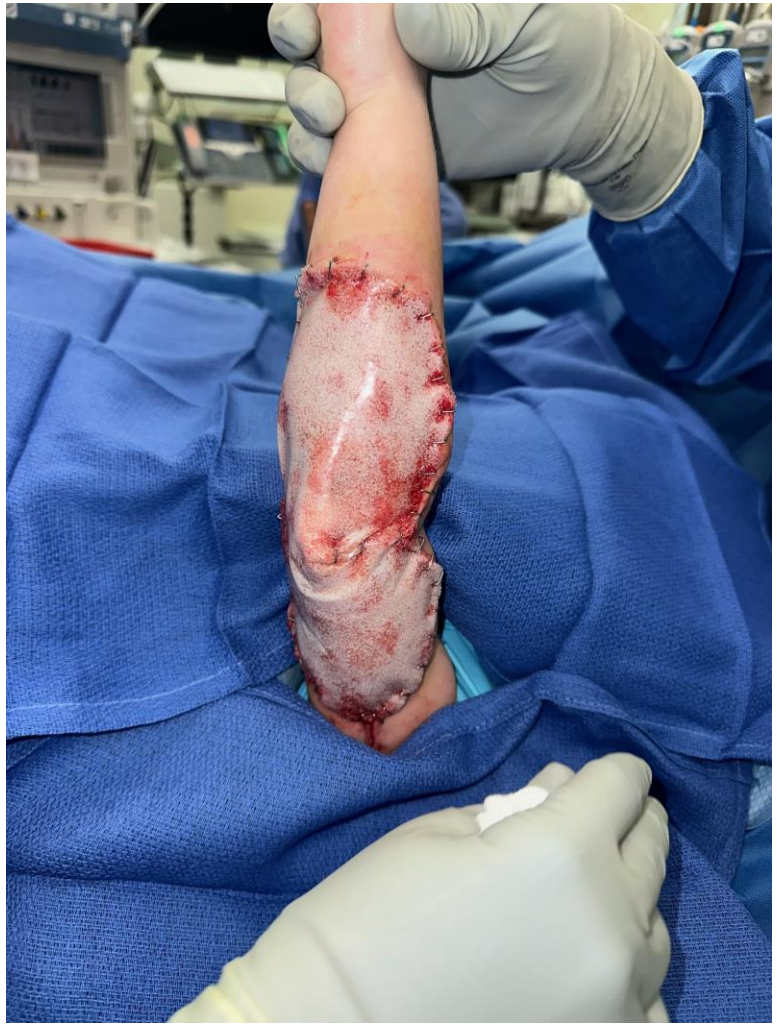


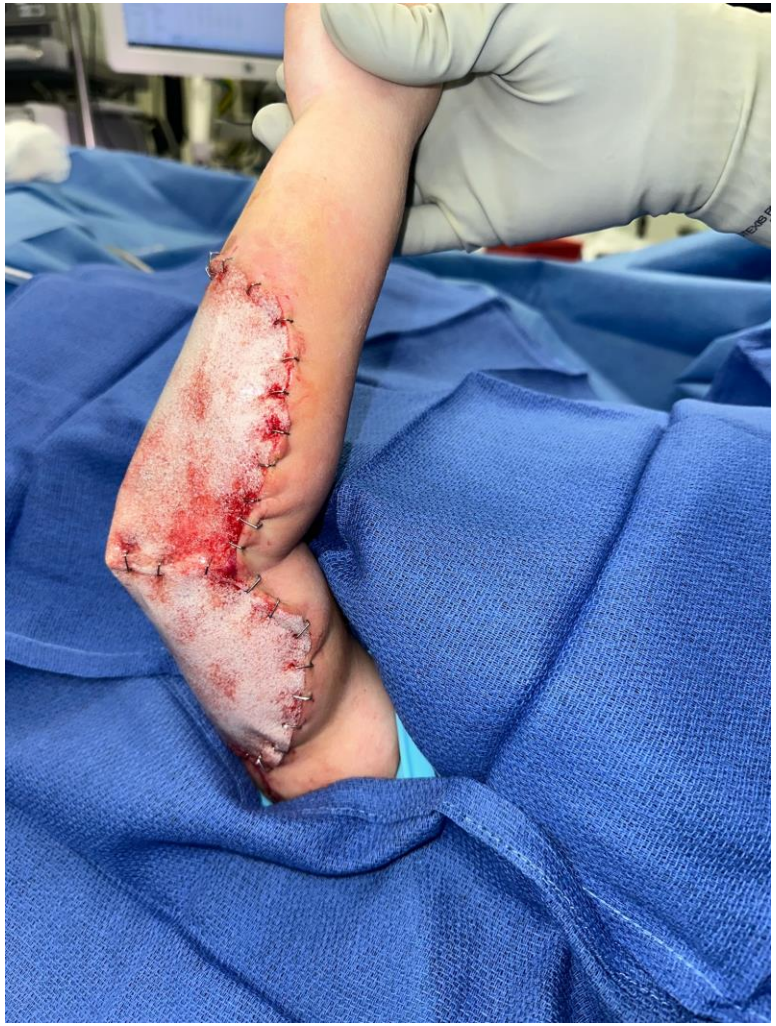


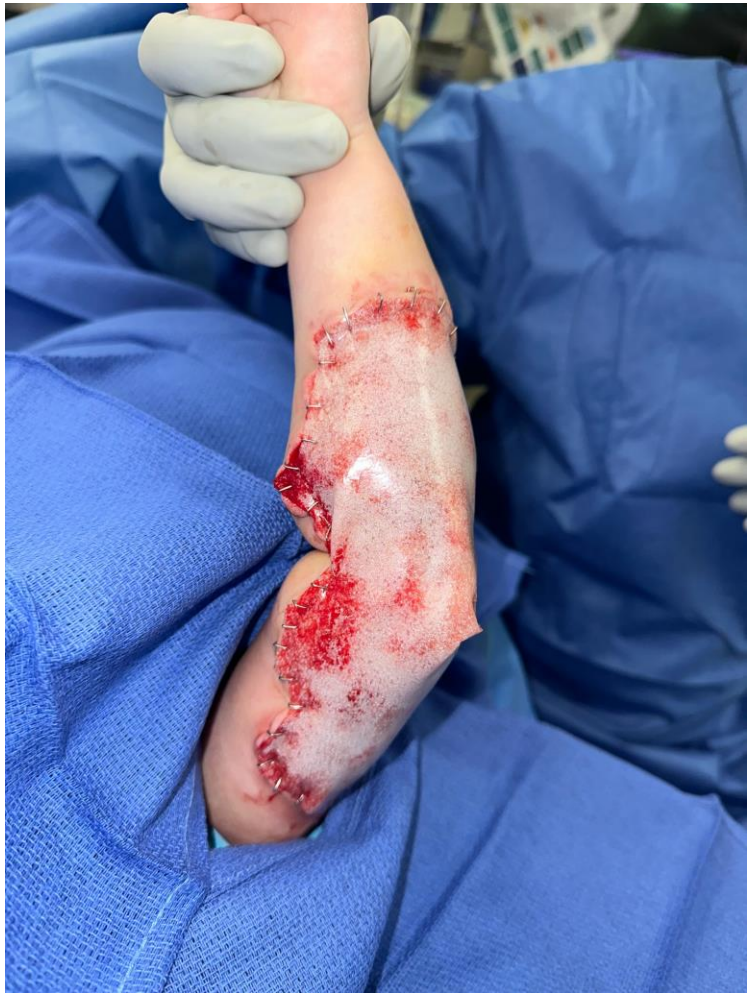




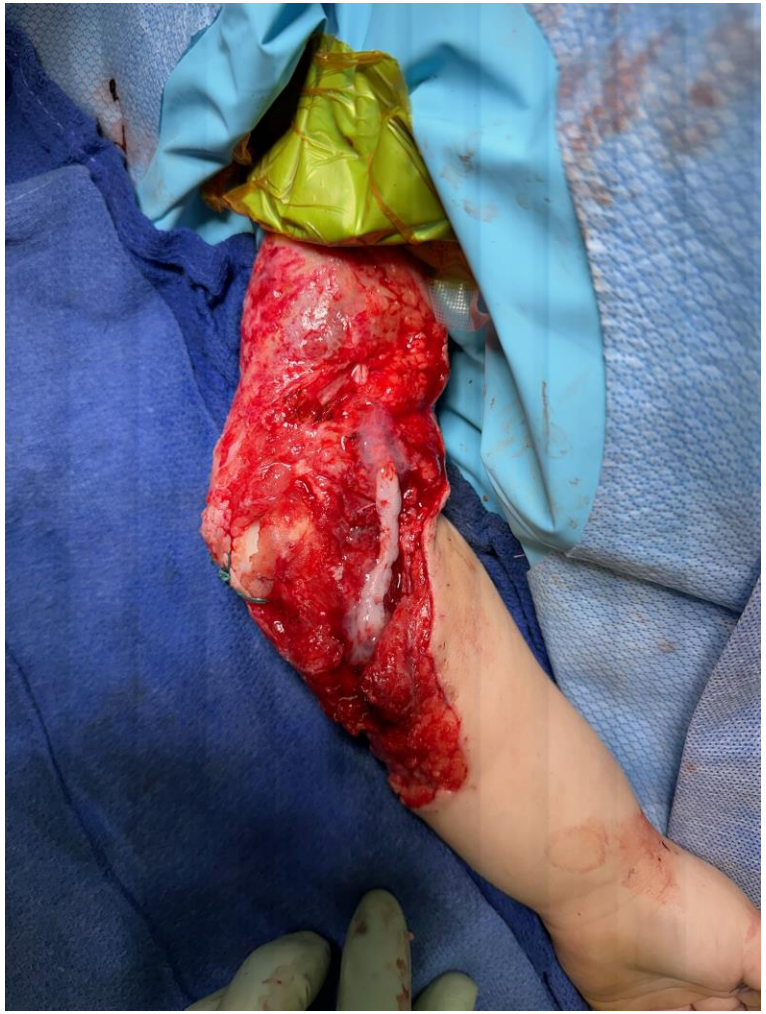
# Indication: Temporizing Wounds



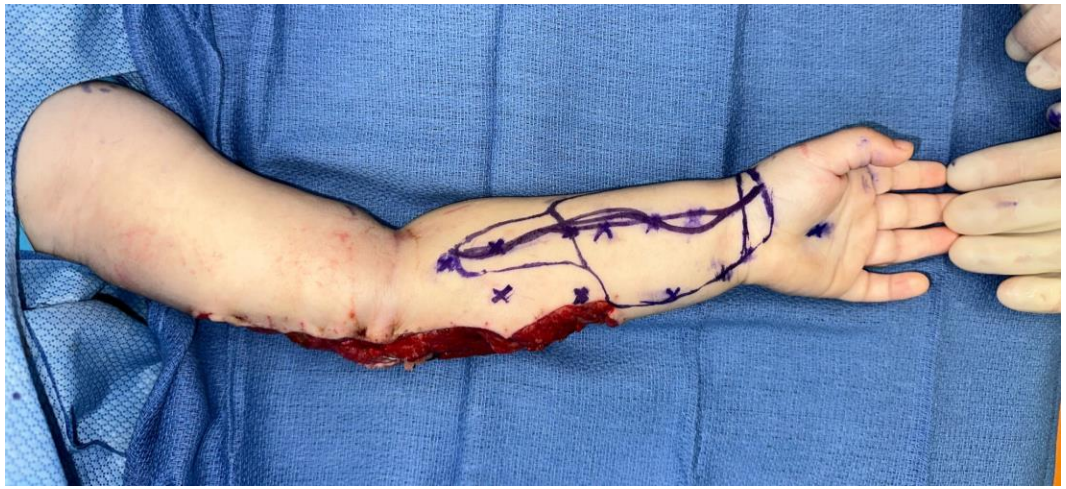


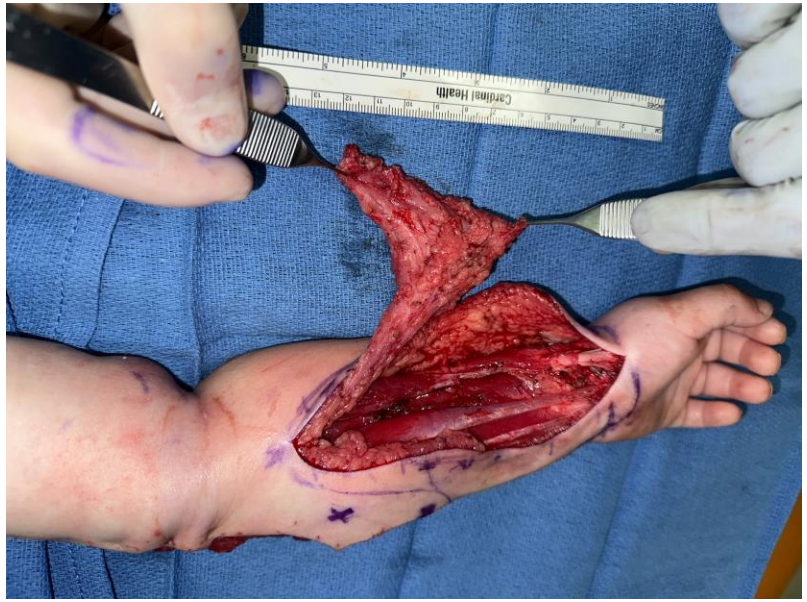


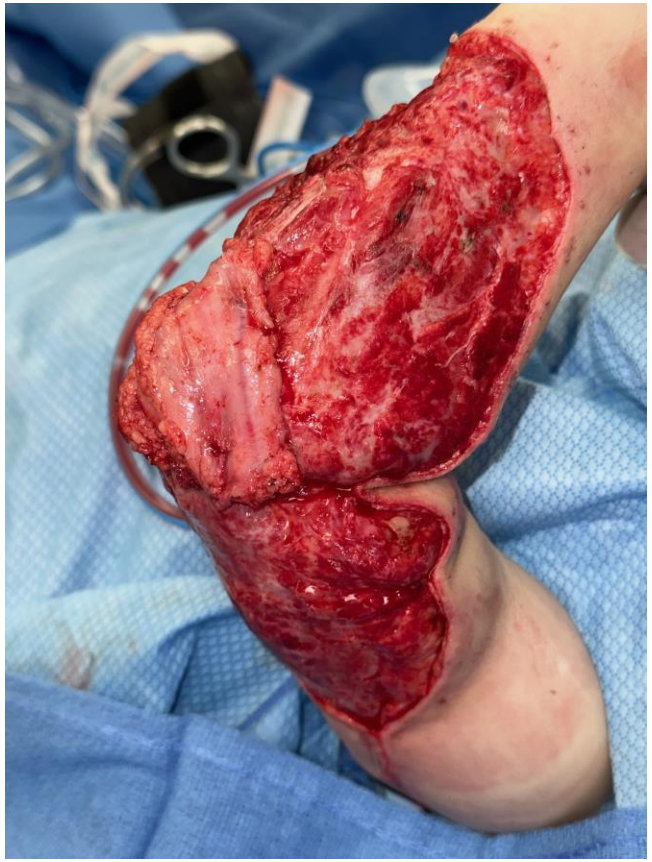
# Indication: Temporizing Wounds

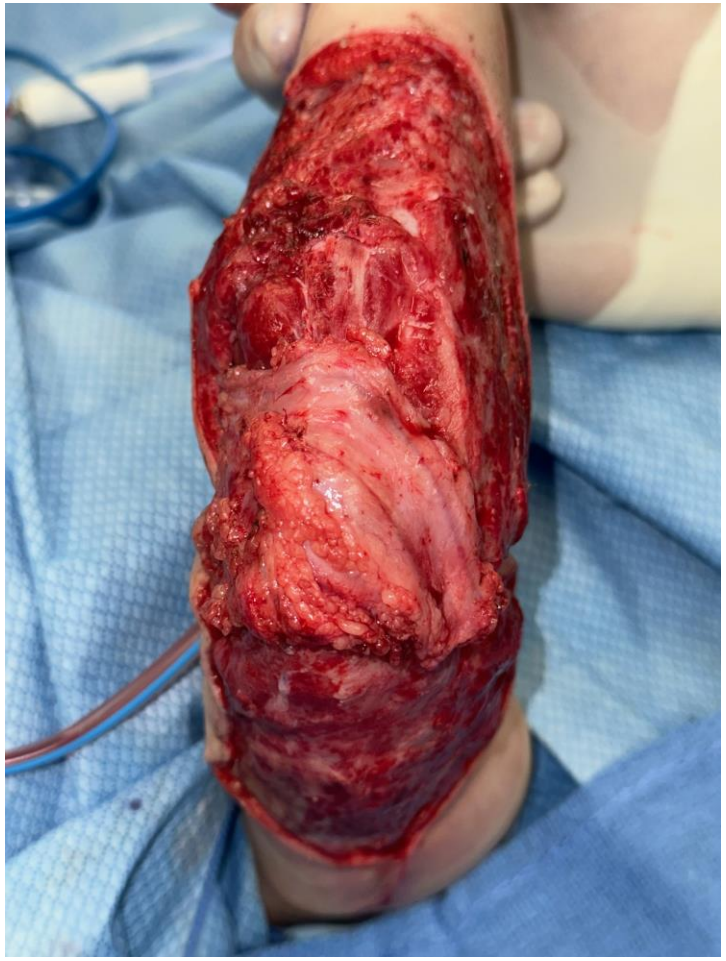


# Additional Indication: Add Tissue Thickness









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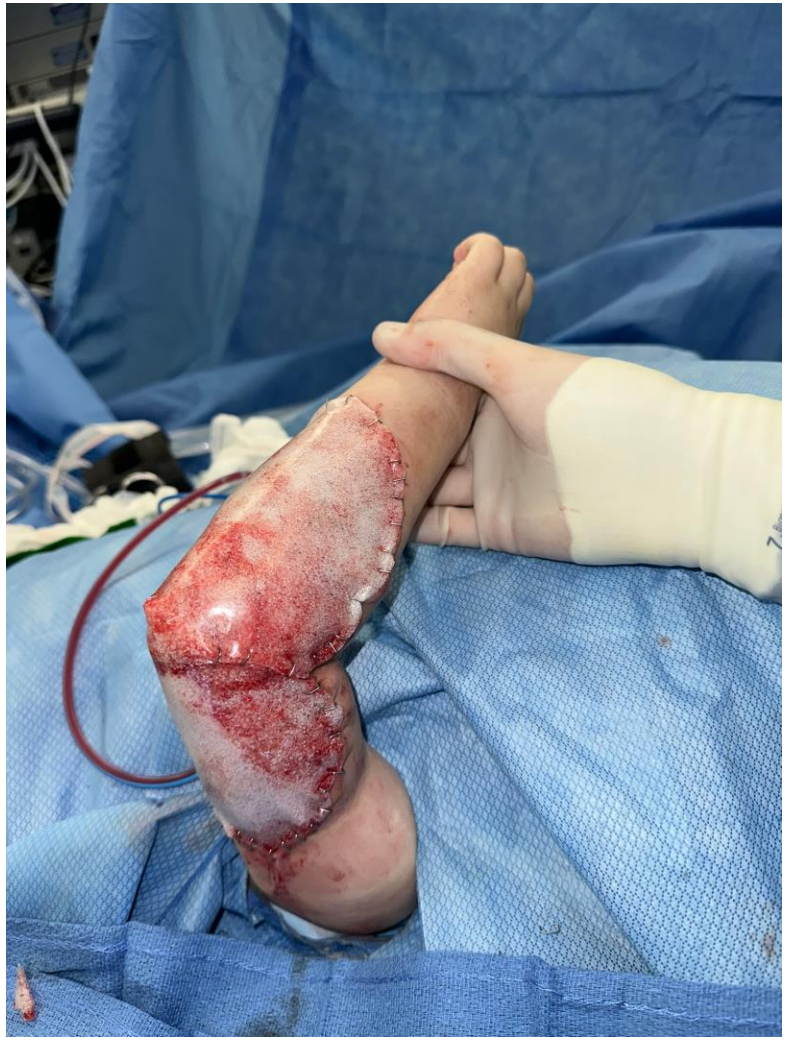

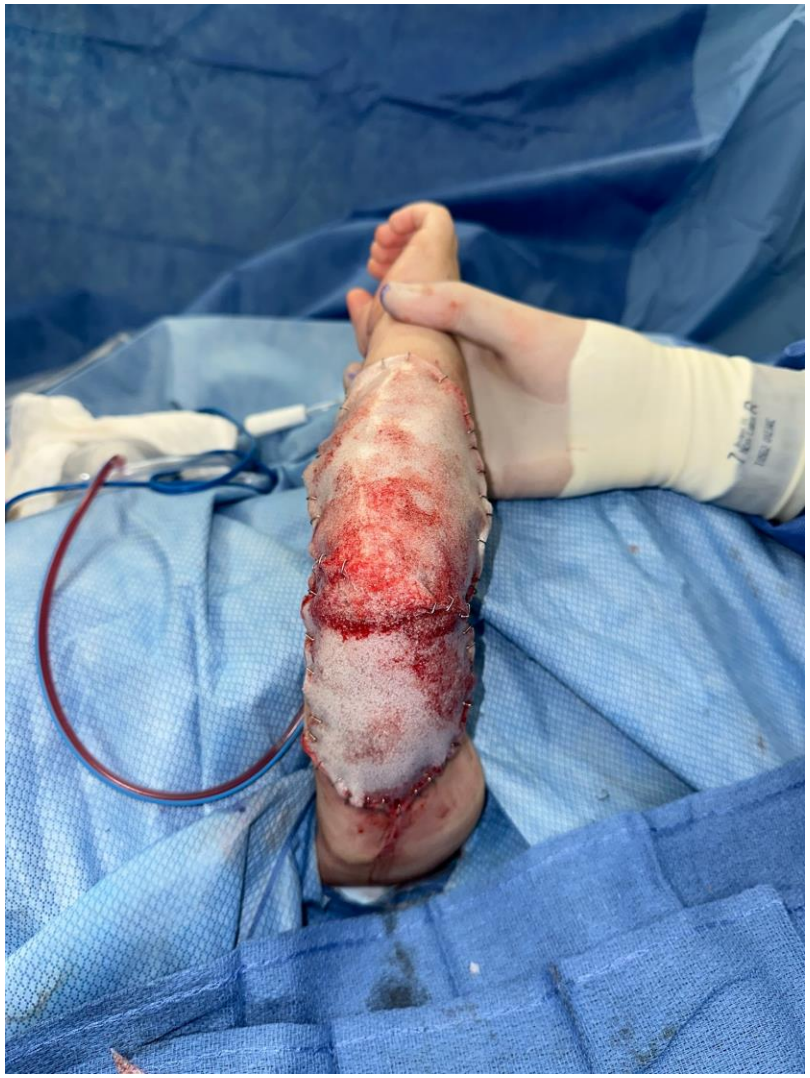

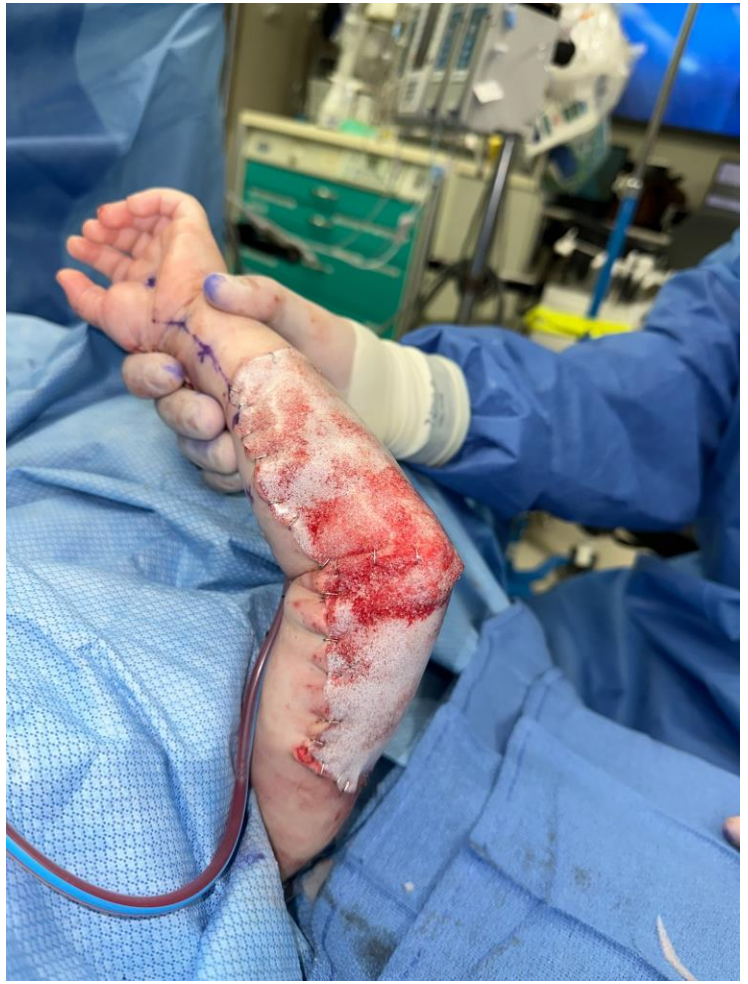

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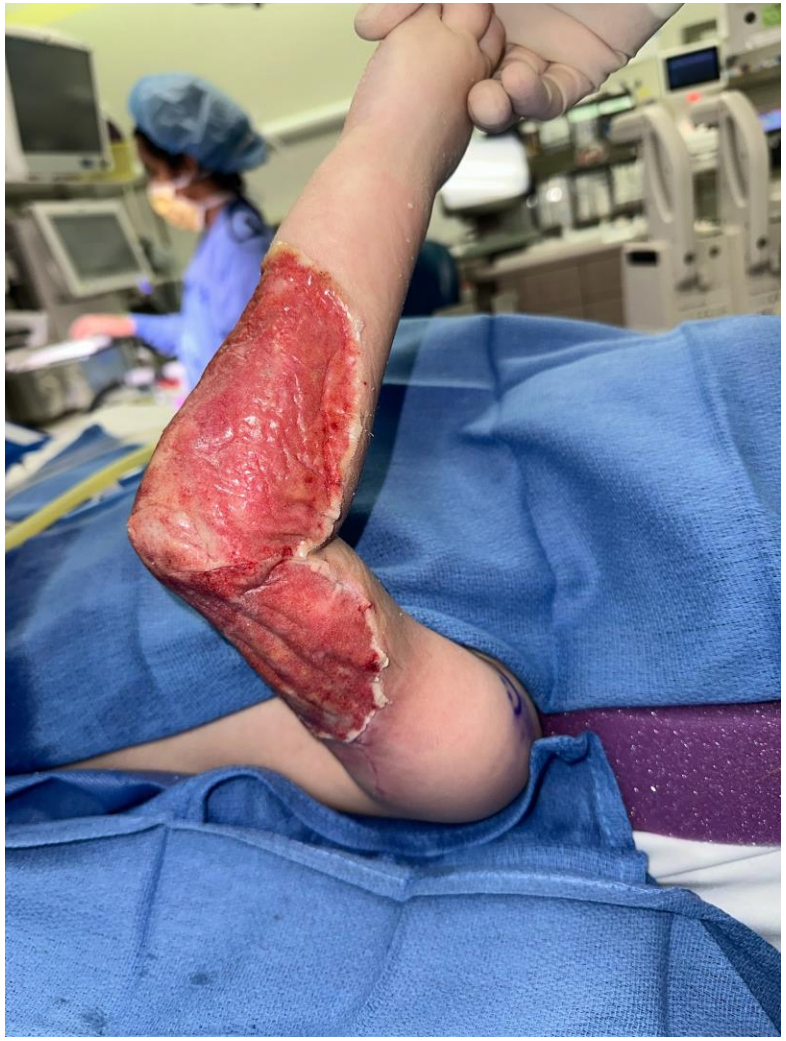

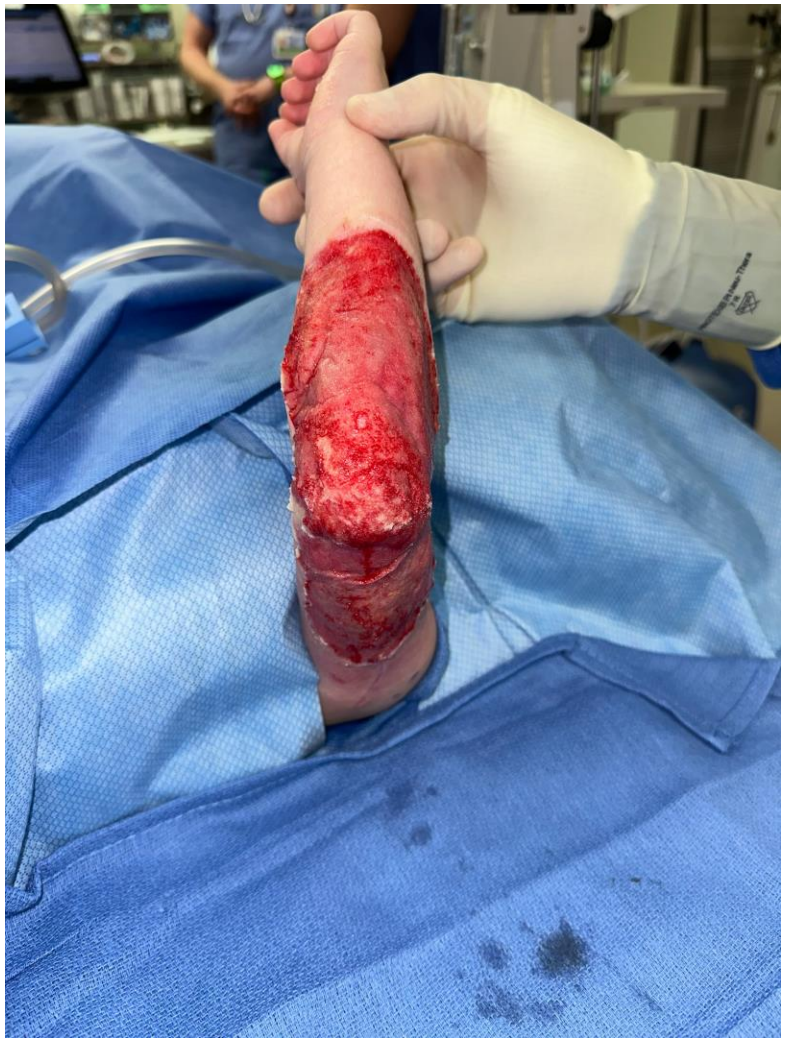

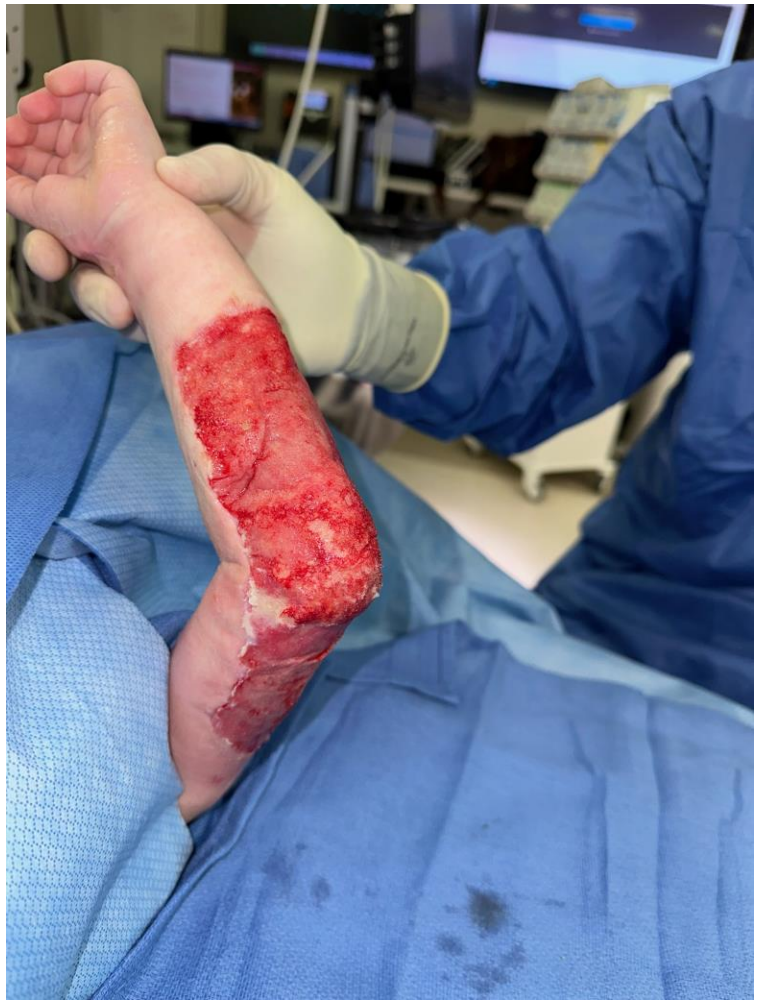

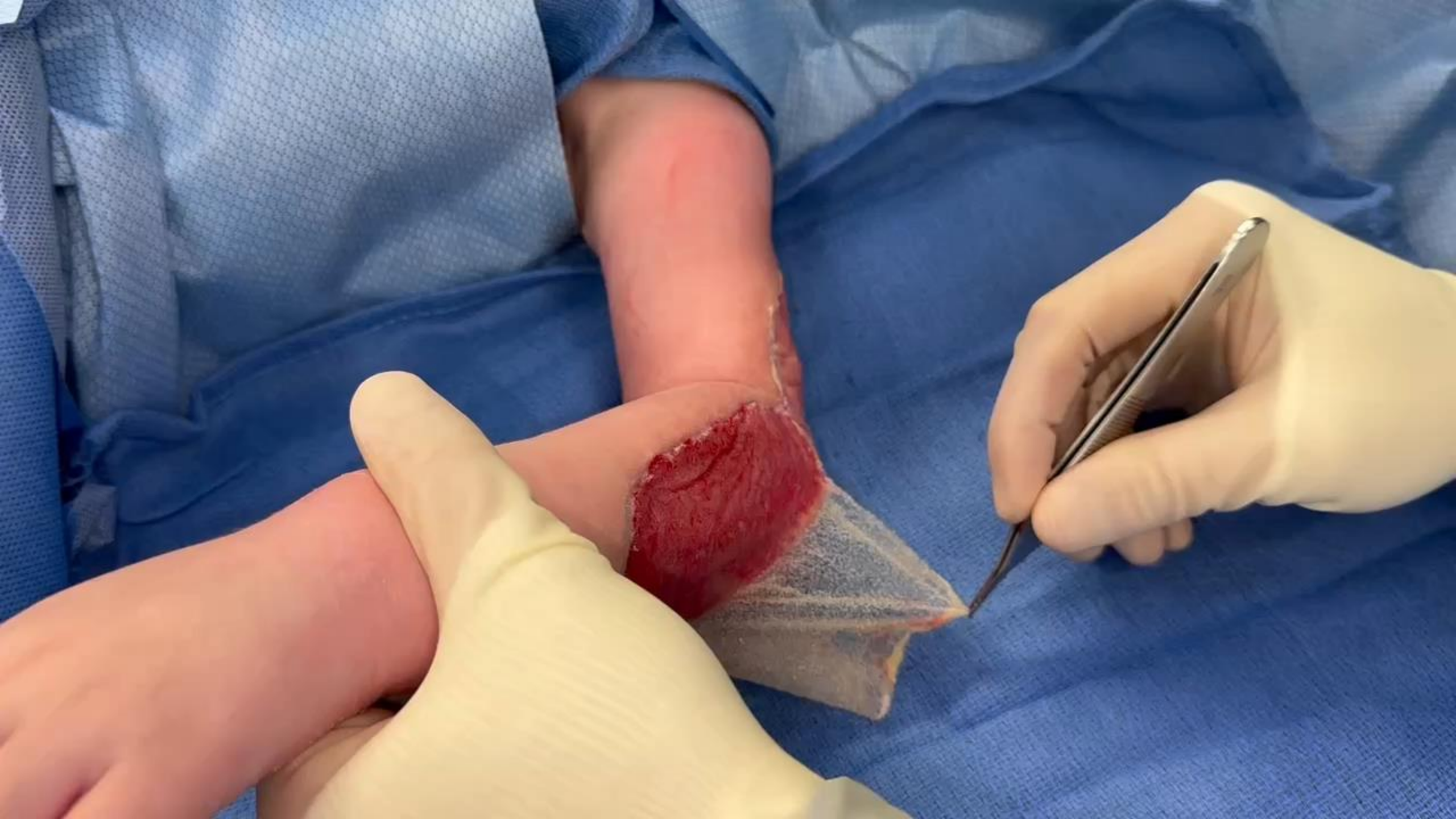

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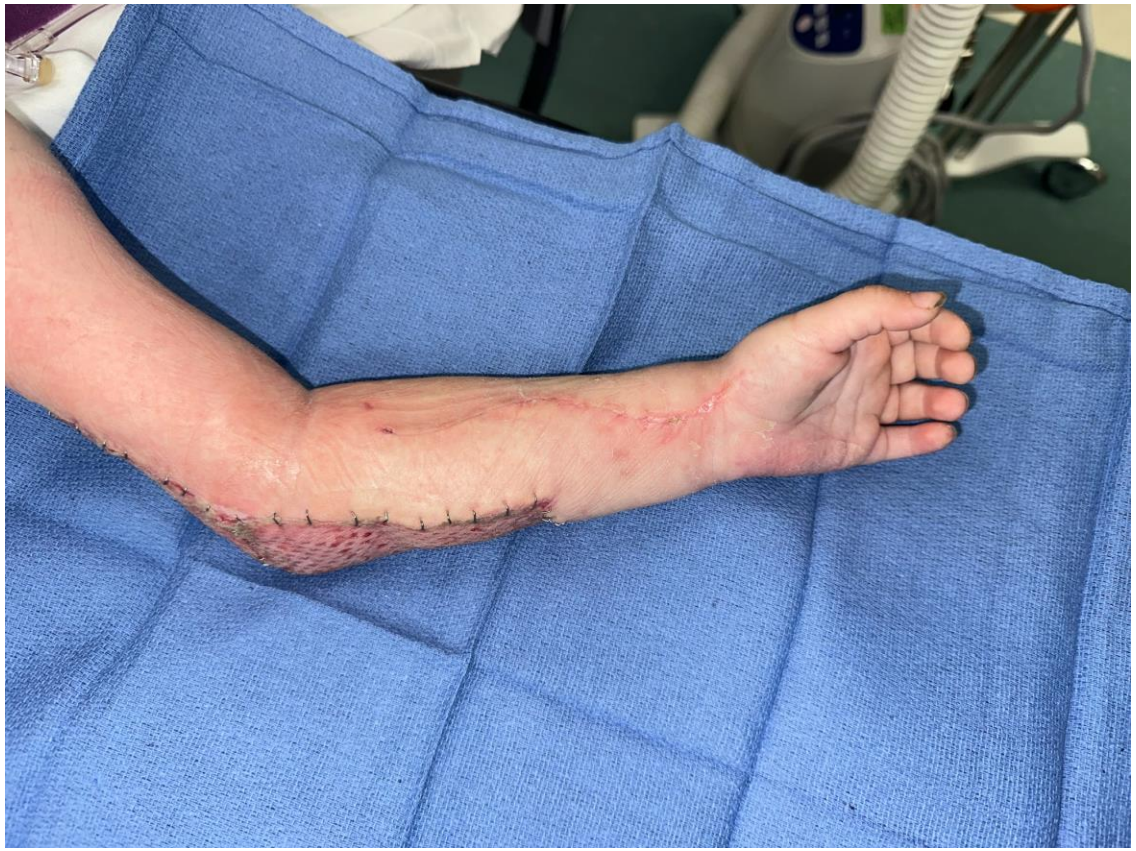

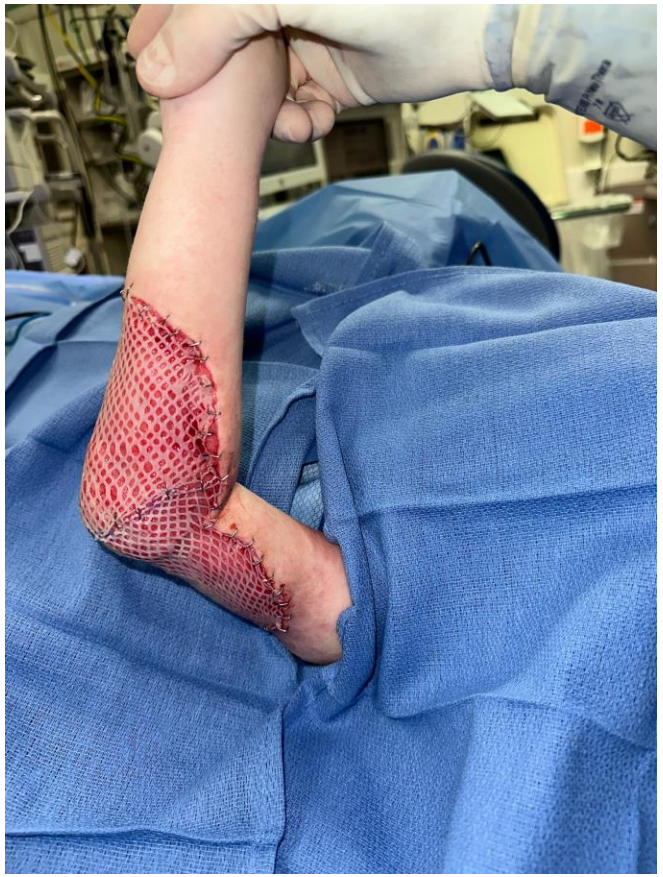

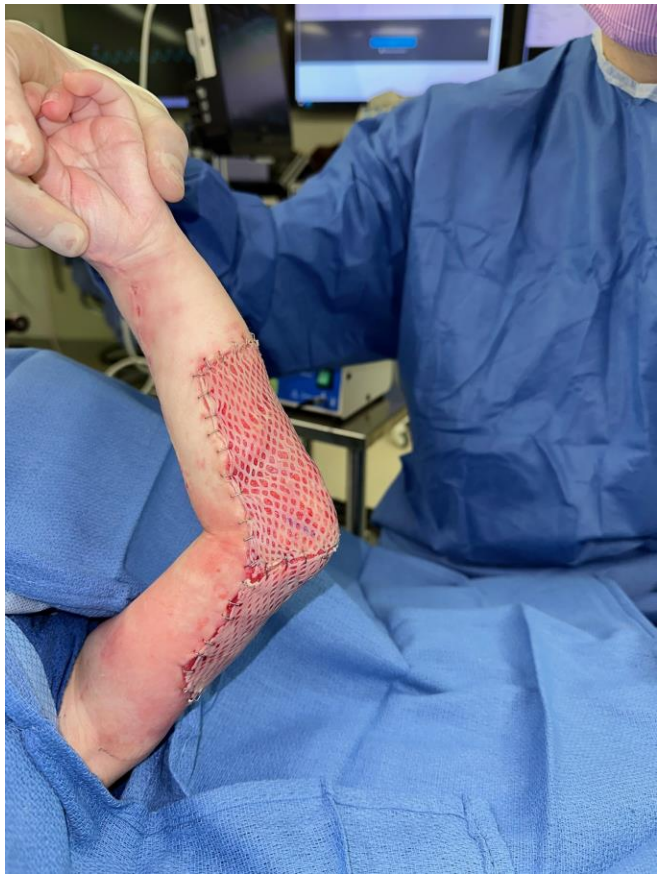

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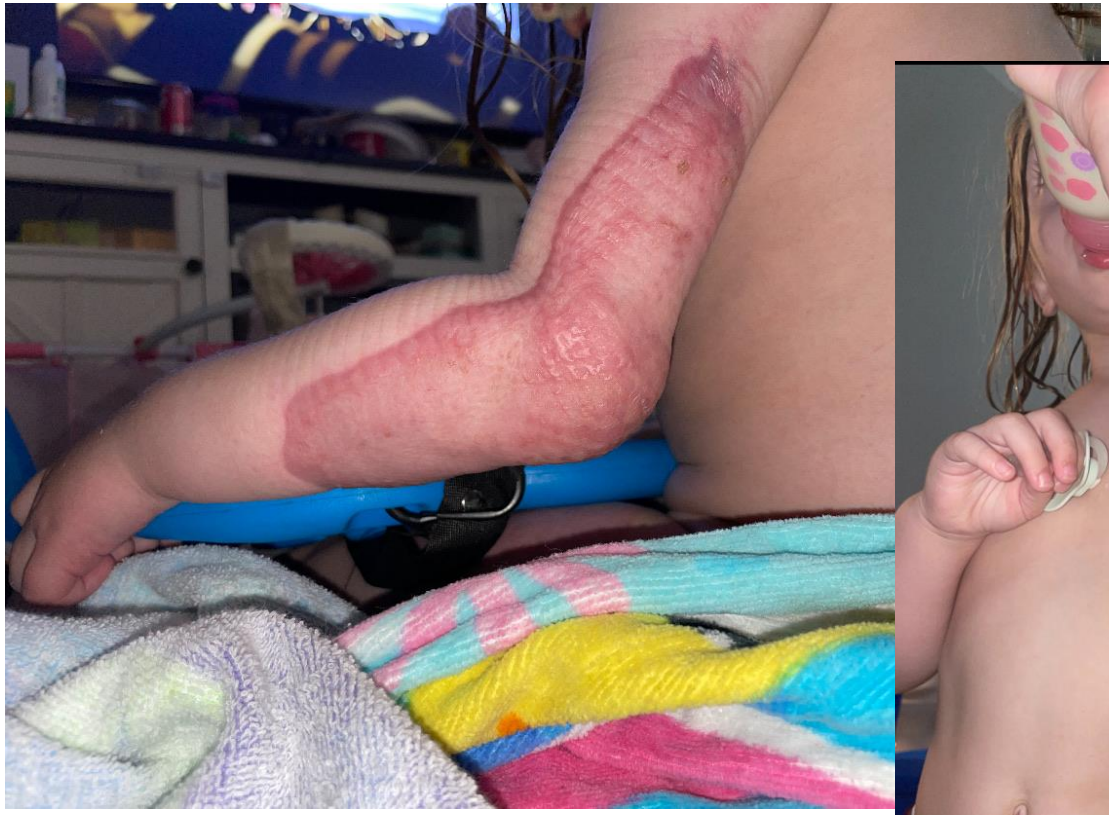
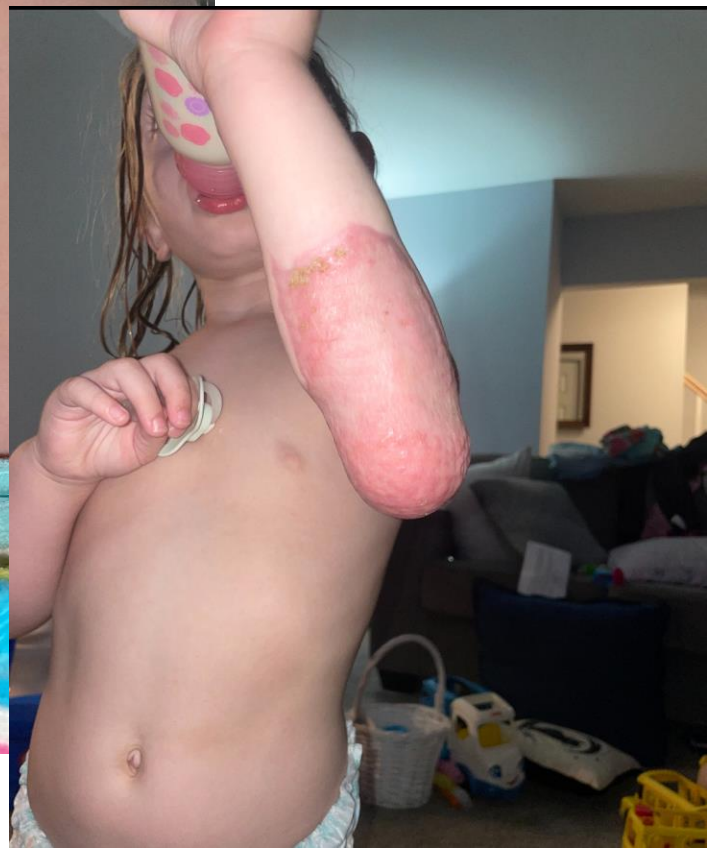
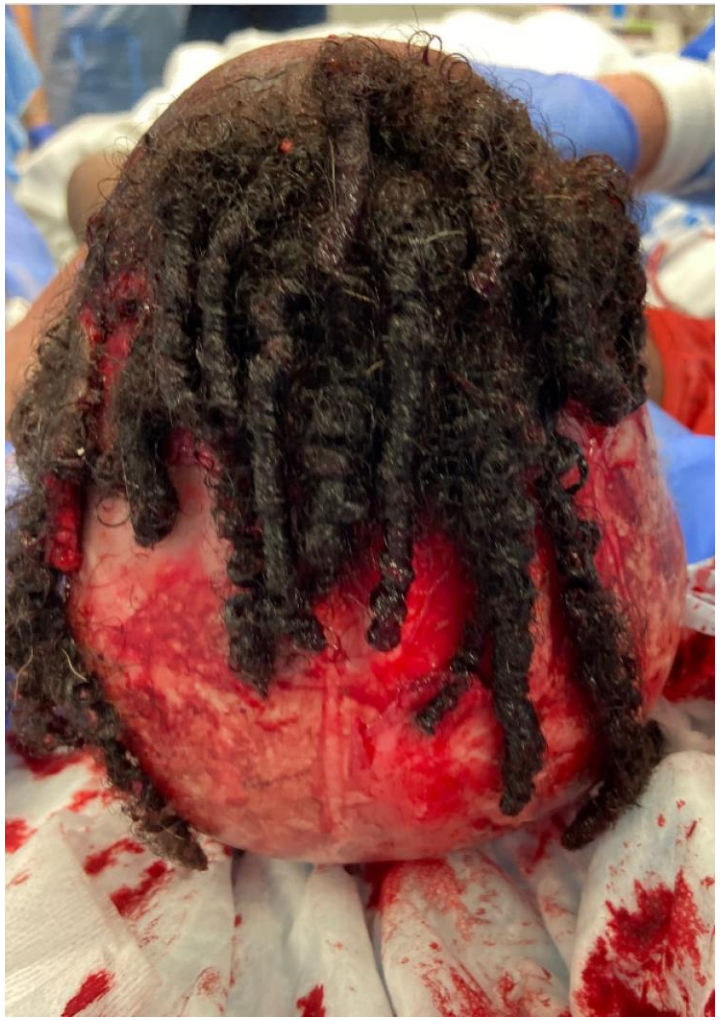


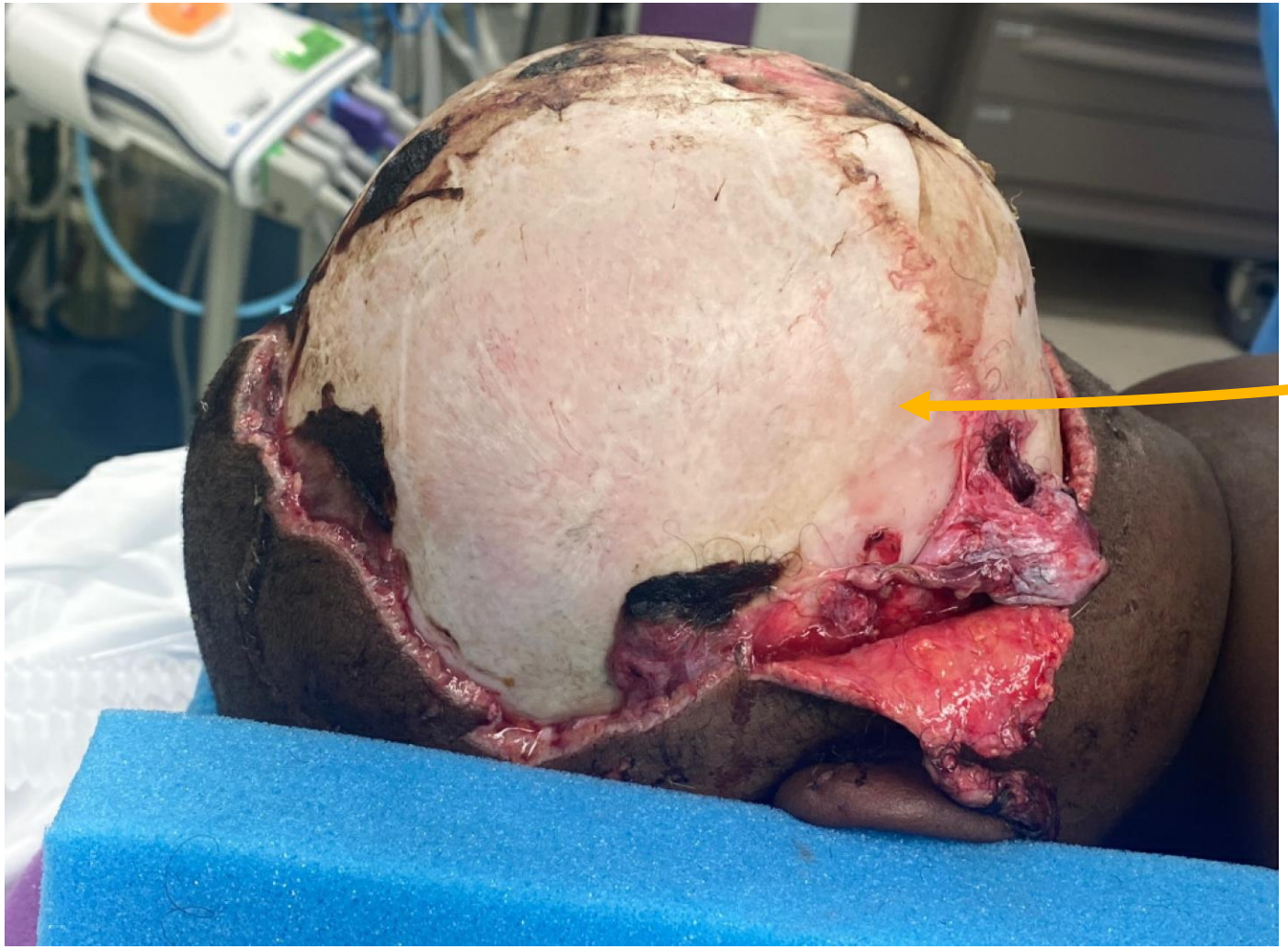


# Indication: Cover Bone, Tendon, and Small Joints



- 3-year-old, dog bite

# Indication: Cover Bone, Tendon, and Small Joints



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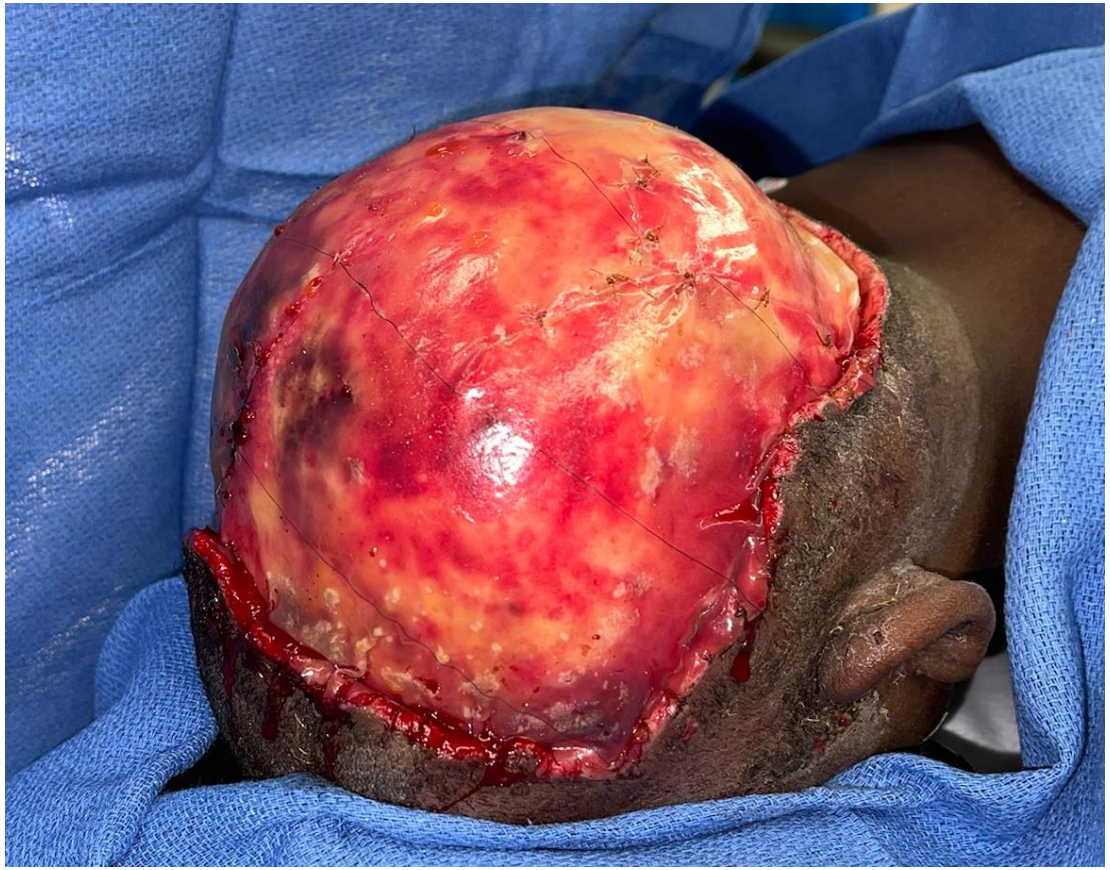
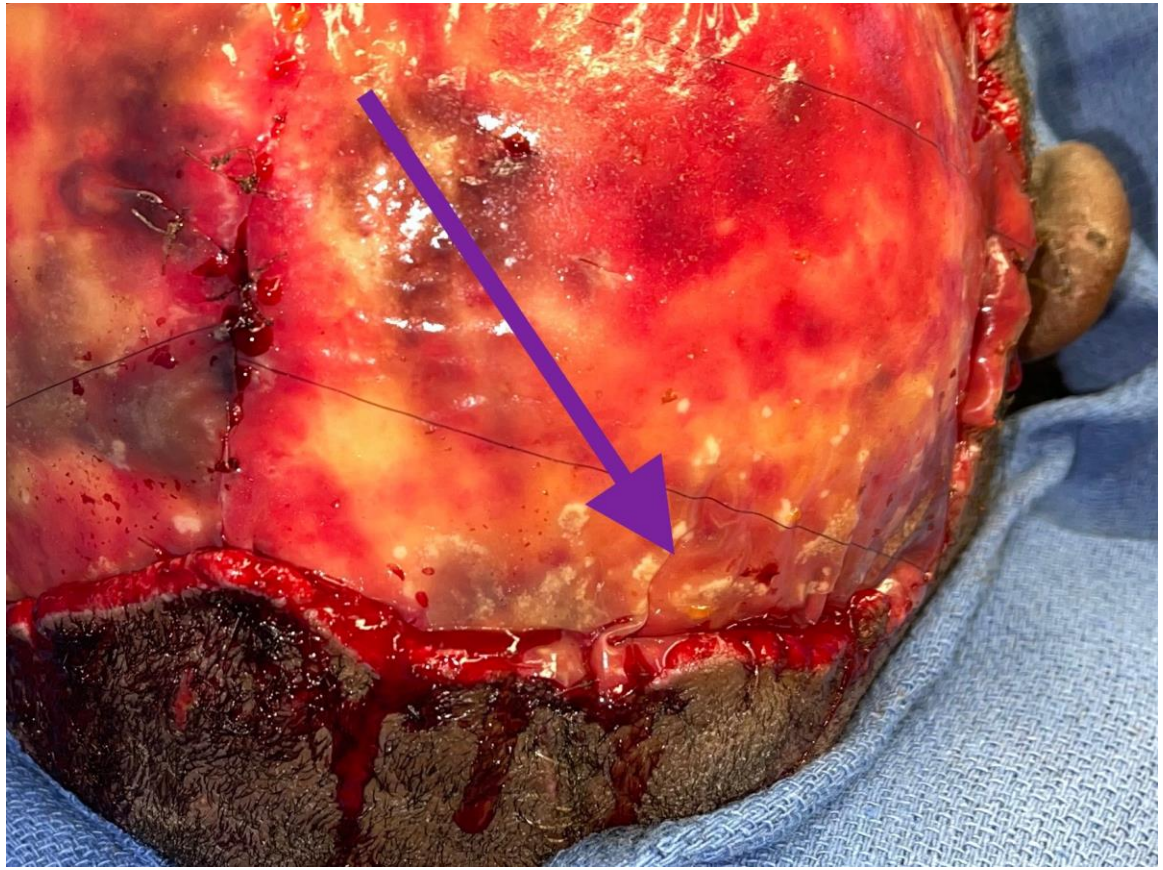


Initially reconstructed with Integra by partner



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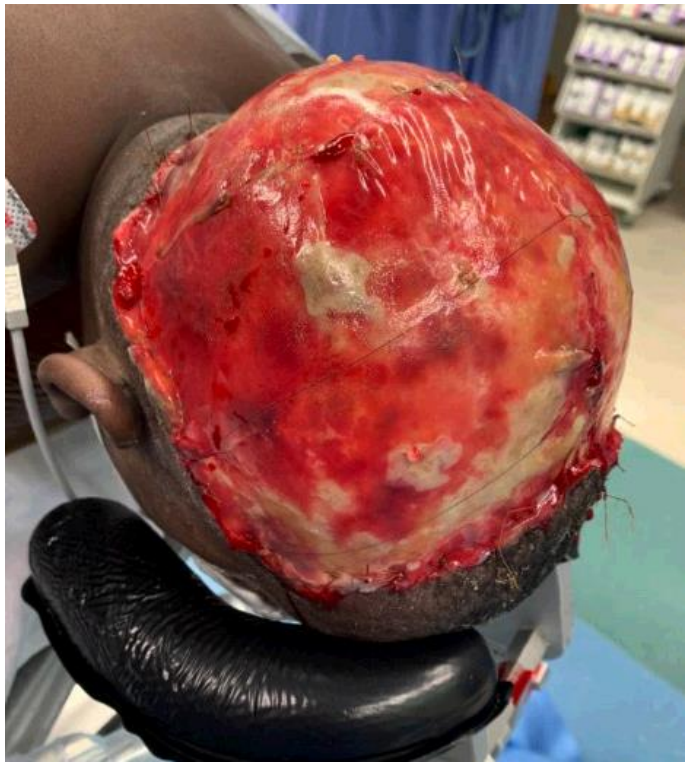

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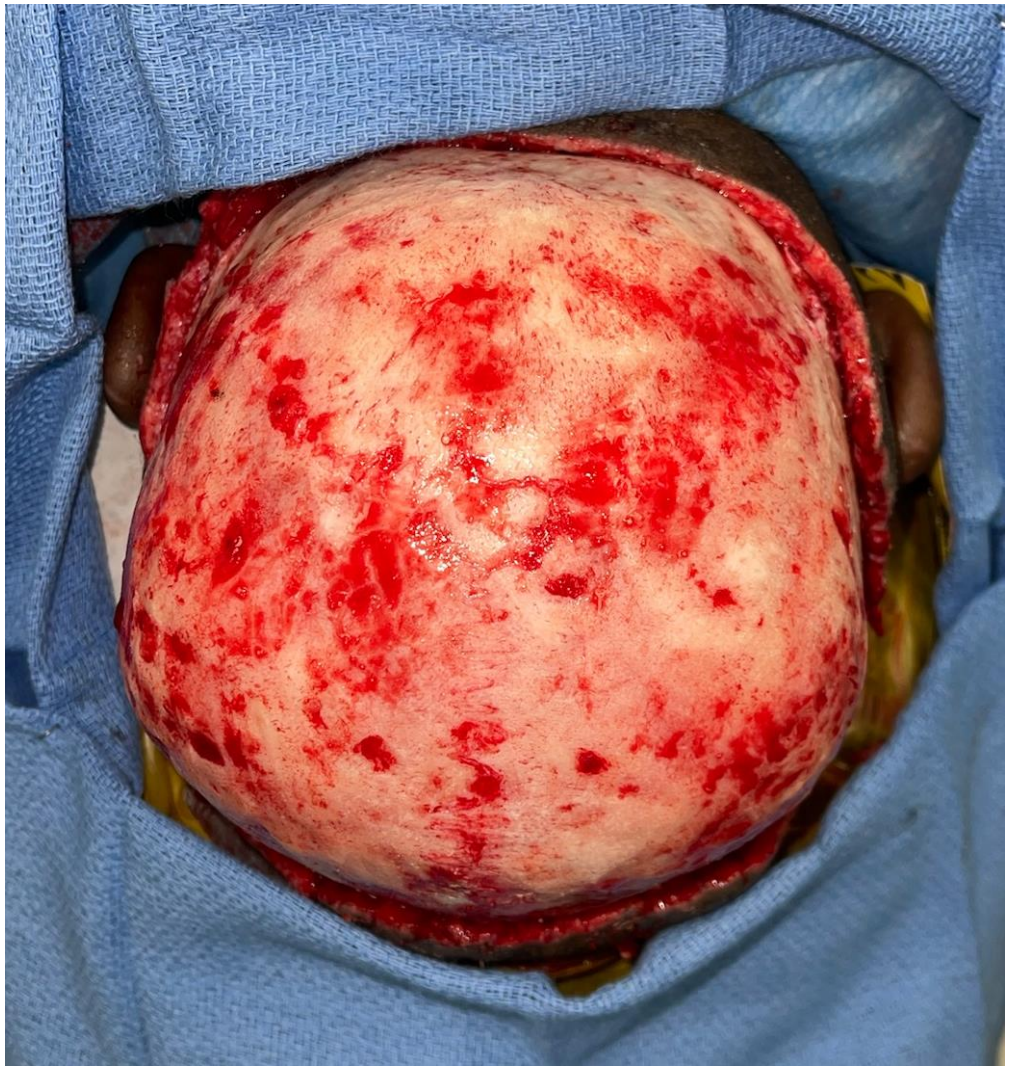

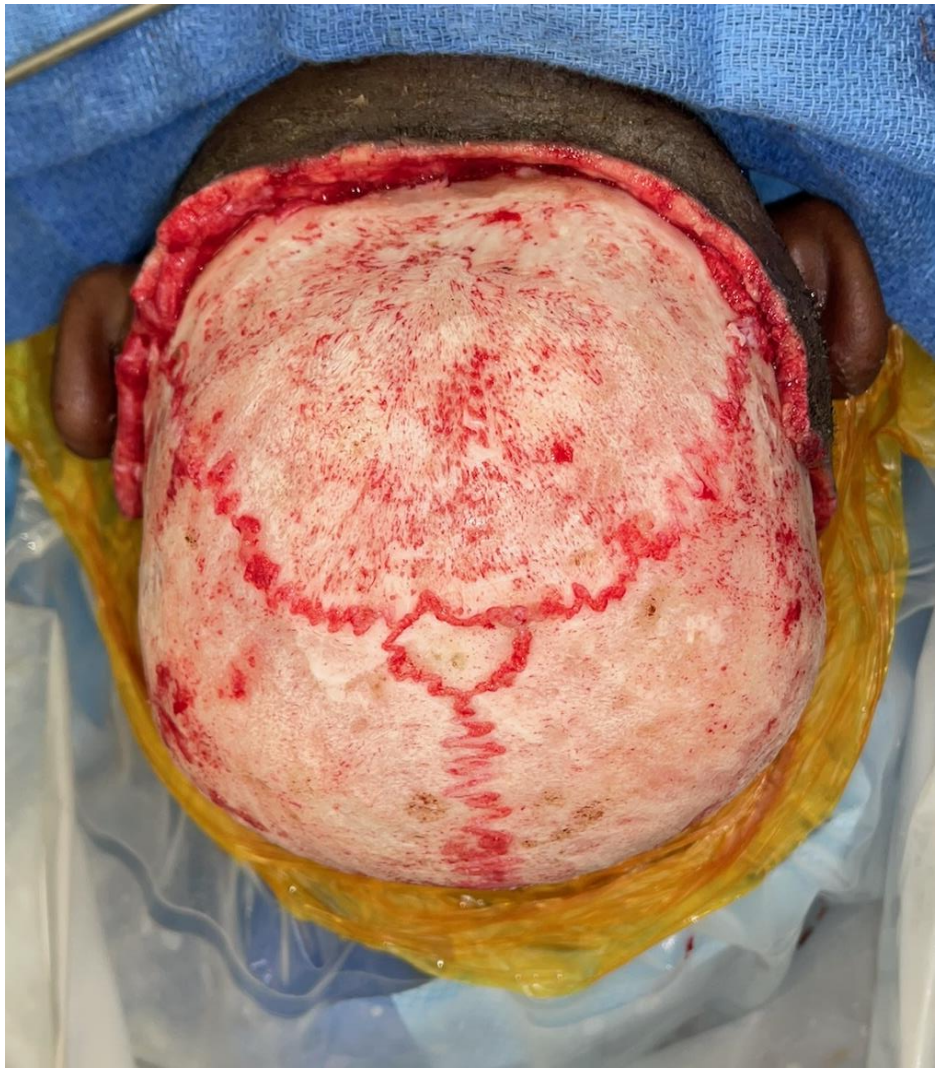

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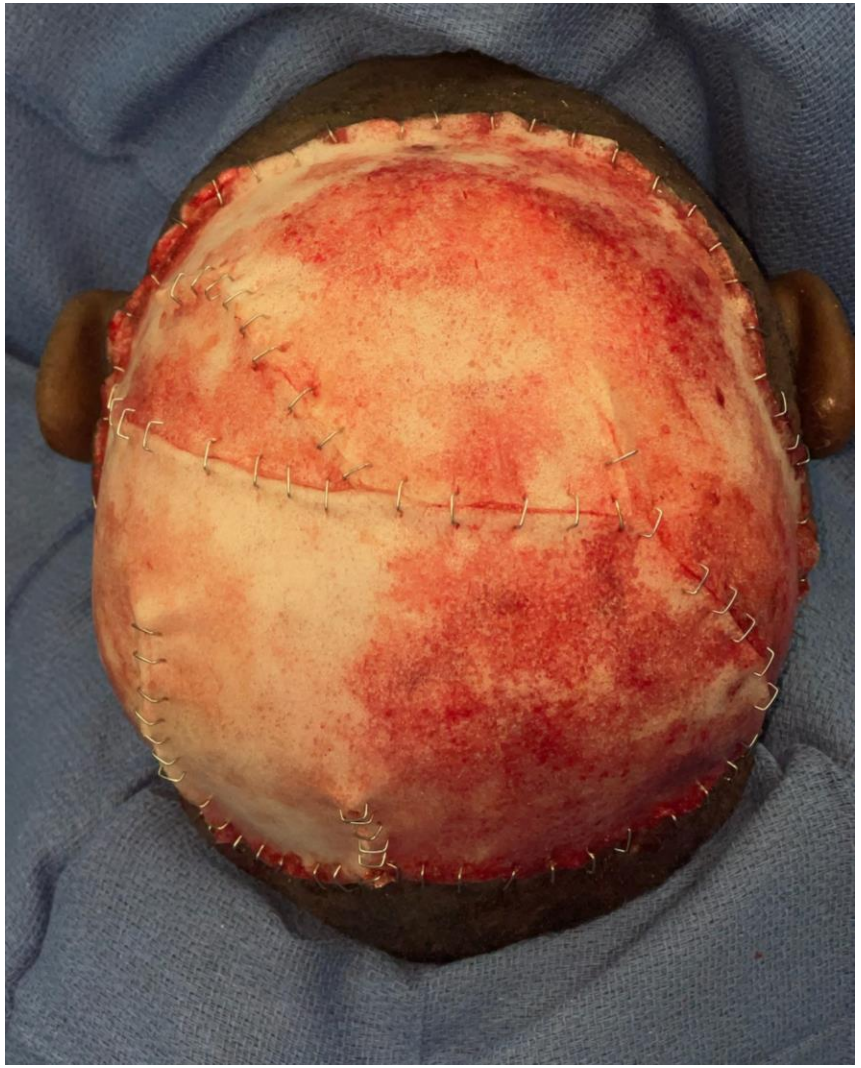

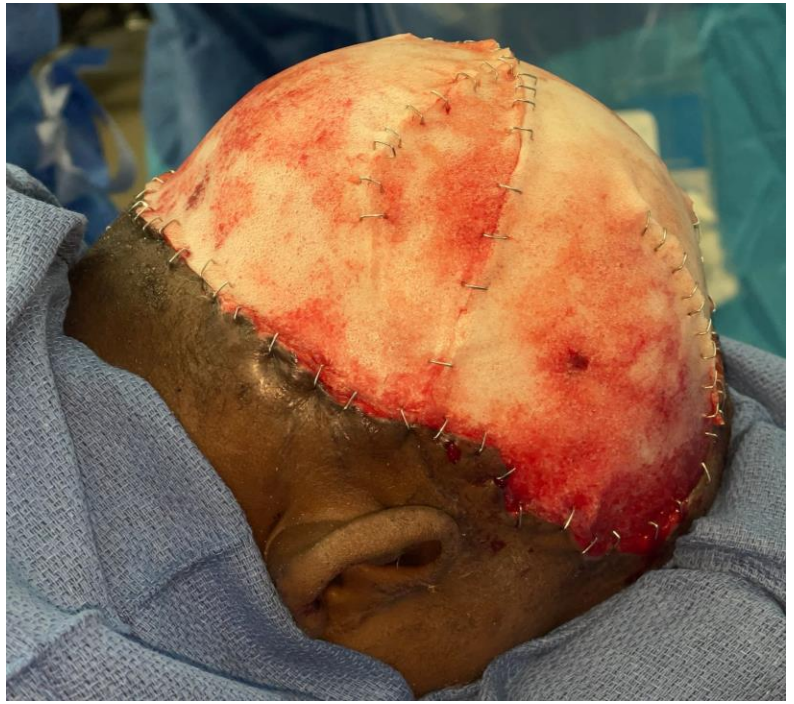

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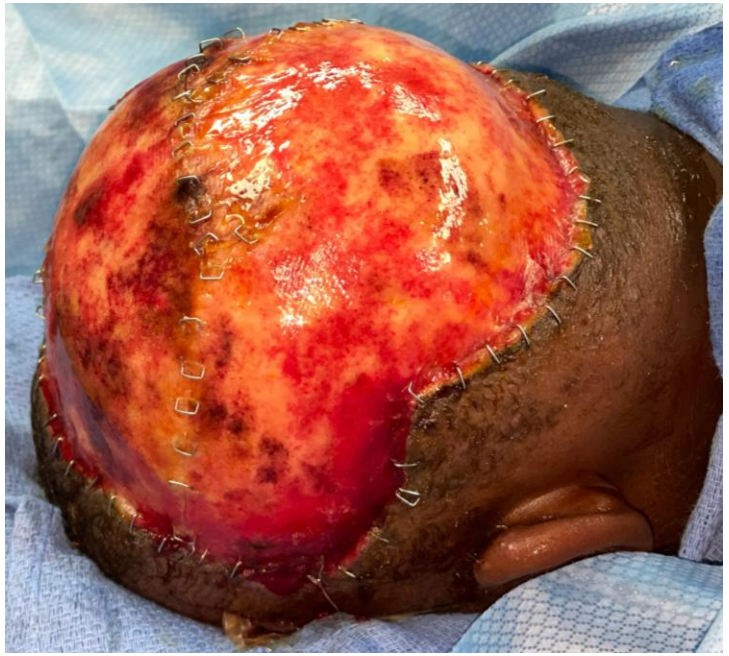
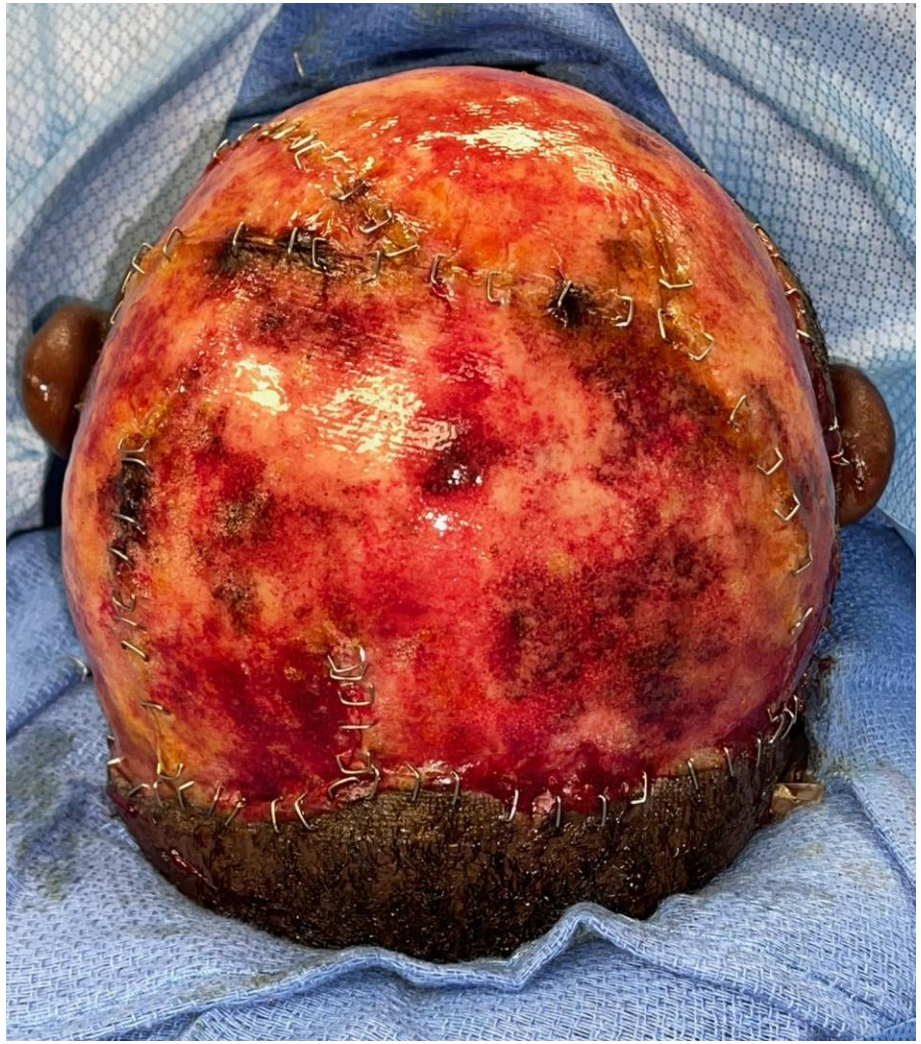
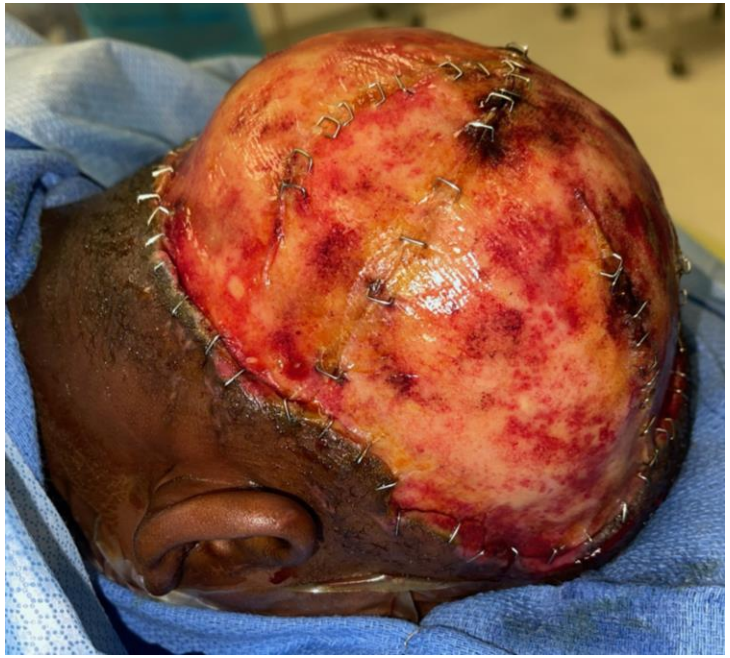


1-week post-op





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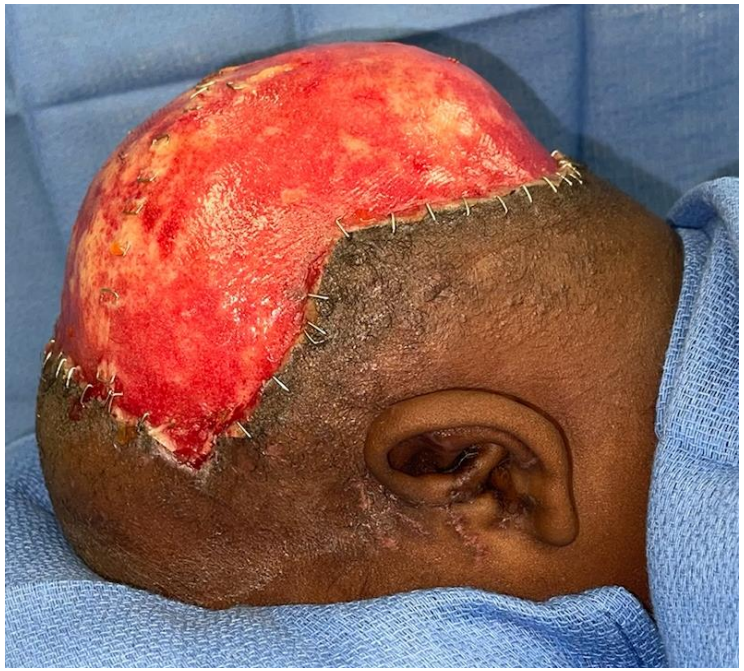
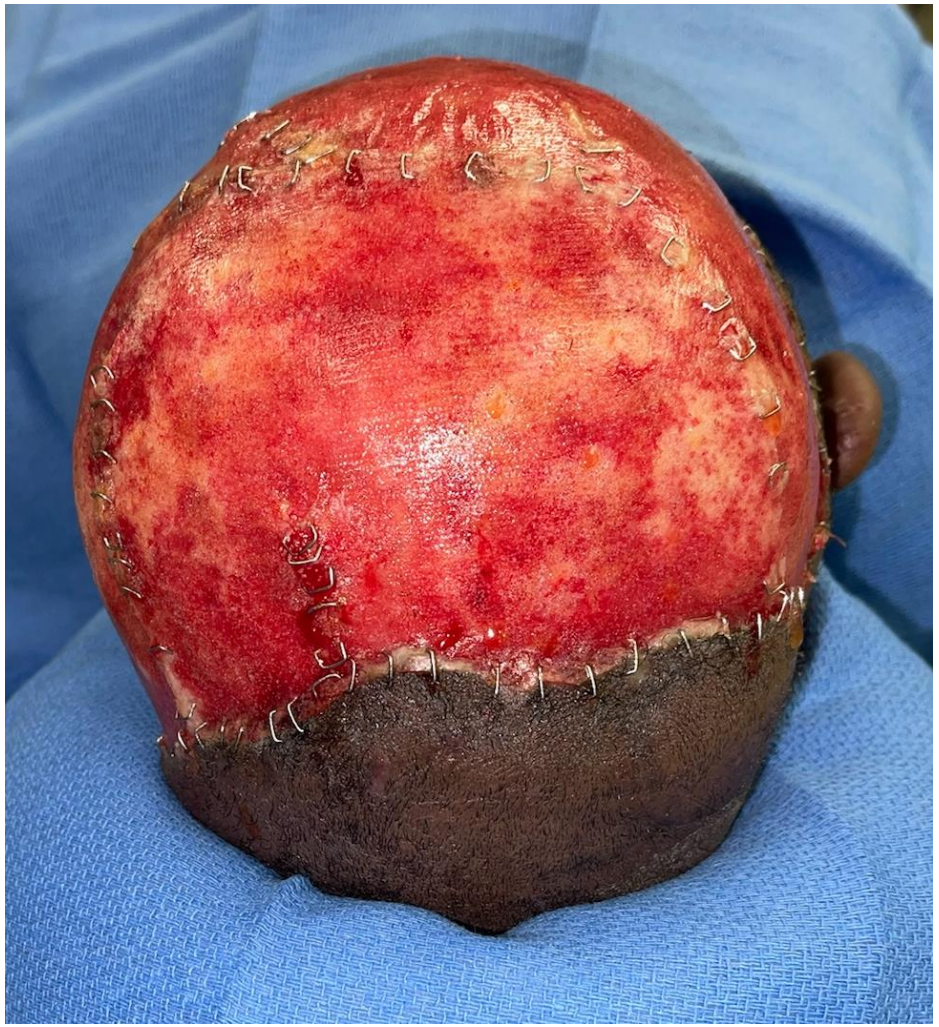
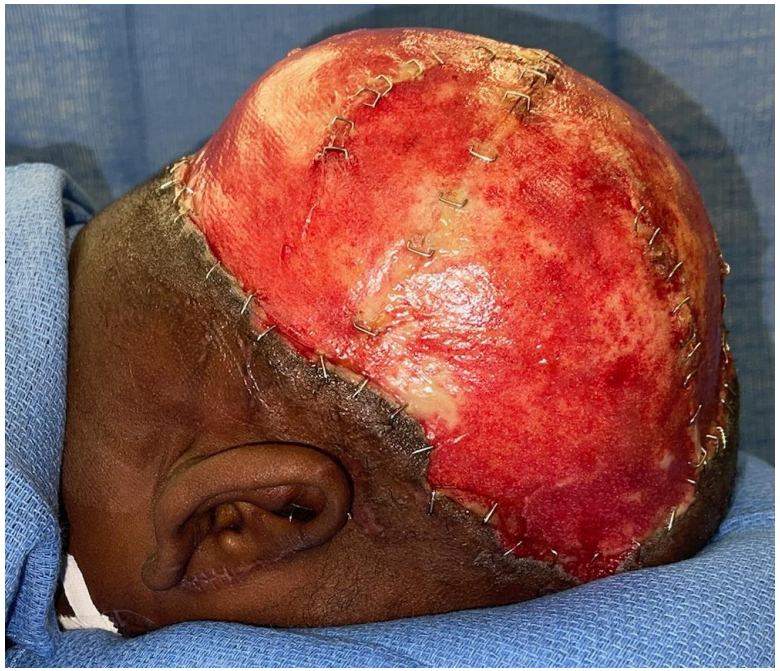
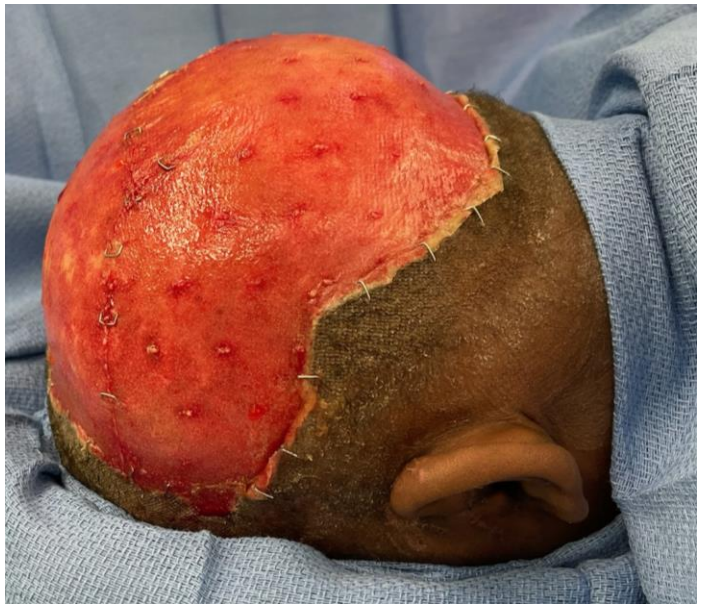


2 weeks post-op

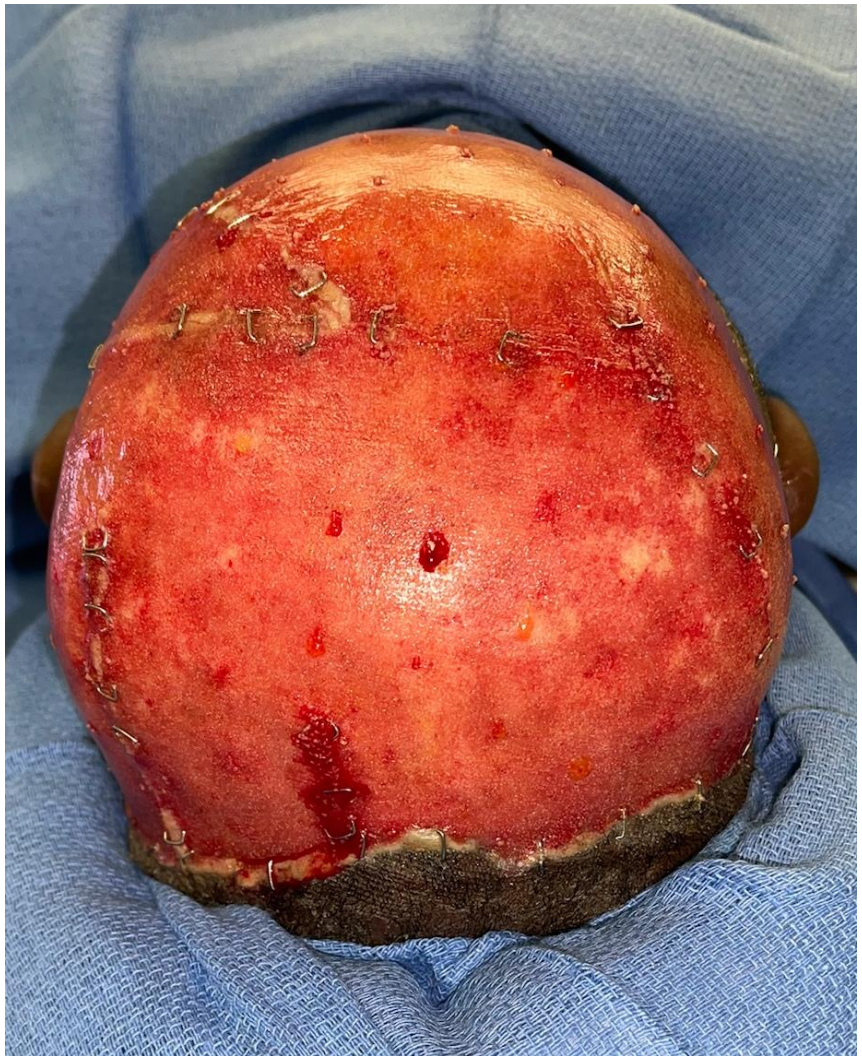


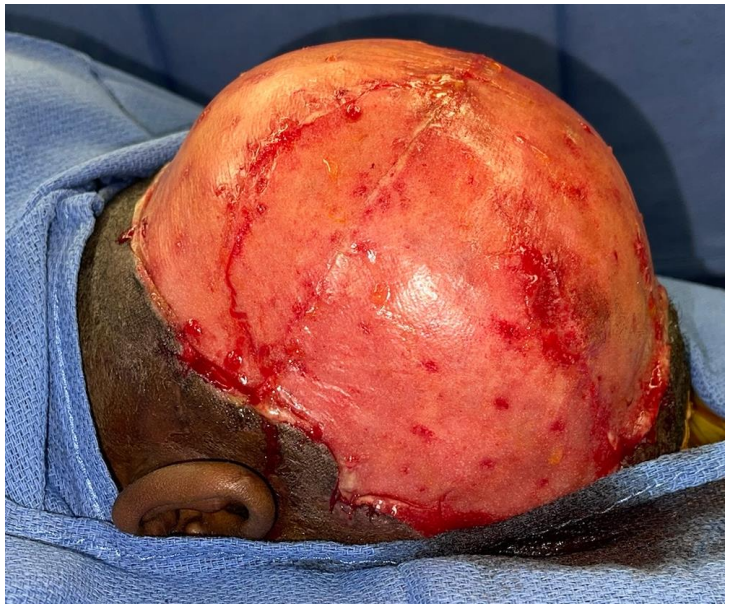


# Indication: Cover Bone, Tendon, and Small Joints



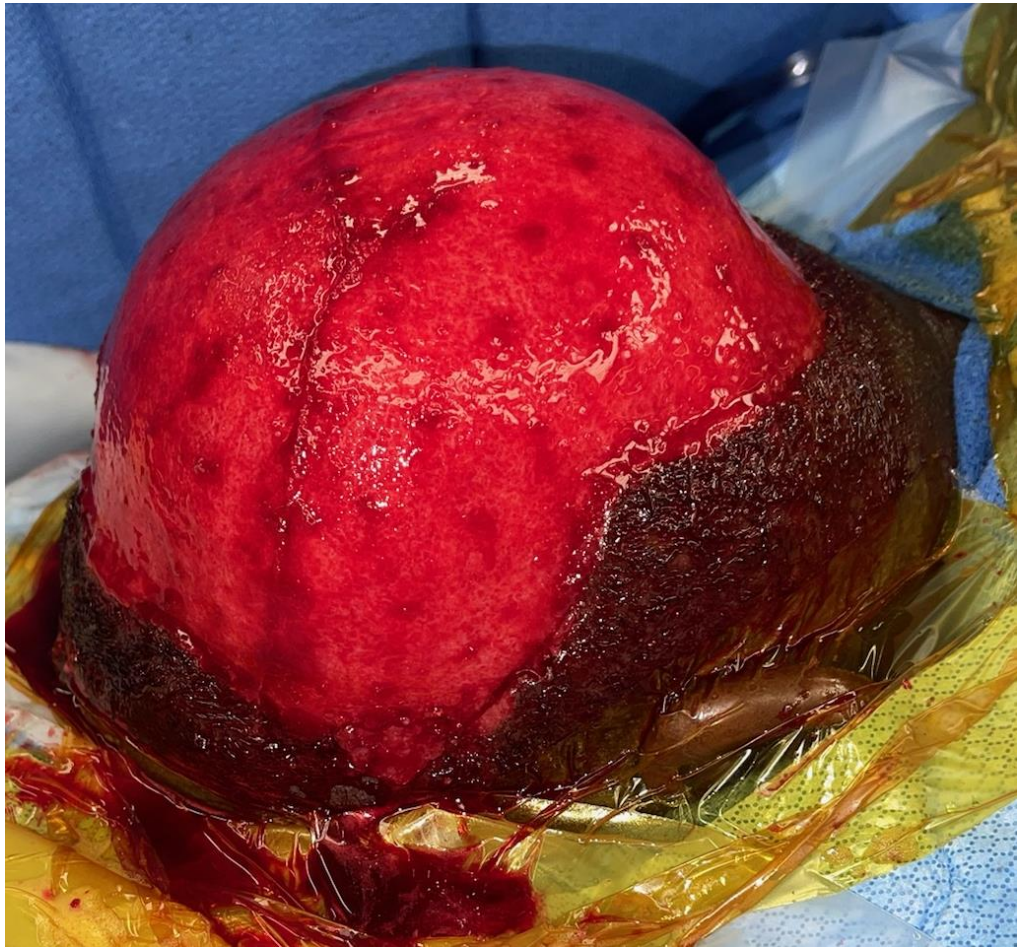
3 weeks post-op

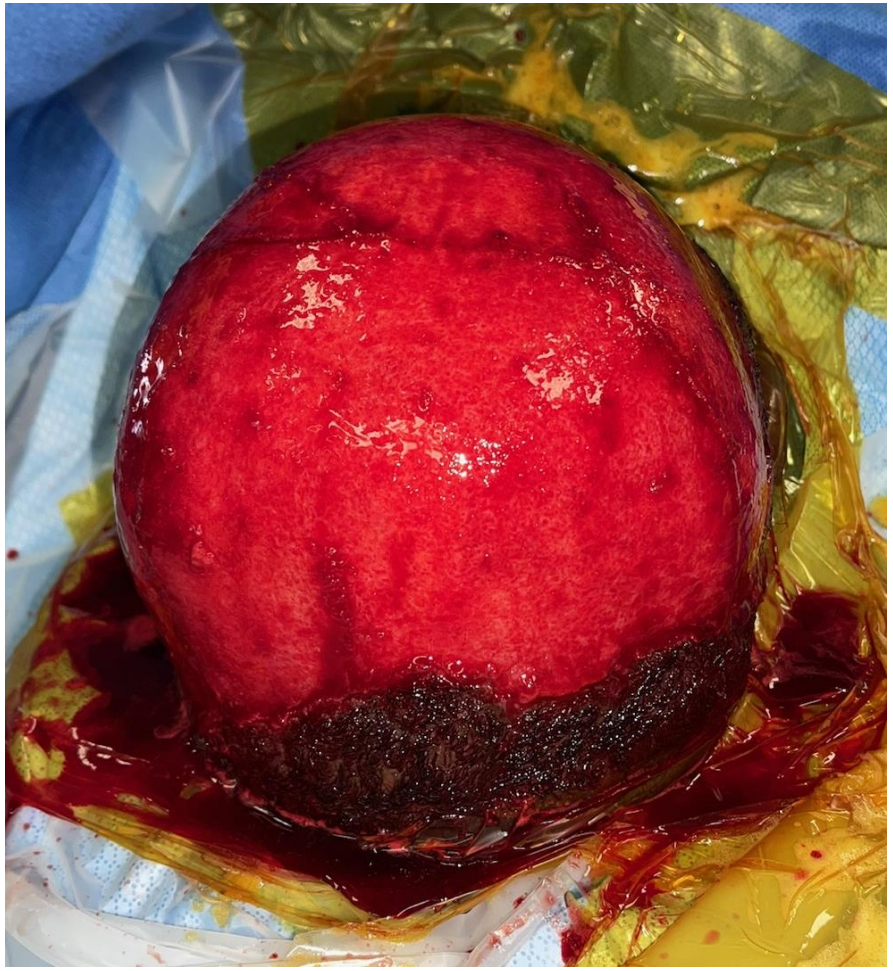




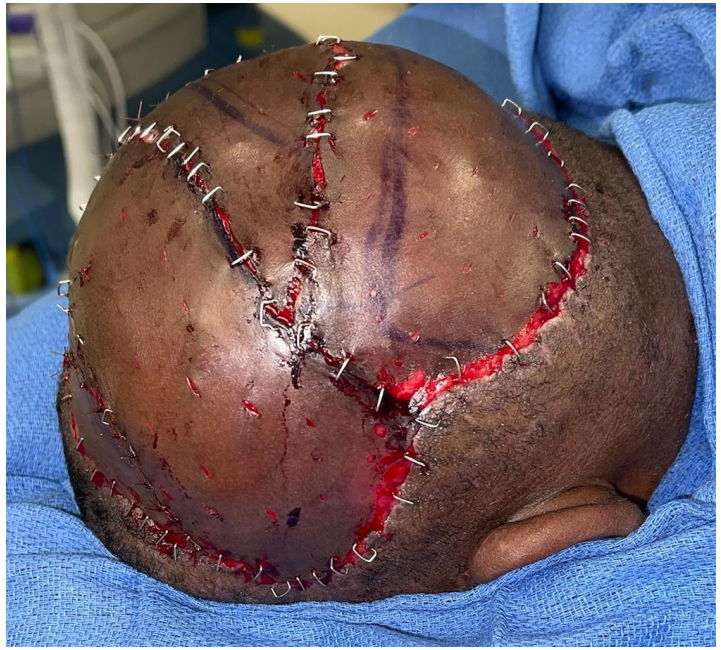
# Indication: Cover Bone, Tendon, and Small Joints

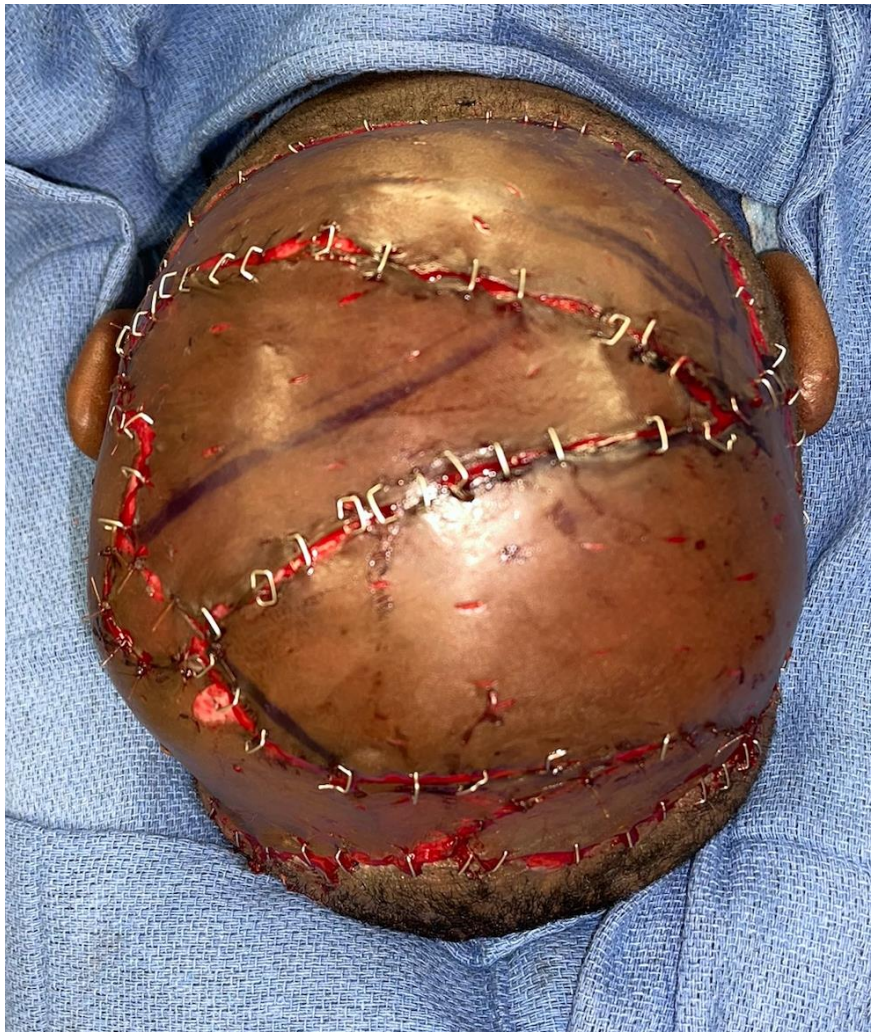
- 4 weeks post-BTM, after delamination



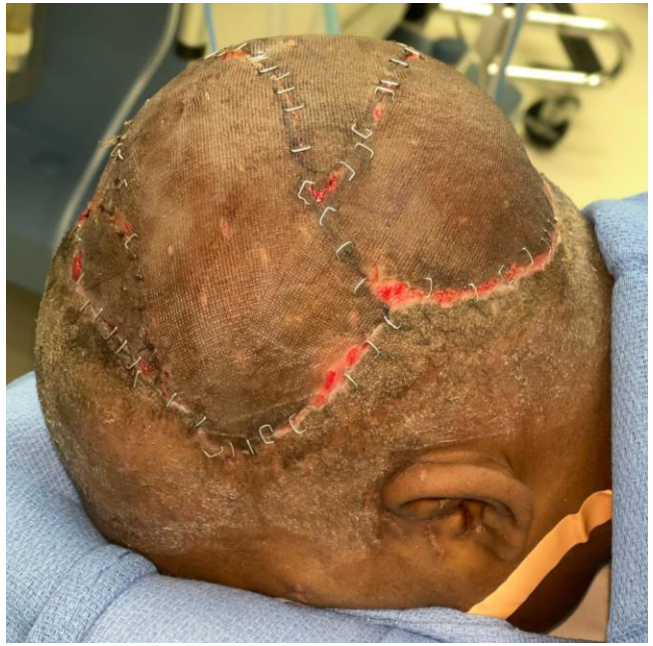


# Indication: Cover Bone, Tendon, and Small Joints

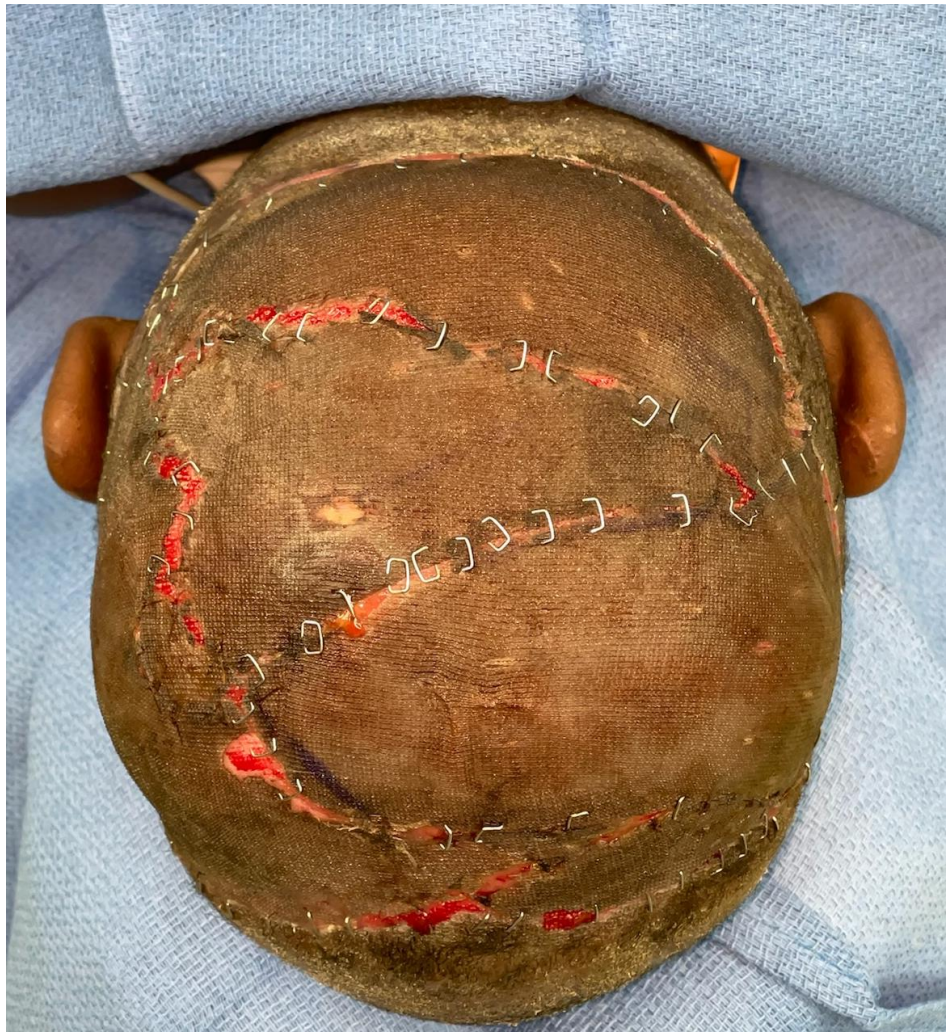


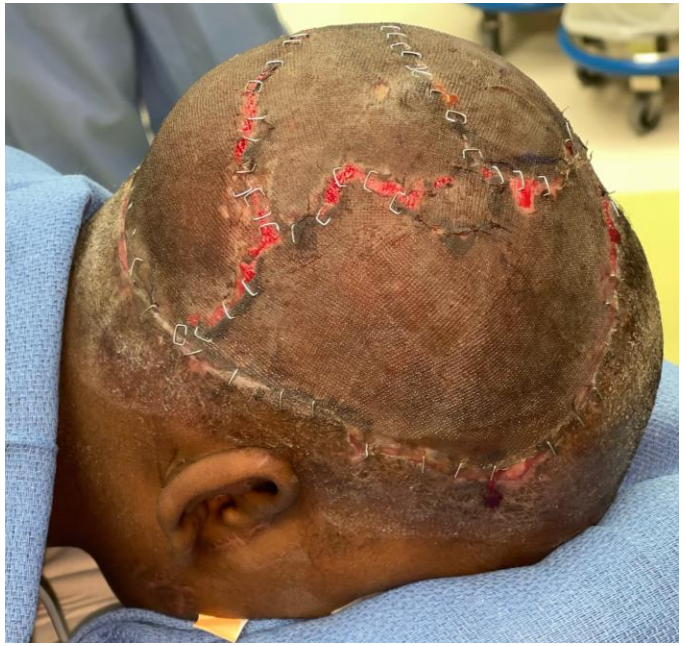


# Indication: Cover Bone, Tendon, and Small Joints

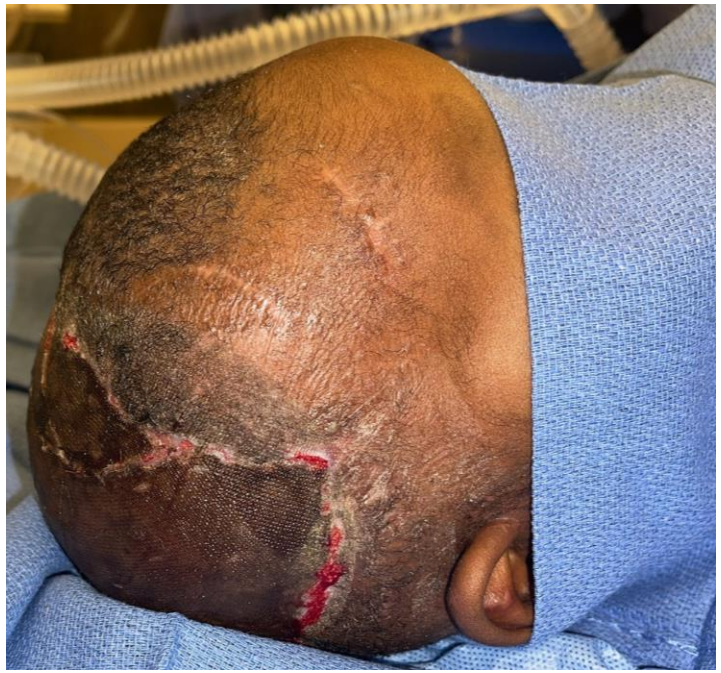


1-week post-skin graft

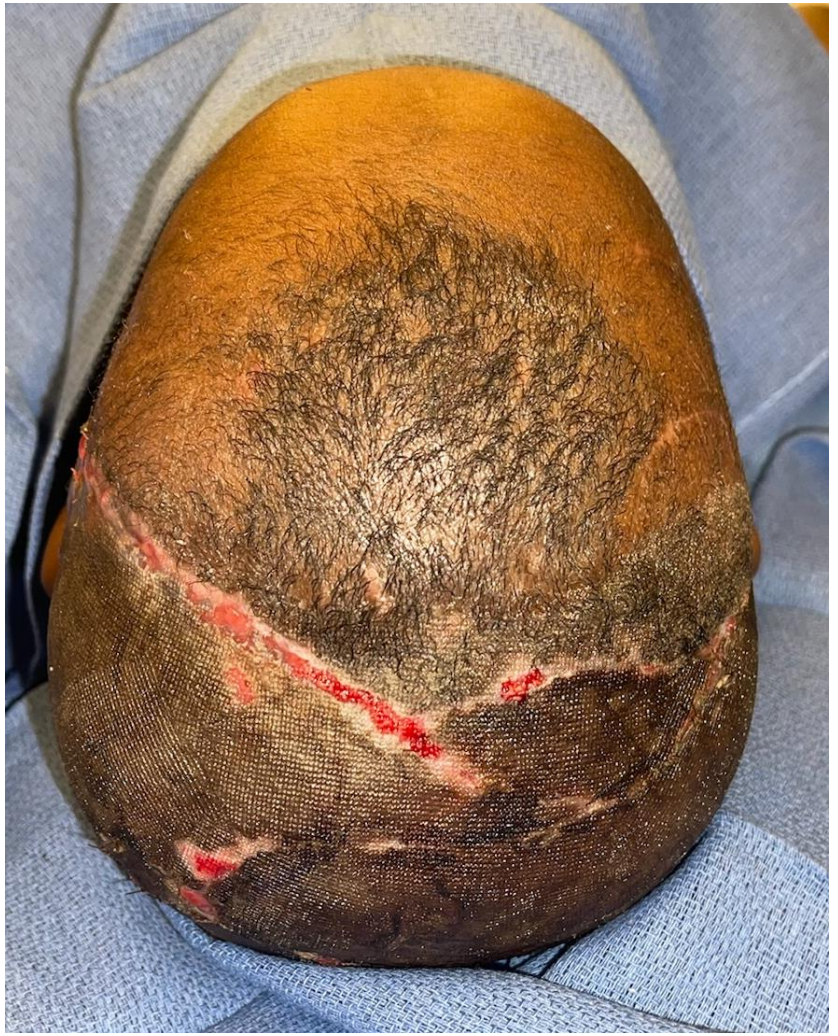


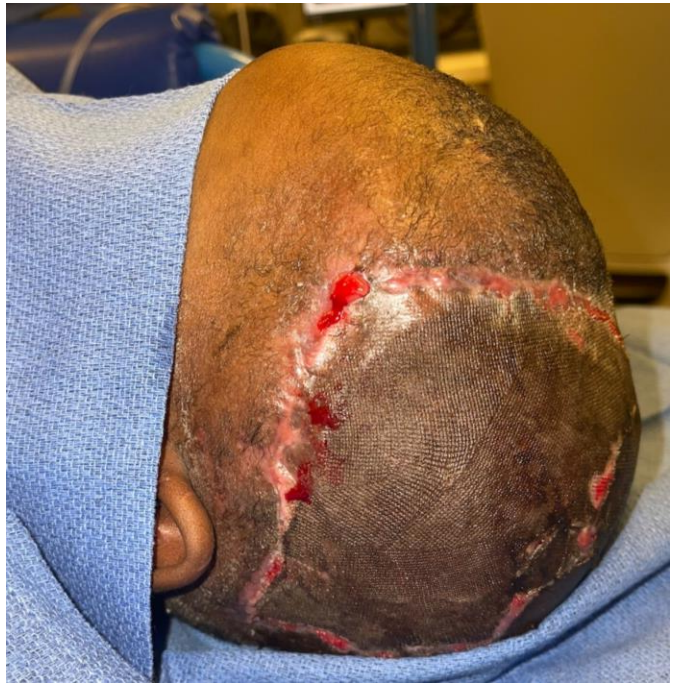


# Indication: Cover Bone, Tendon, and Small Joints

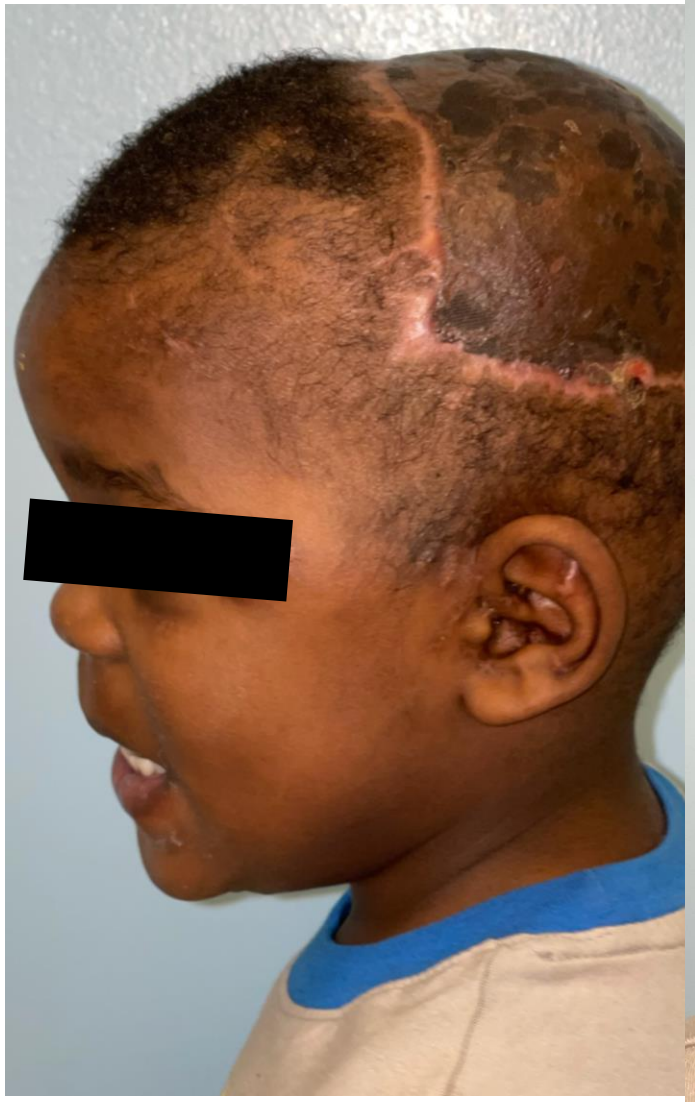


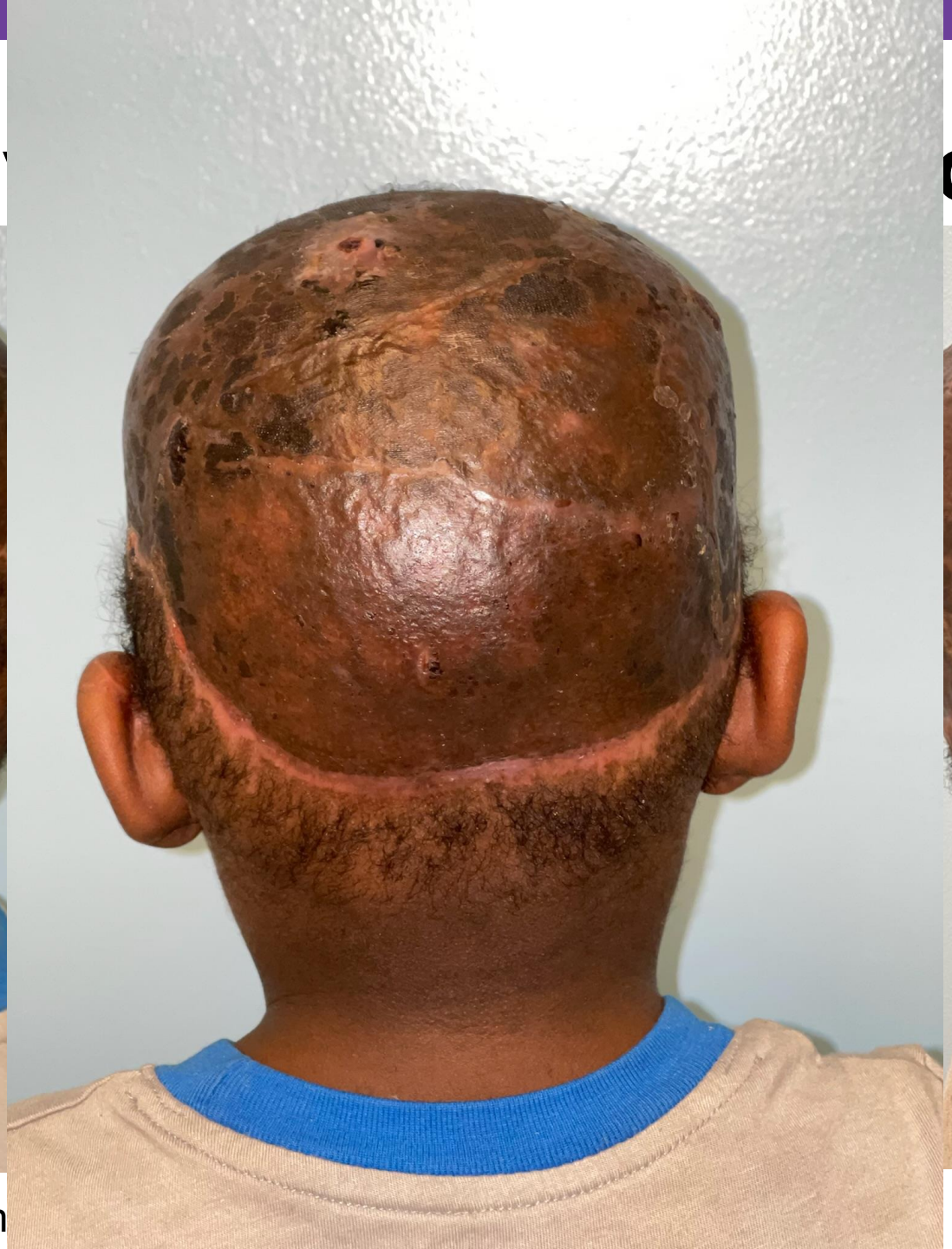
2 weeks post-skin graft





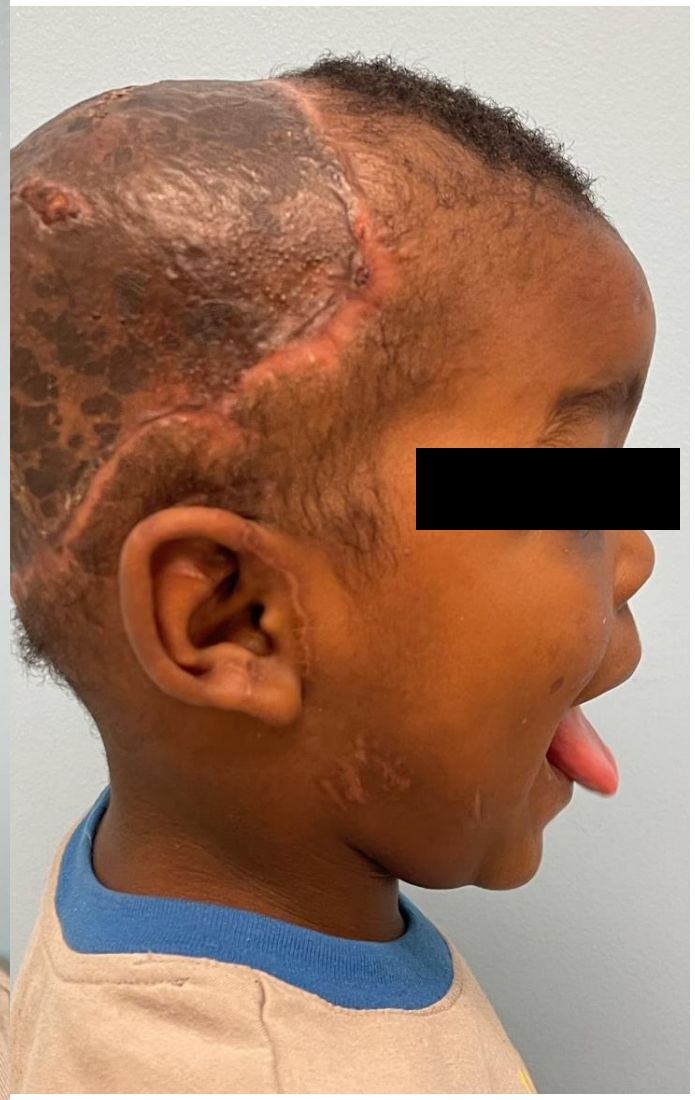
# Indication: Co





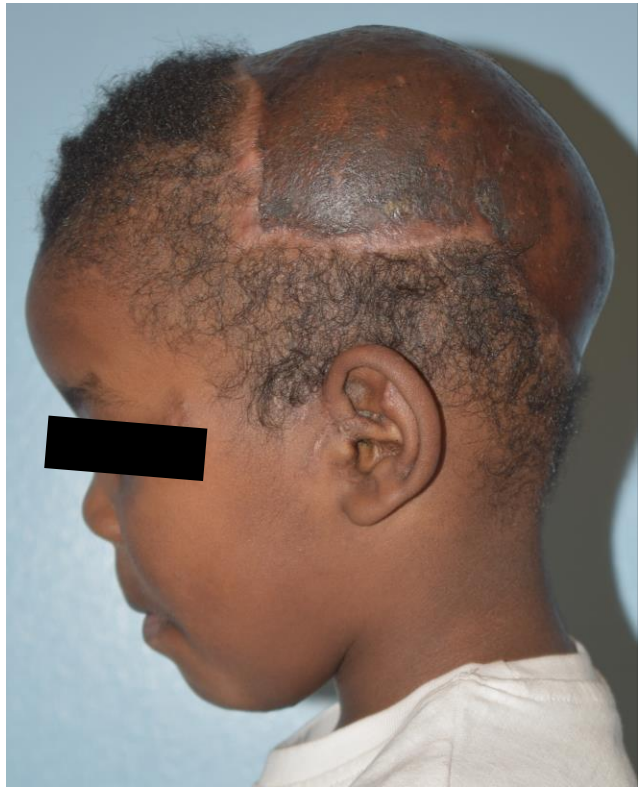
1-m

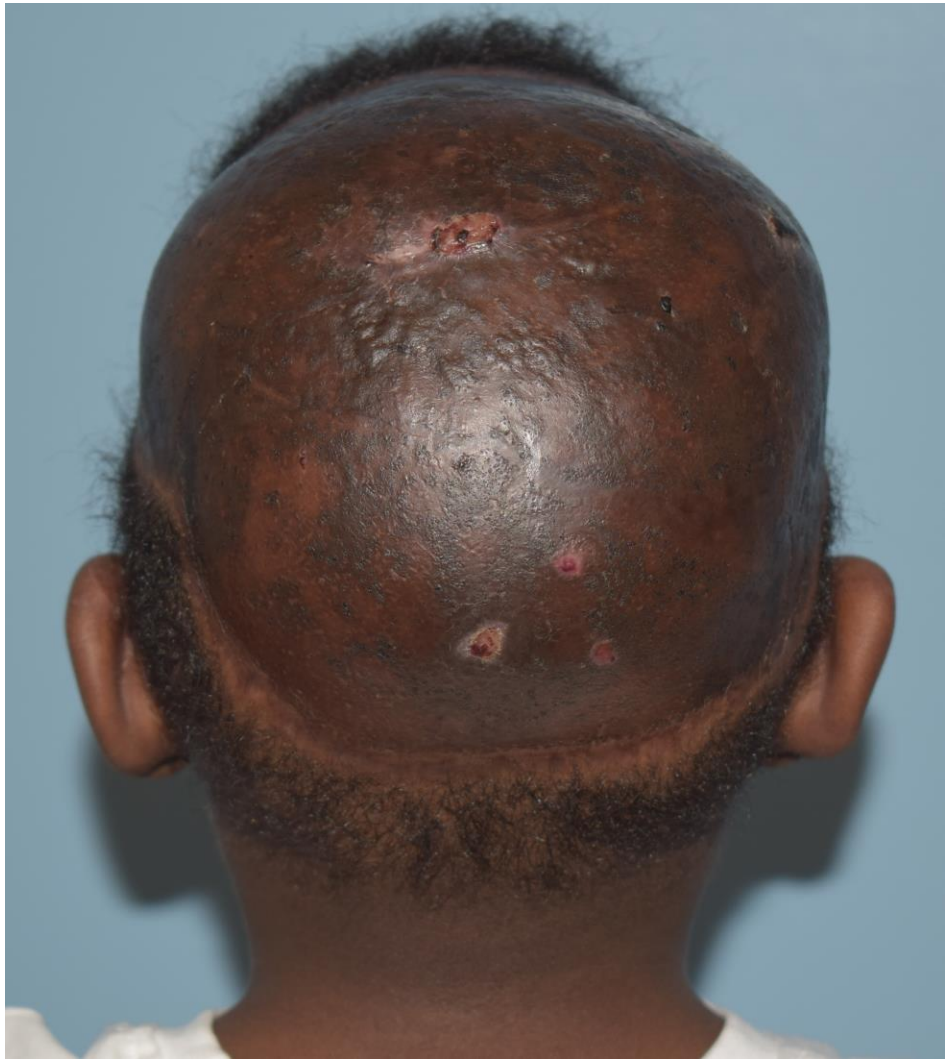
# d Small Joints

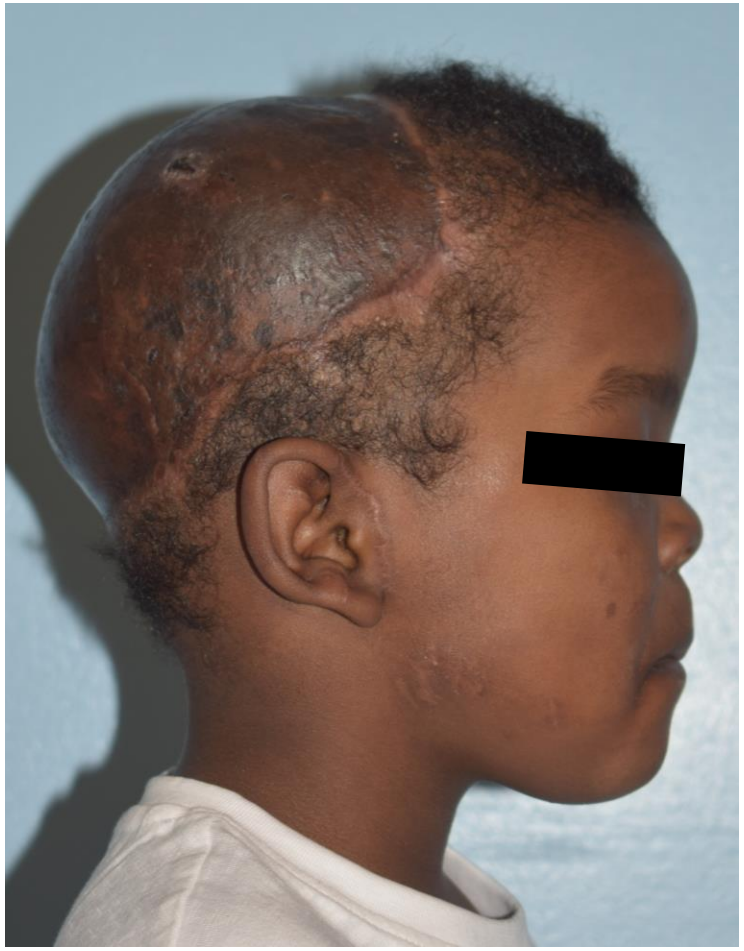


# Indication: Cover Bone, Tendon, and Small Joints

- 3 months post-skin graft

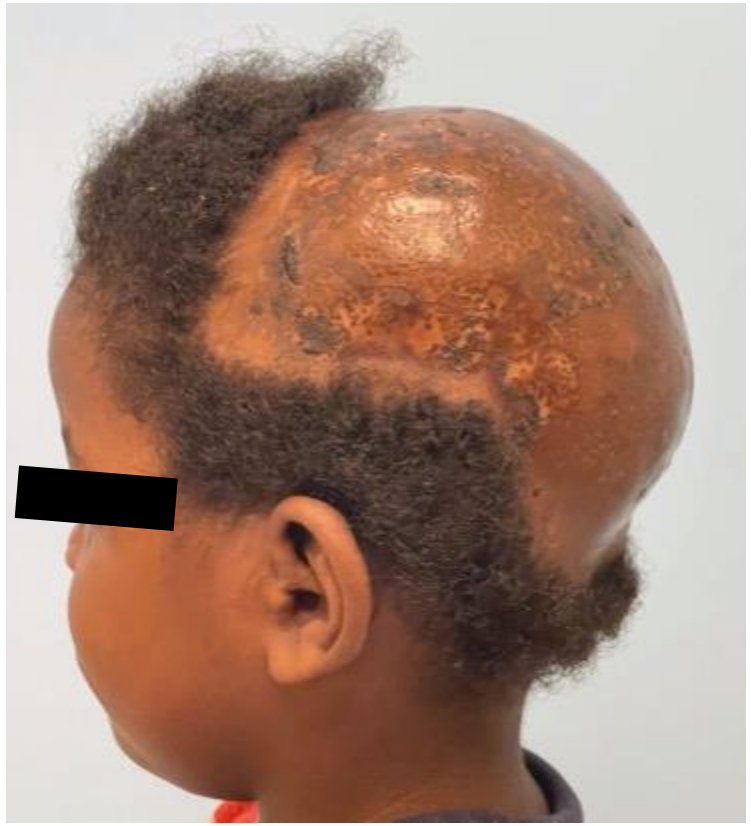


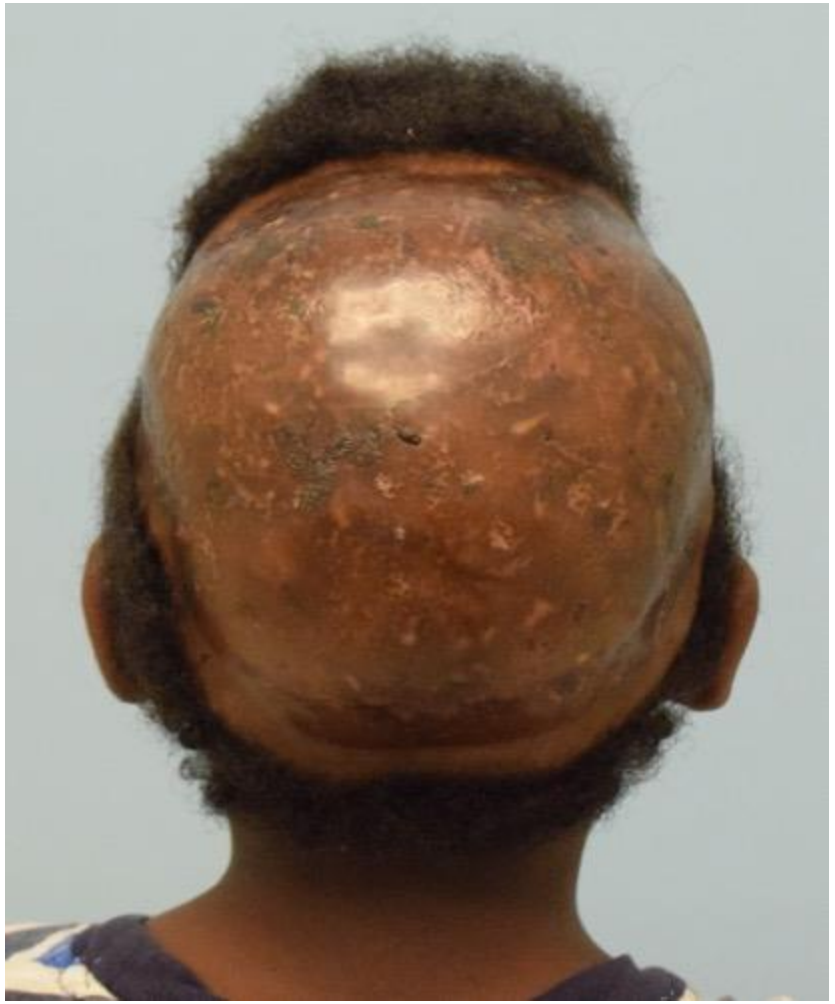


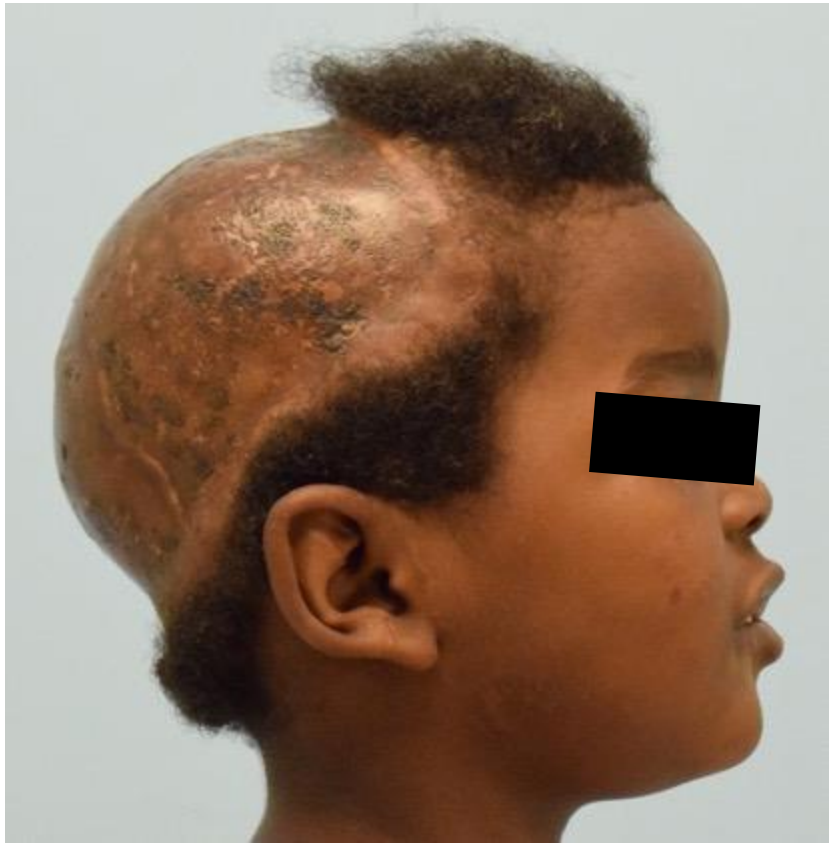


# Indication: Cover Bone, Tendon, and Small Joints

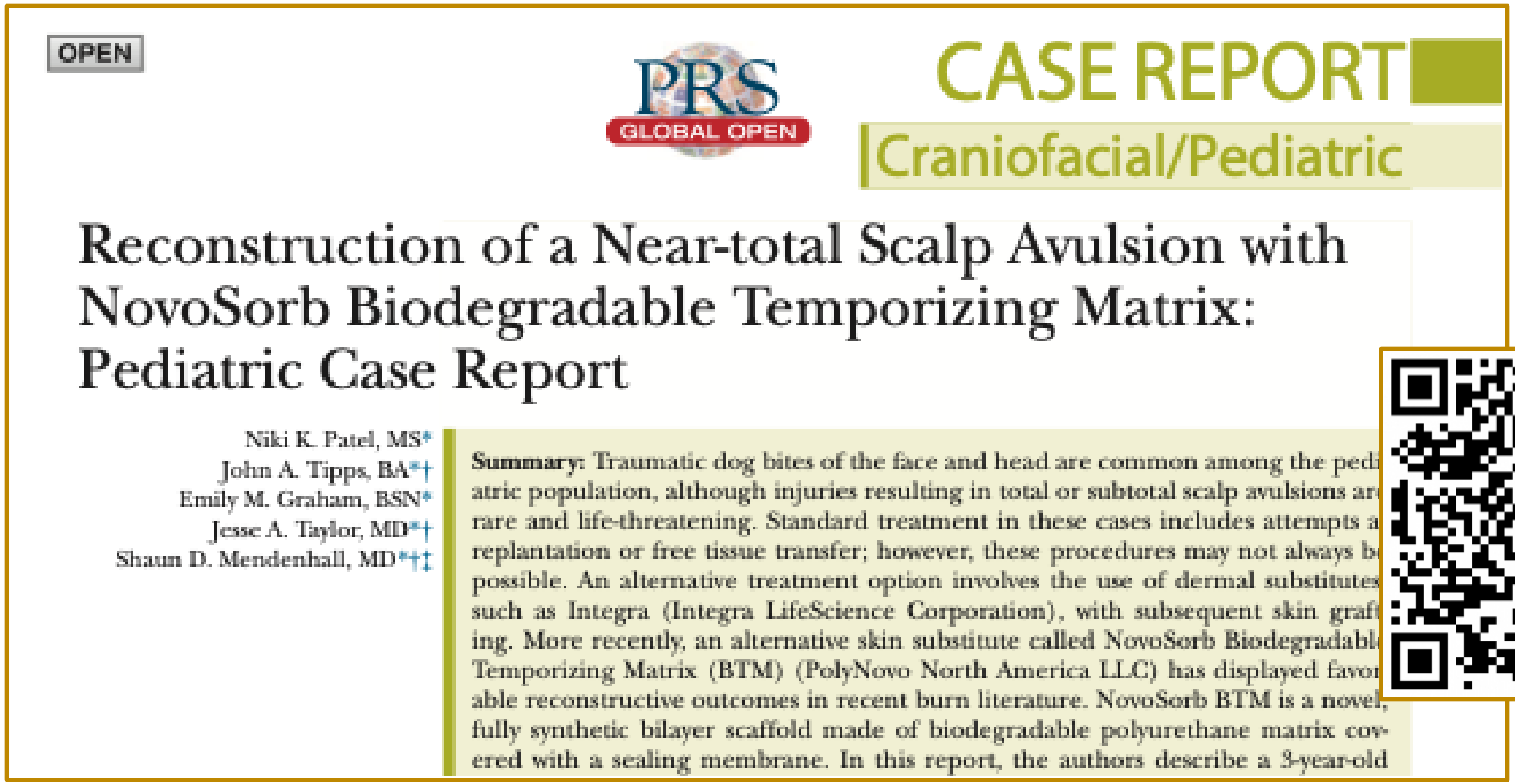
- 6 months post-op







# Indication: Cover Bone, Tendon, and Small Joints



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CASE REPORT

Craniofacial/Pediatric

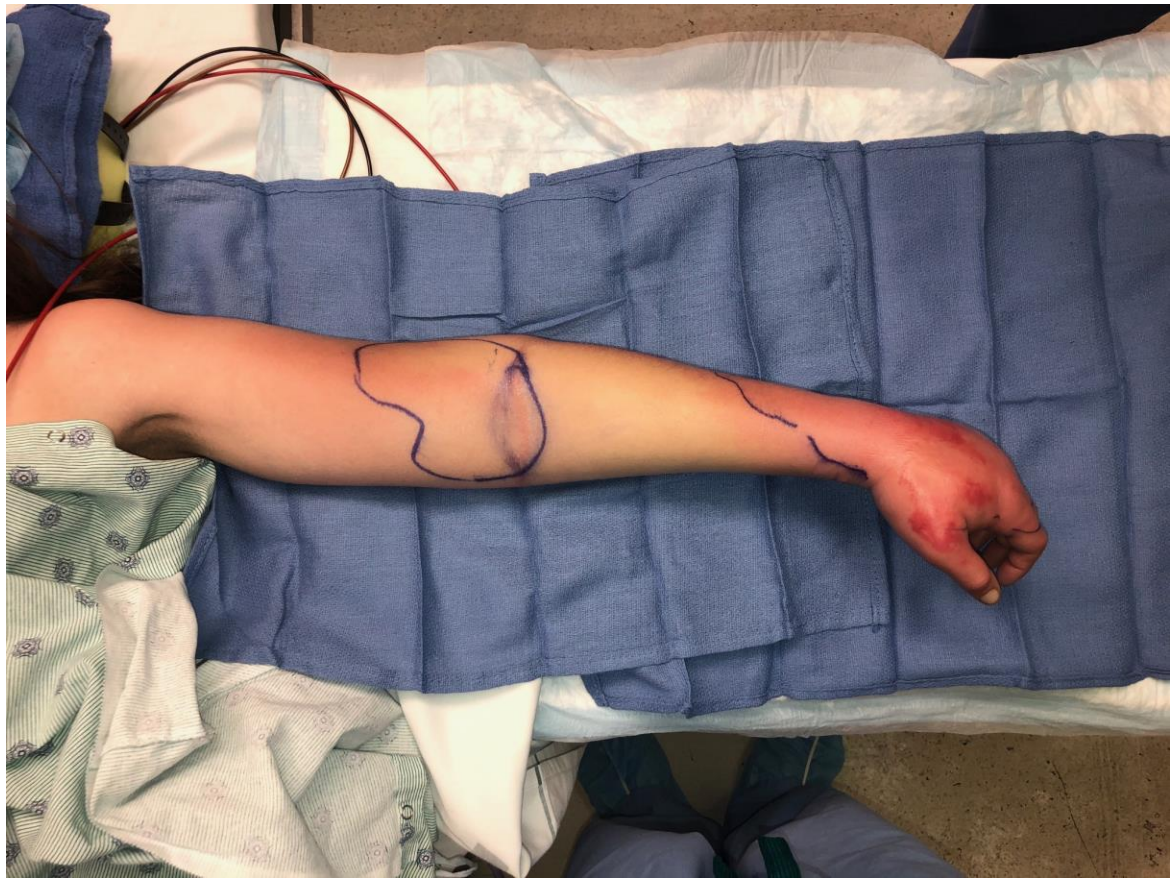
## Reconstruction of a Near-total Scalp Avulsion with NovoSorb Biodegradable Temporizing Matrix: Pediatric Case Report

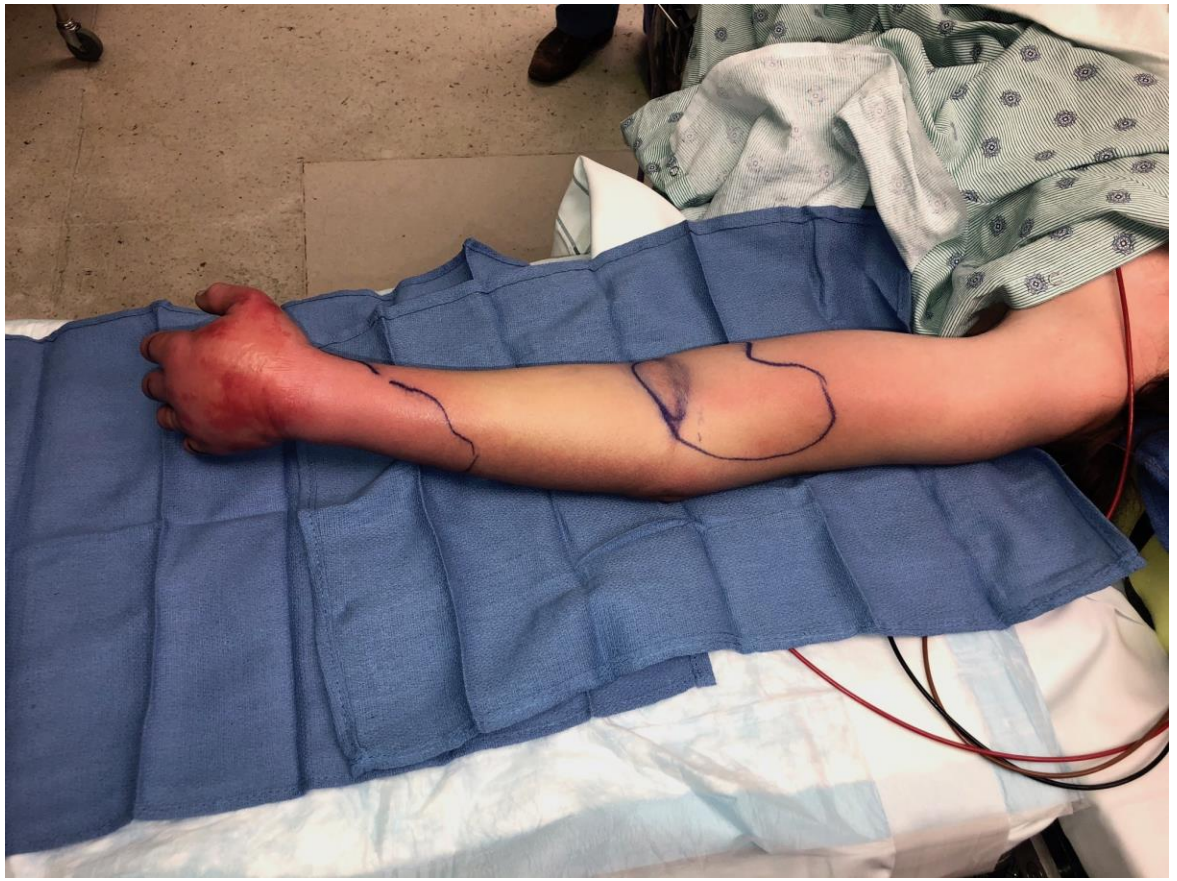
Niki K. Patel, MS*
John A. Tipps, BA*†
Emily M. Graham, BSN*
Jesse A. Taylor, MD*†
Shaun D. Mendenhall, MD*†‡

**Summary:** Traumatic dog bites of the face and head are common among the pedi atric population, although injuries resulting in total or subtotal scalp avulsions ar rare and life-threatening. Standard treatment in these cases includes attempts a replantation or free tissue transfer; however, these procedures may not always b possible. An alternative treatment option involves the use of dermal substitutes such as Integra (Integra LifeScience Corporation), with subsequent skin graf ing. More recently, an alternative skin substitute called NovoSorb Biodegradabl Temporizing Matrix (BTM) (PolyNovo North America LLC) has displayed favor able reconstructive outcomes in recent burn literature. NovoSorb BTM is a novel, fully synthetic bilayer scaffold made of biodegradable polyurethane matrix cov- ered with a sealing membrane. In this report, the authors describe a 3-year-old

Patel NK, et al. *Plast Reconstr Surg Glob Open*. 2022;10(12):e4717.

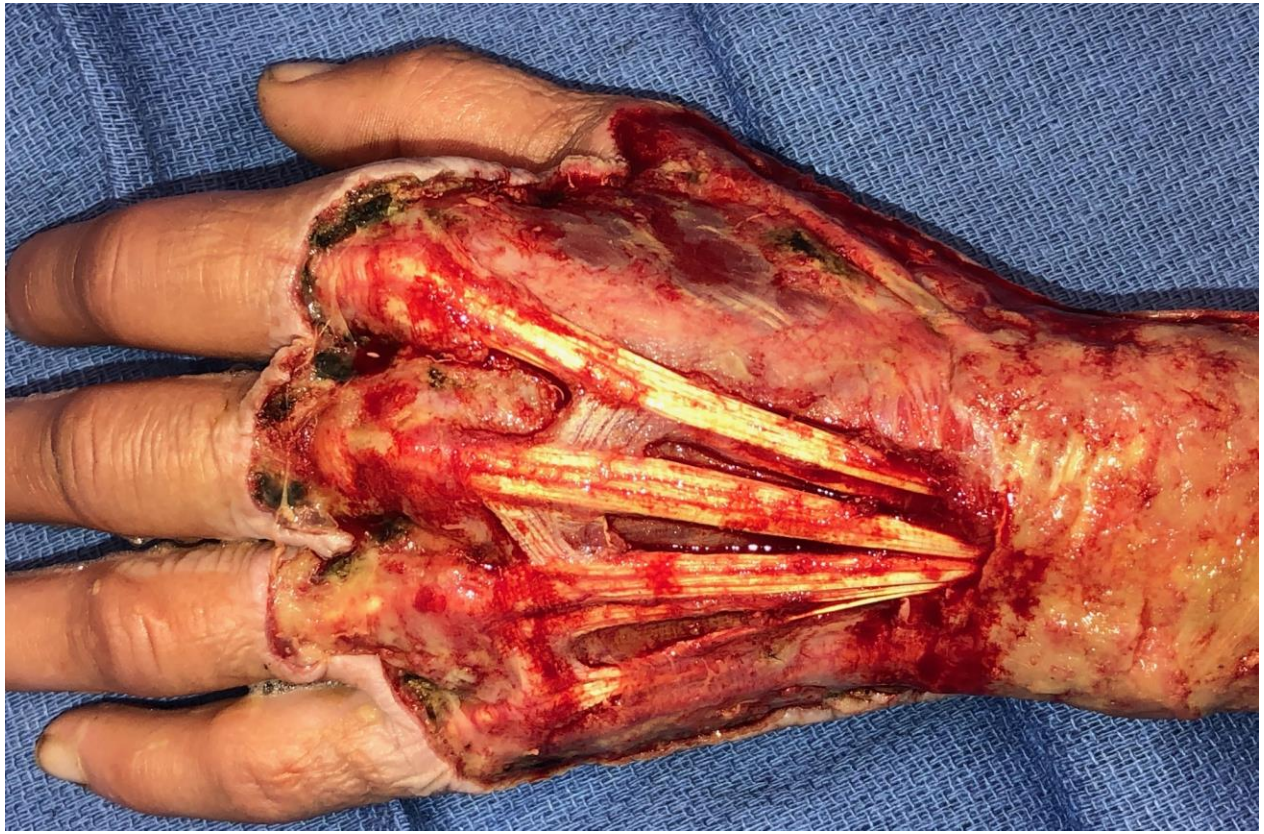
# Indication: Cover Bone, Tendon, and Small Joints

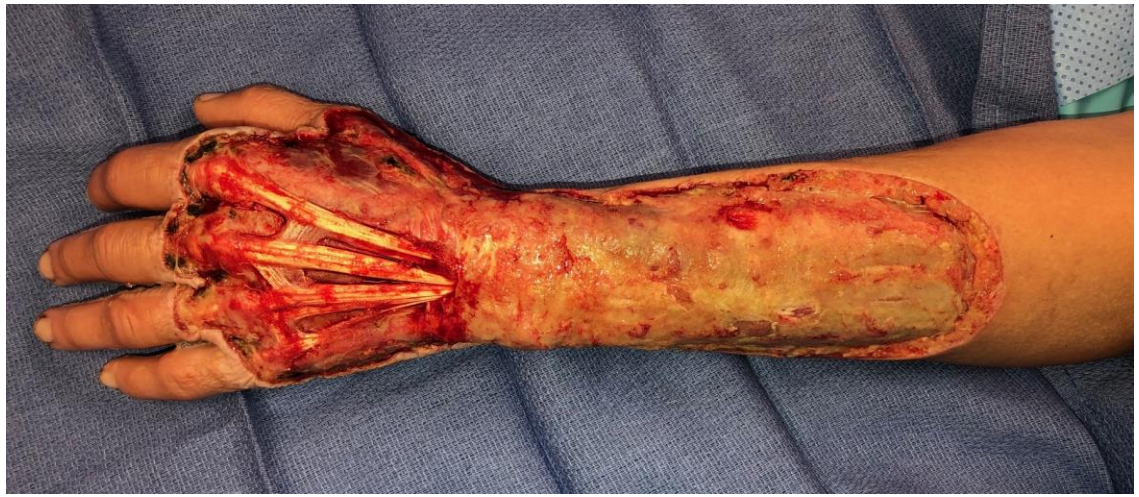




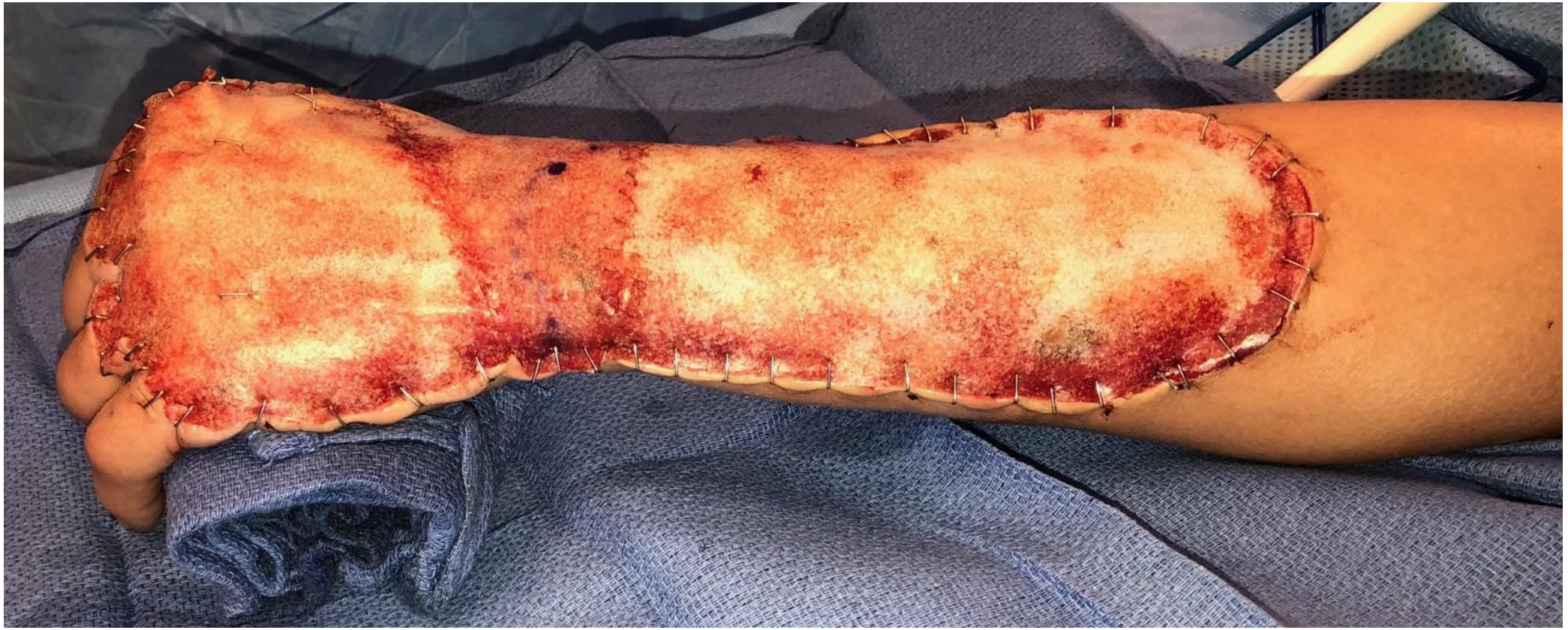
31-year-old female IV drug necrotizing fasciitis

# Indication: Cover Bone, Tendon, and Small Joints

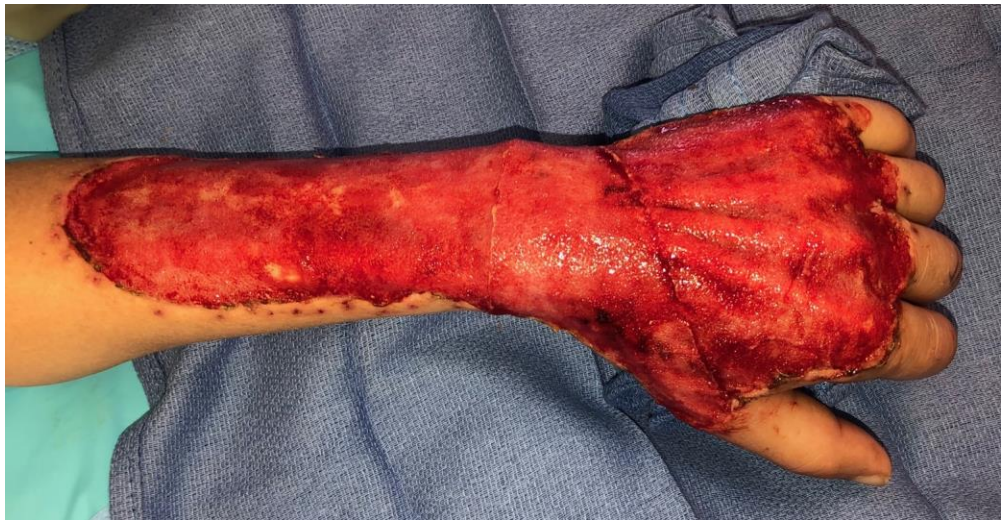


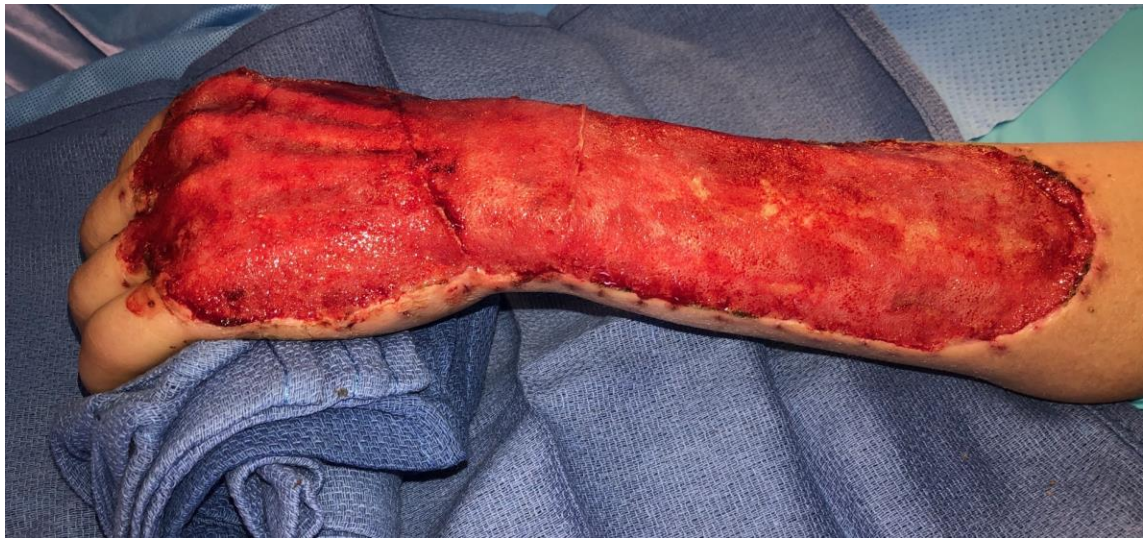


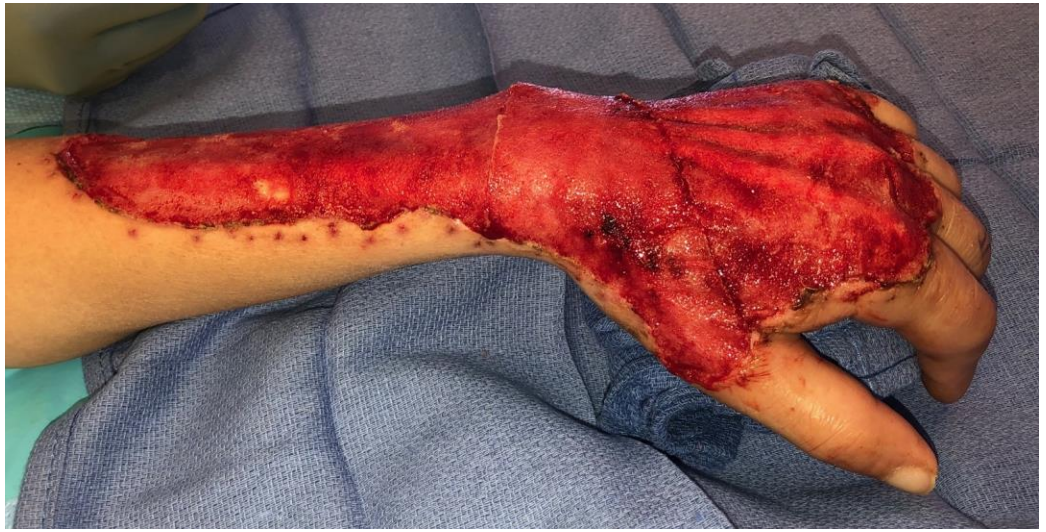
# Indication: Cover Bone, Tendon, and Small Joints



# Indication: Cover Bone, Tendon, and Small Joints

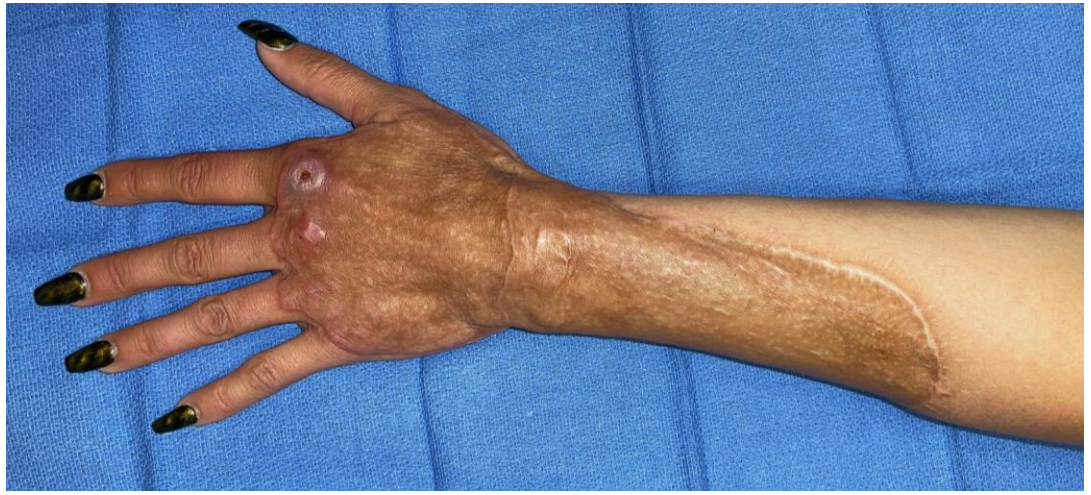


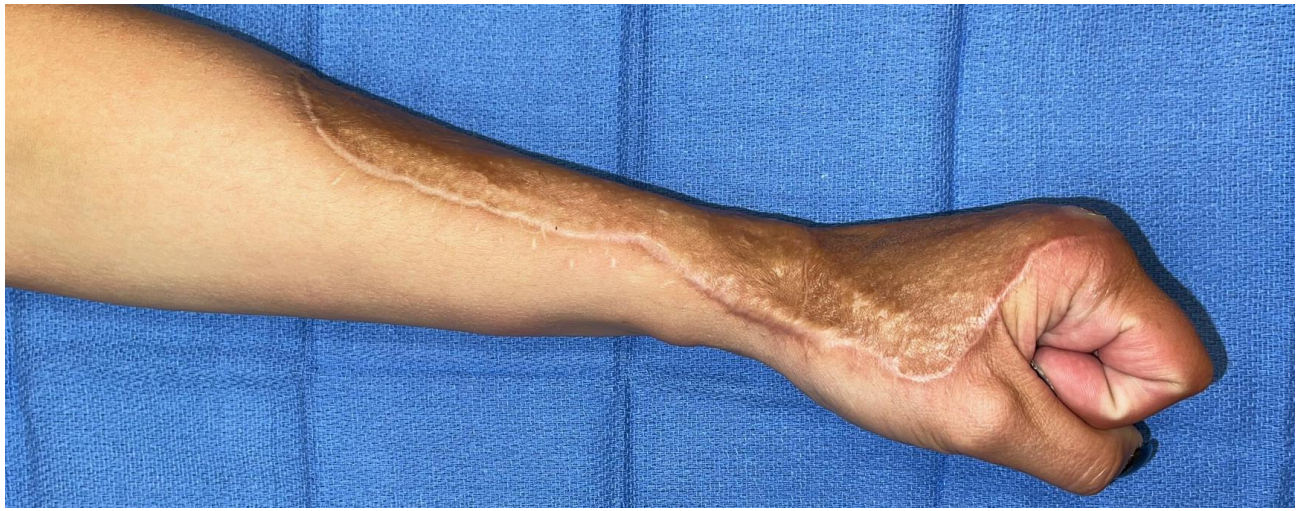


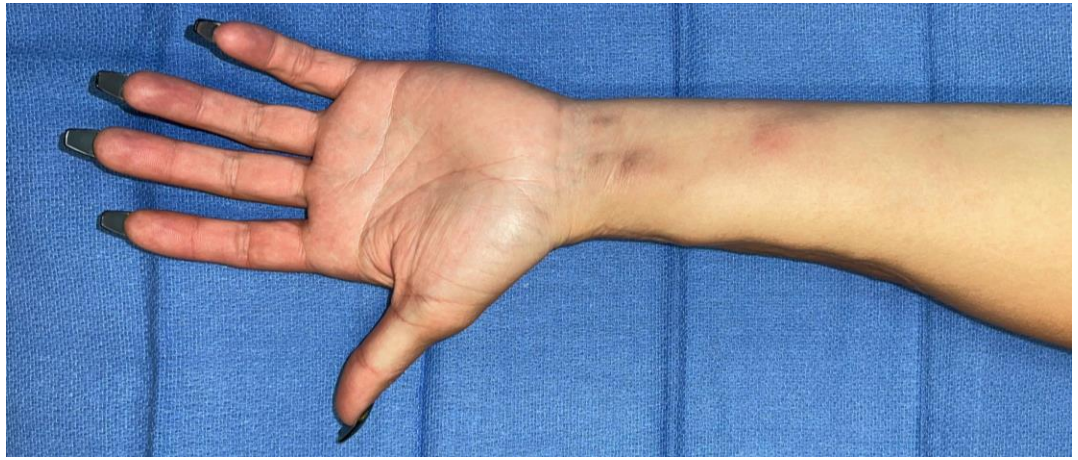


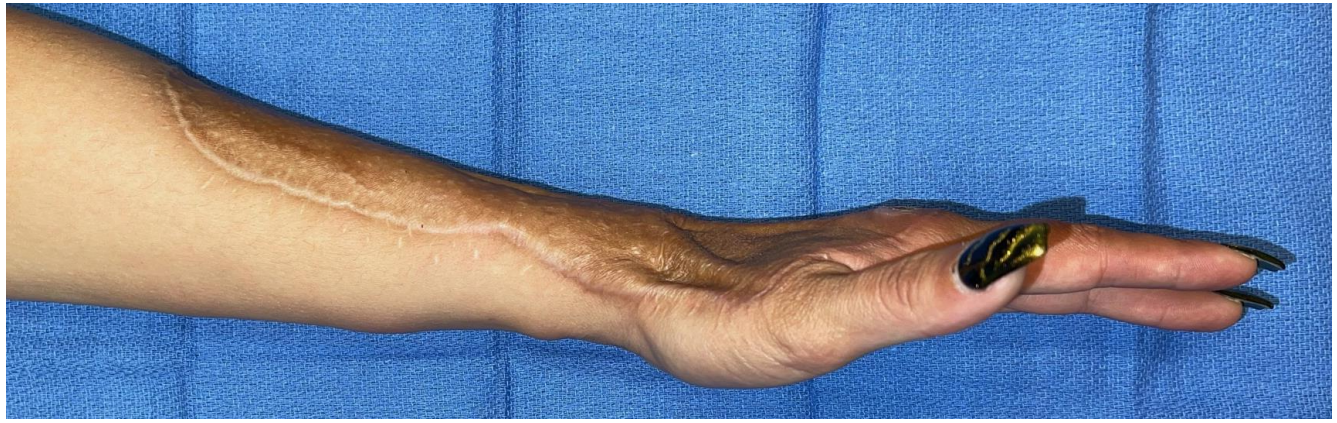
# Indication: Cover Bone, Tendon, and Small Joints

- 16 months s/p skin grafting

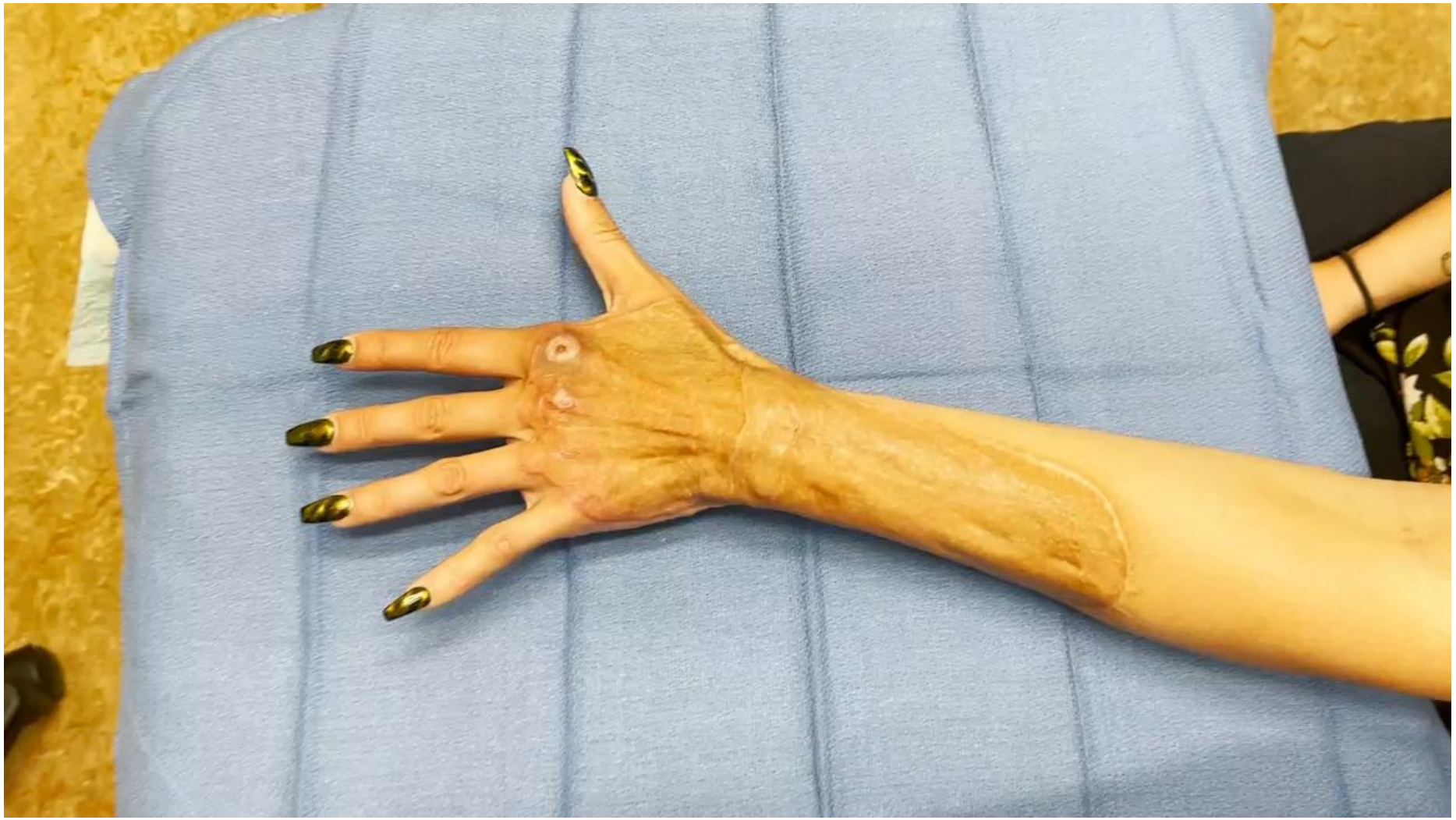






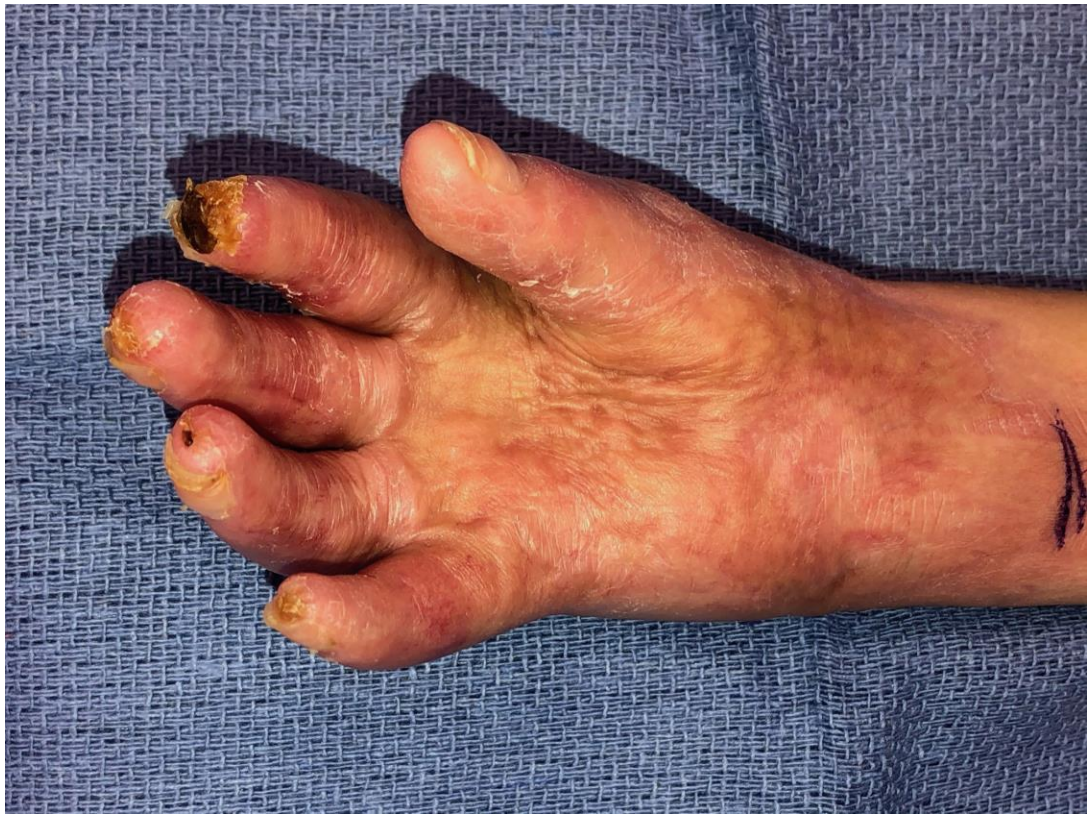


# 16 Months Post-Skin Graft

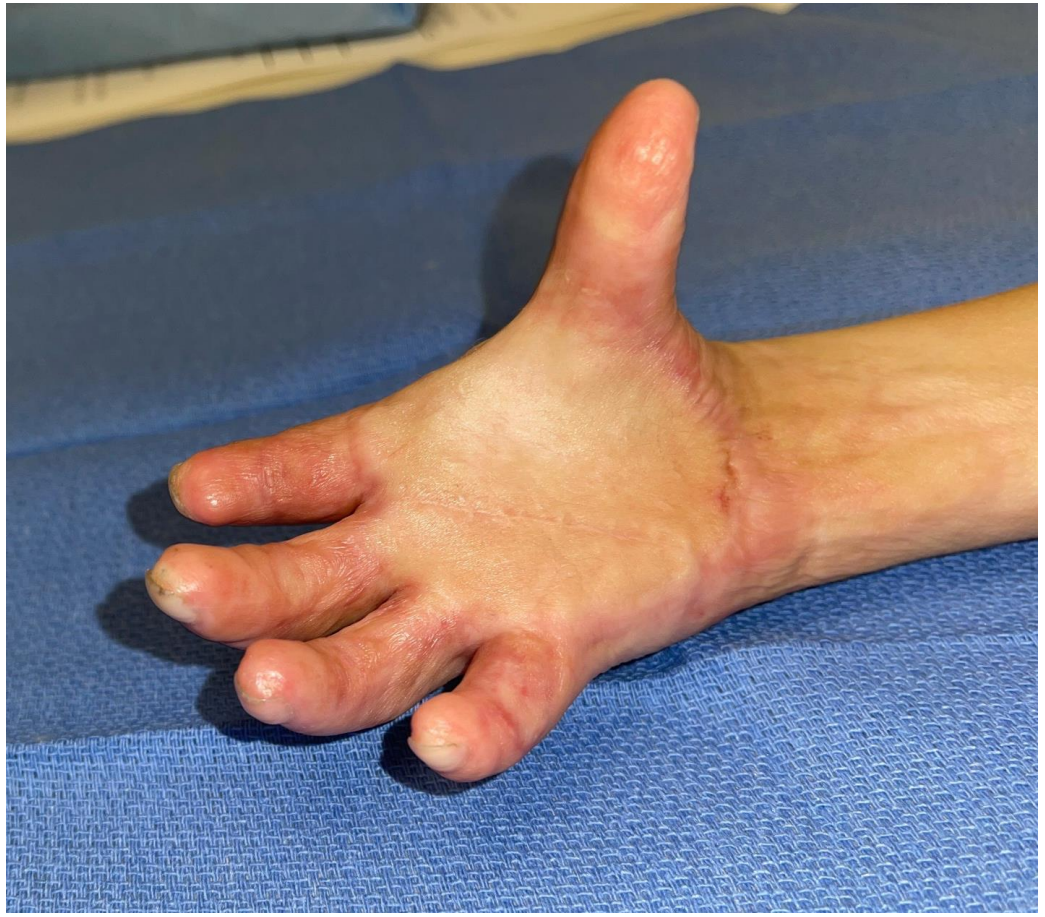


# Indication: Scar Contracture Release (Resurfacing)

- 3-year-old with palm scar contracture

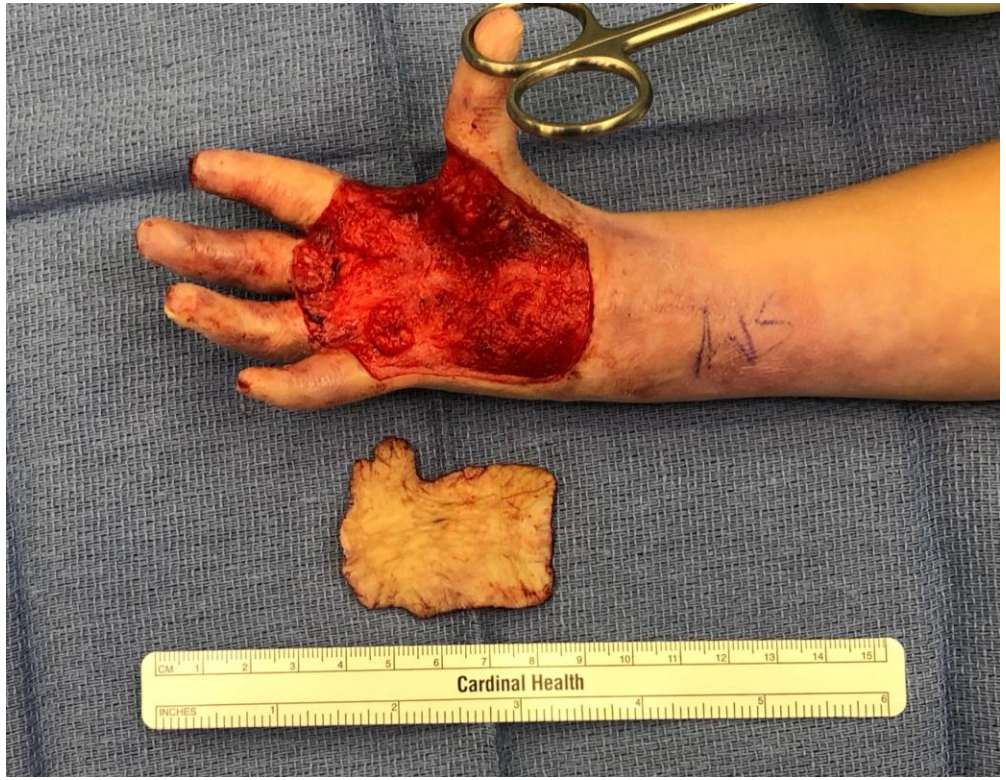


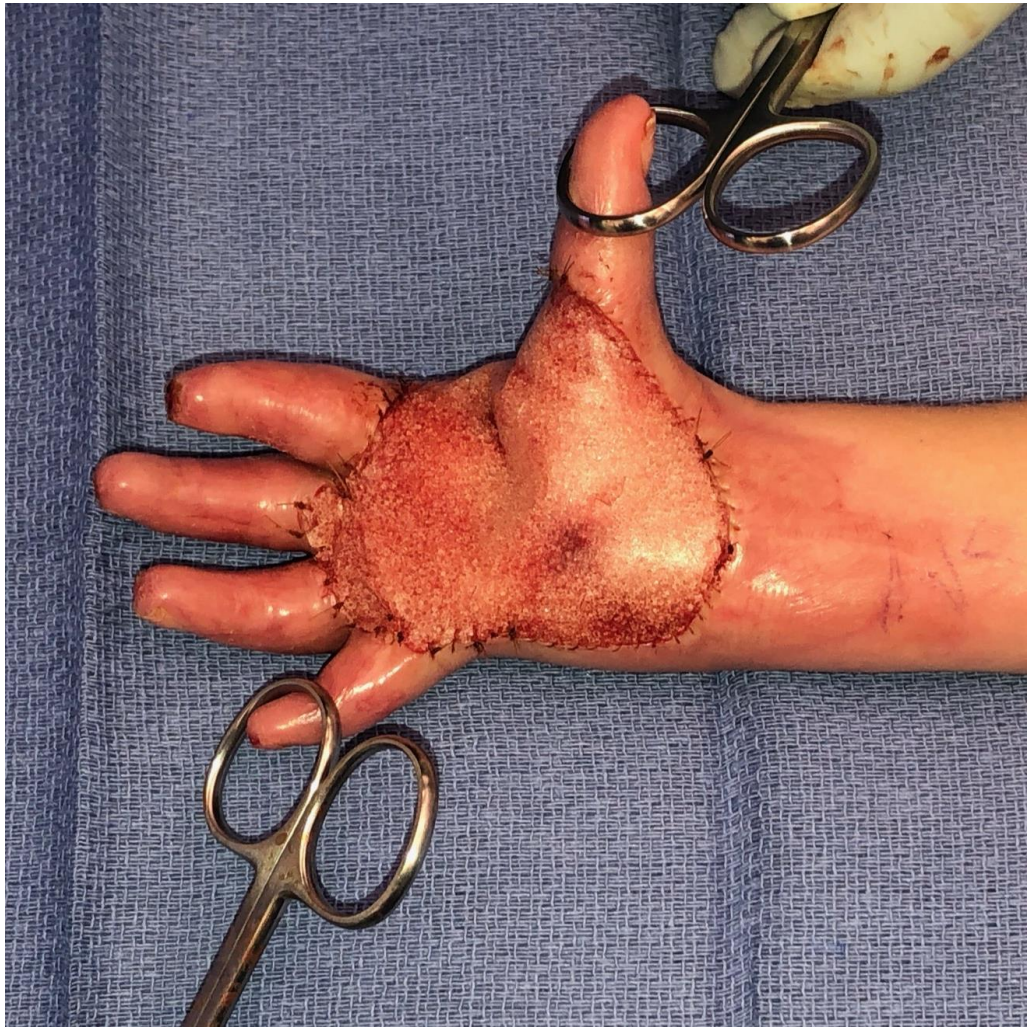
BTM



# Indication: Scar Contracture Release (Resurfacing)

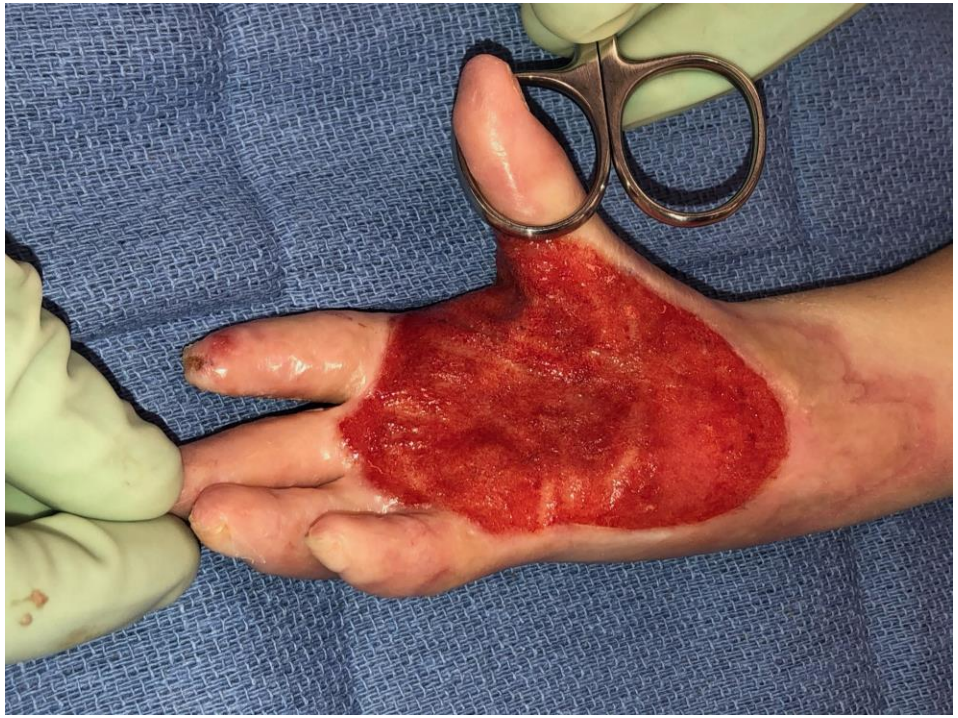
- 3-year-old with palm scar contracture

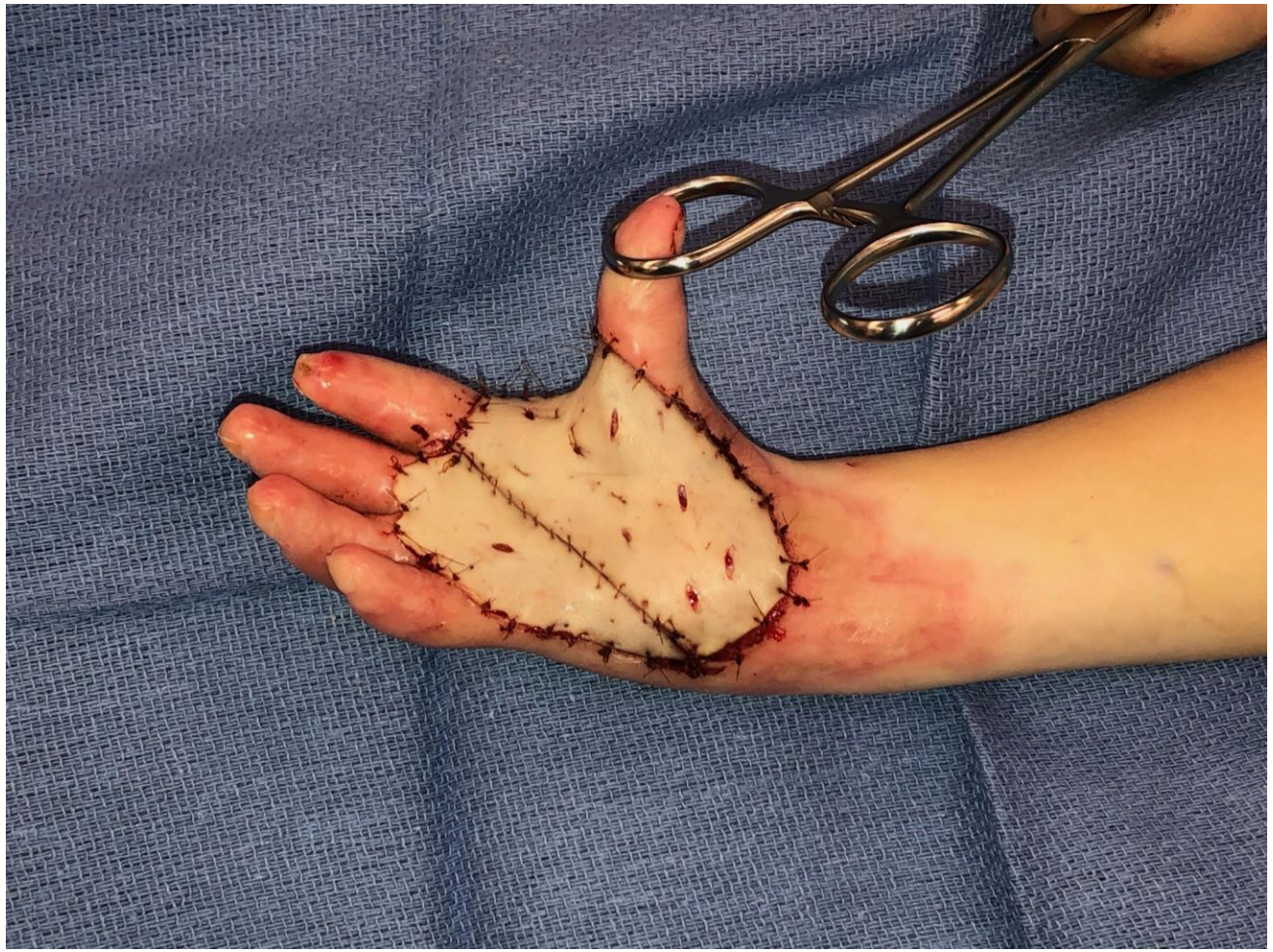


# Indication: Scar Contracture Release (Resurfacing)

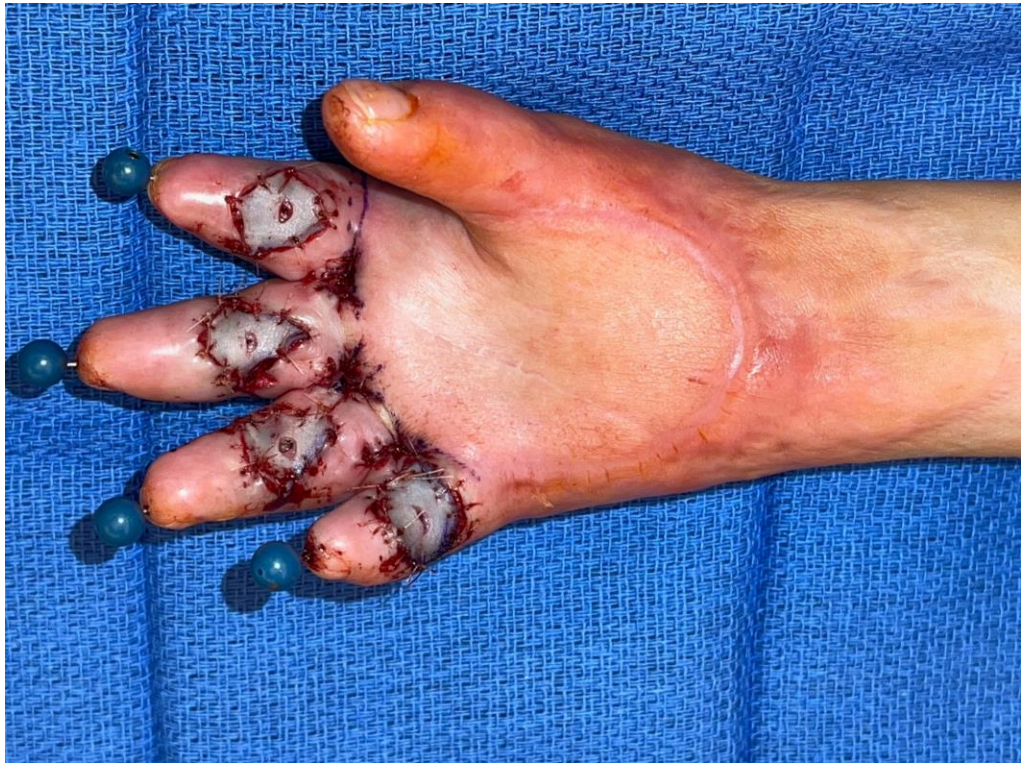
- 3-year-old with palm scar contracture



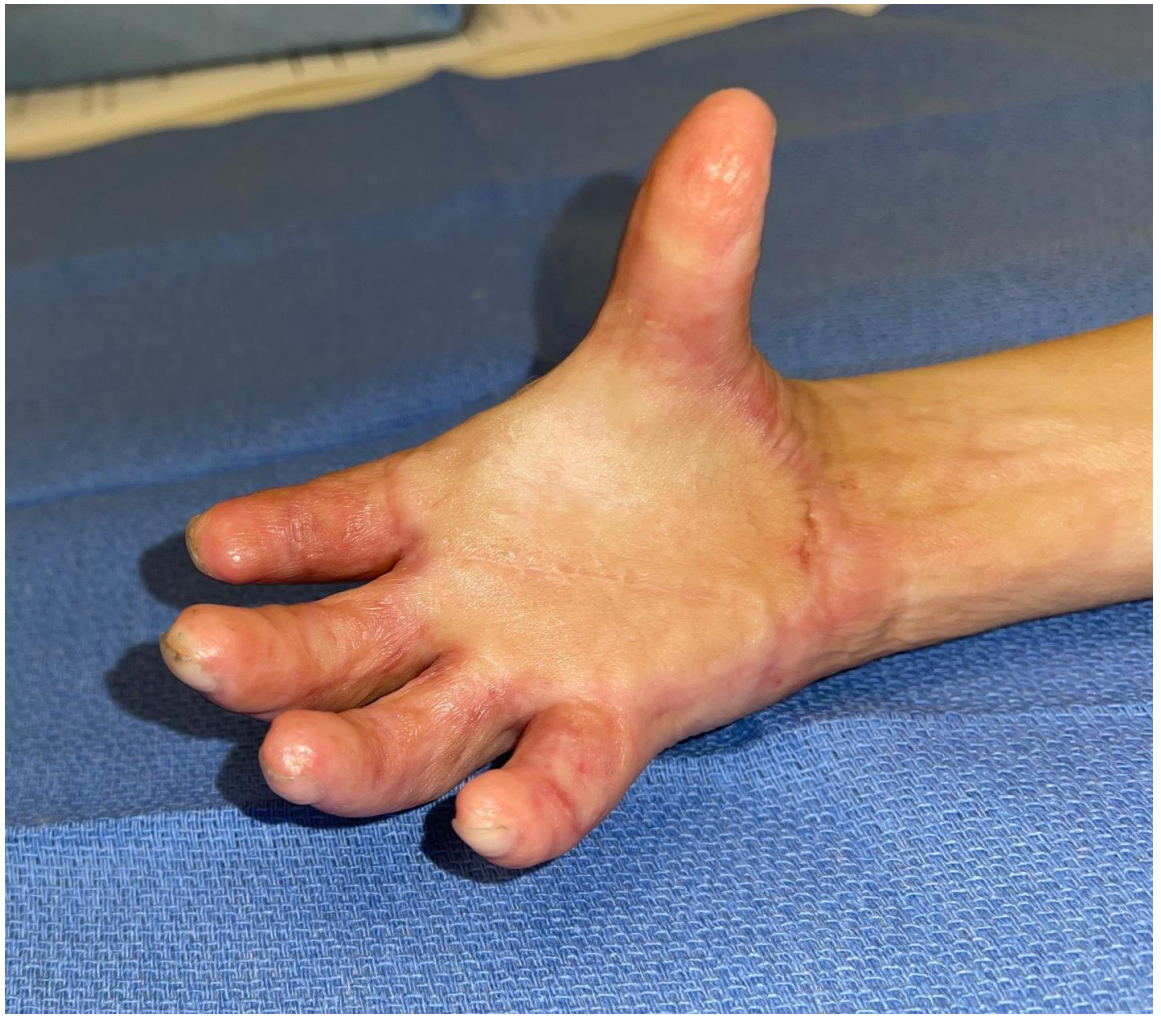


# Indication: Scar Contracture Release (Resurfacing)

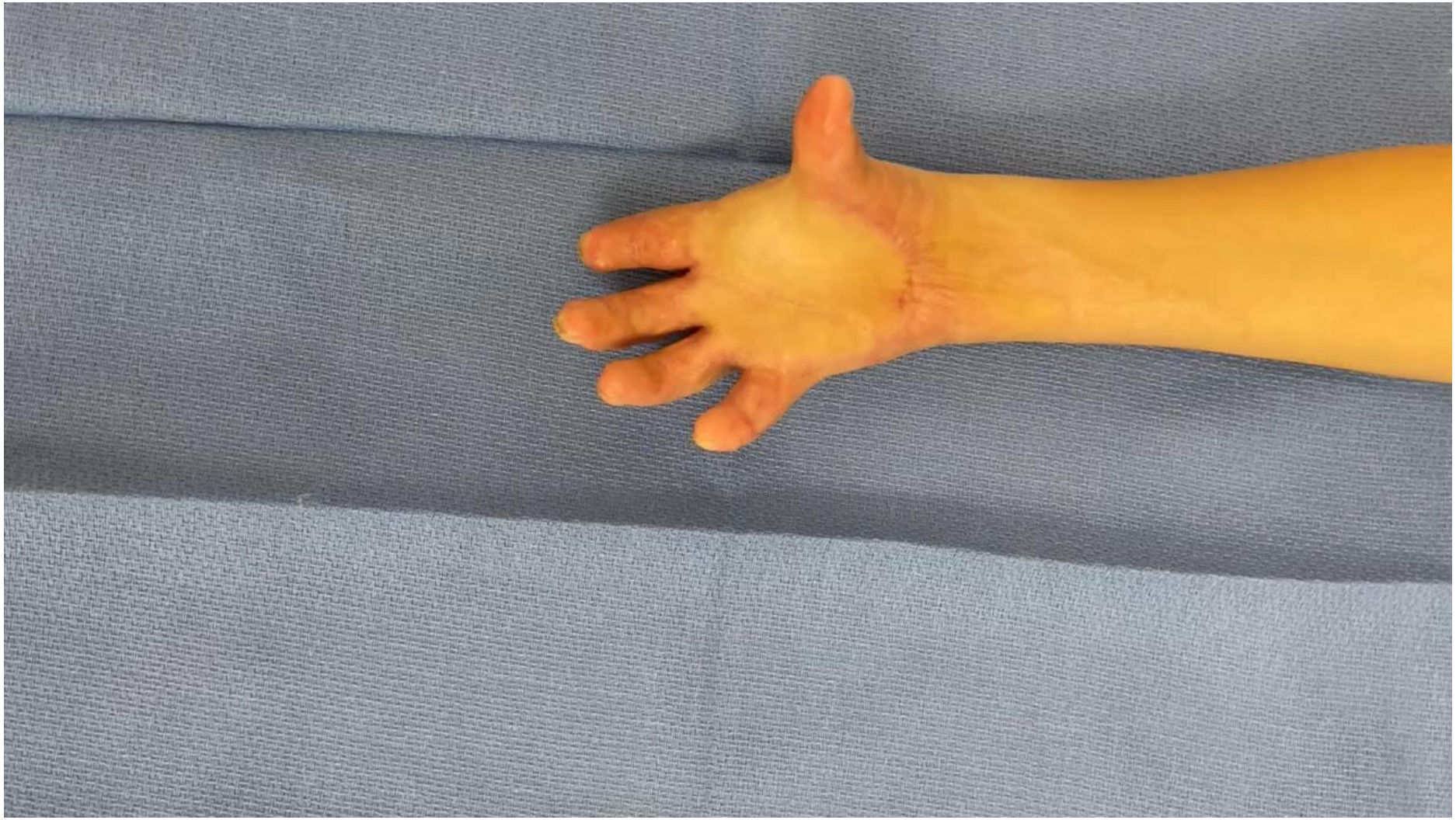
- 3-year-old with palm scar contracture



Second stage for finger releases

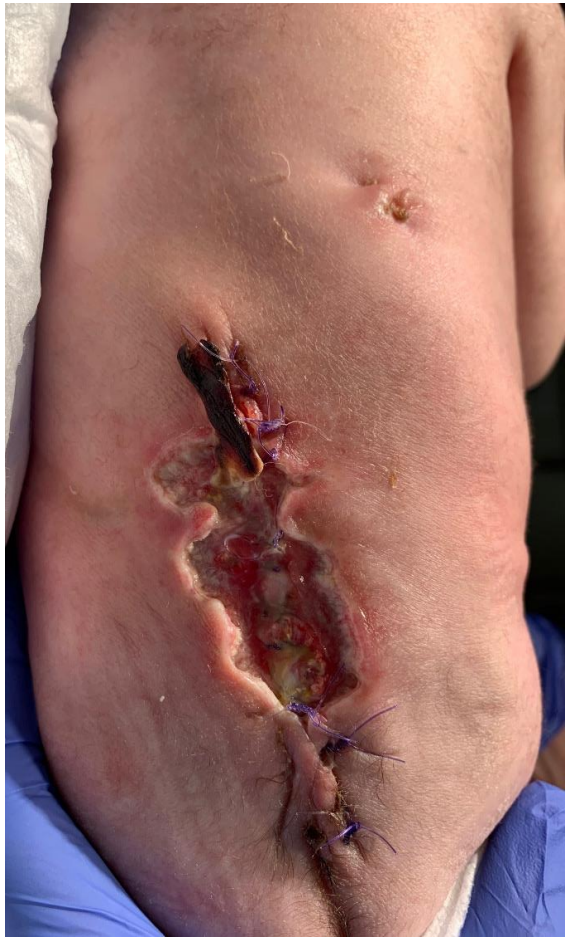
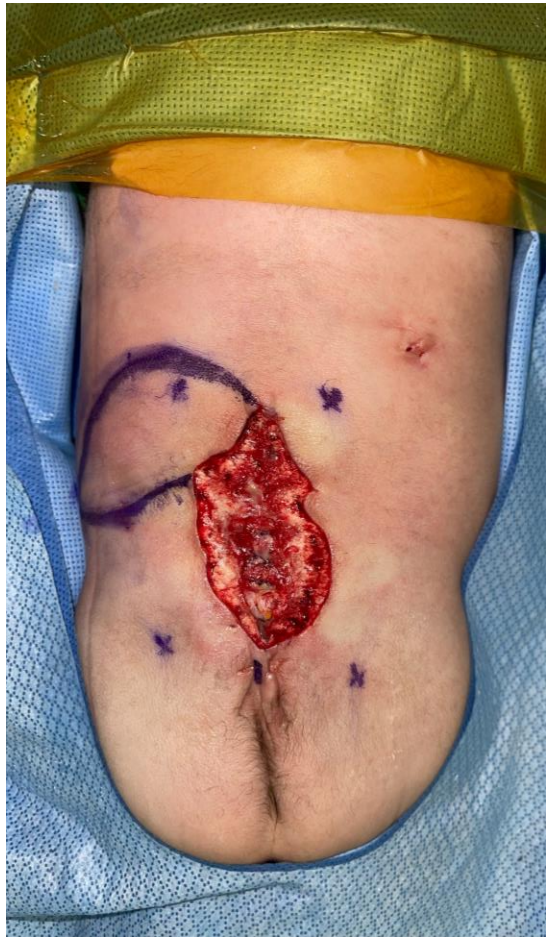
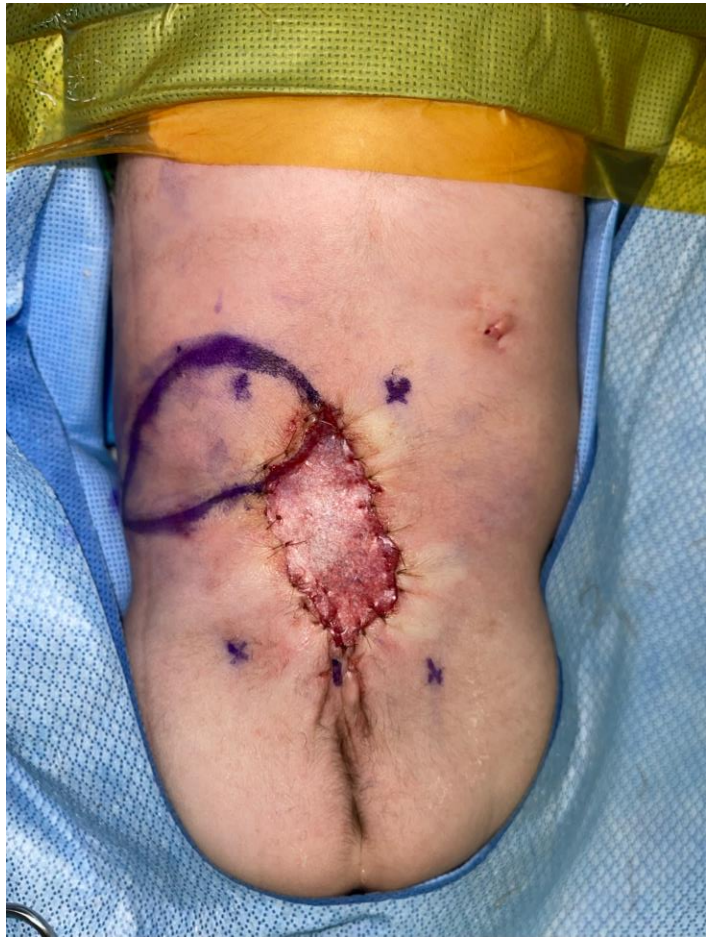
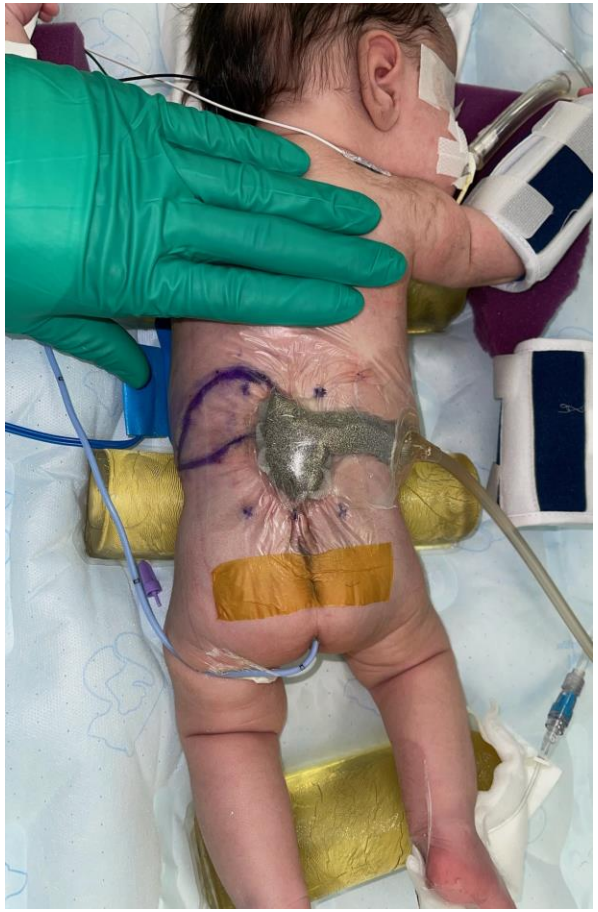


# Indication: Scar Contracture Release (Resurfacing)

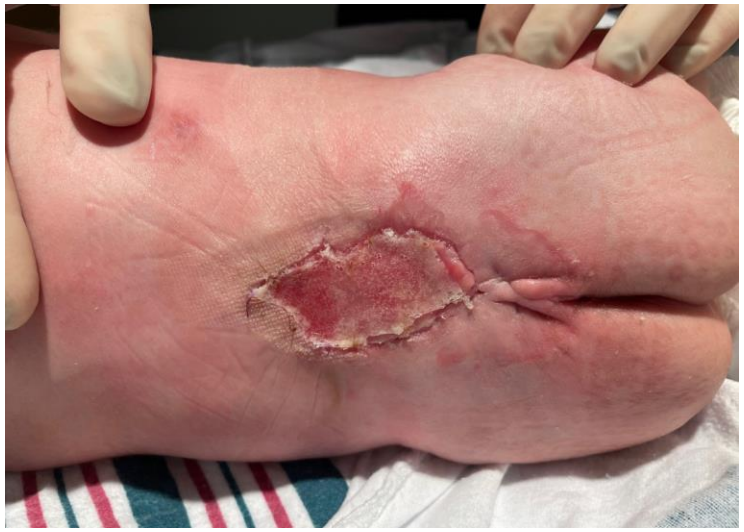


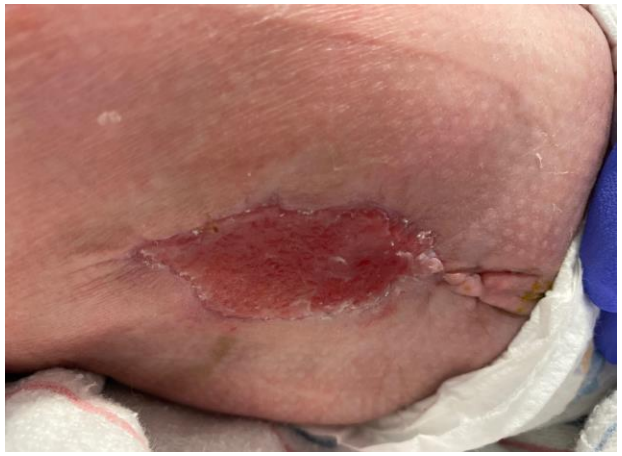
# Bails Me Out of Tough Situations

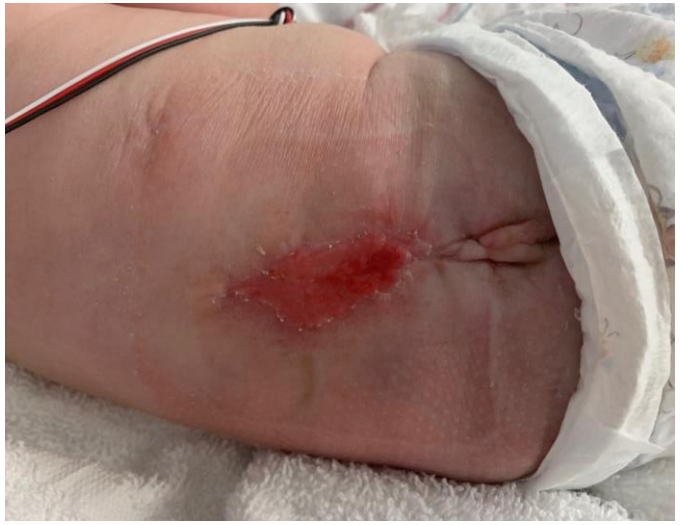
- 21-day-old with skin breakdown after spina bifida closure

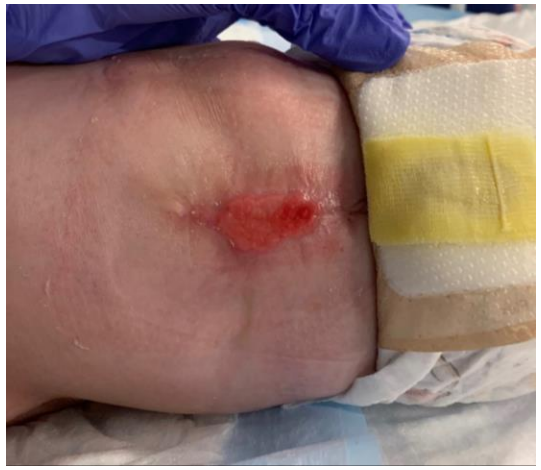





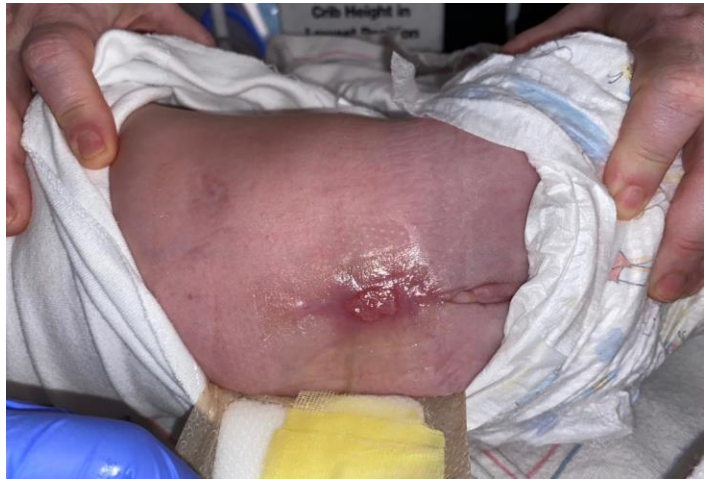
# Bails Me Out of Tough Situations

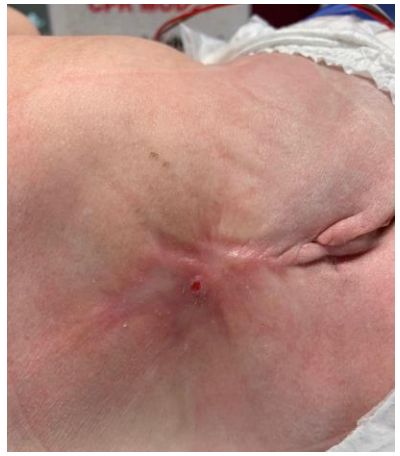


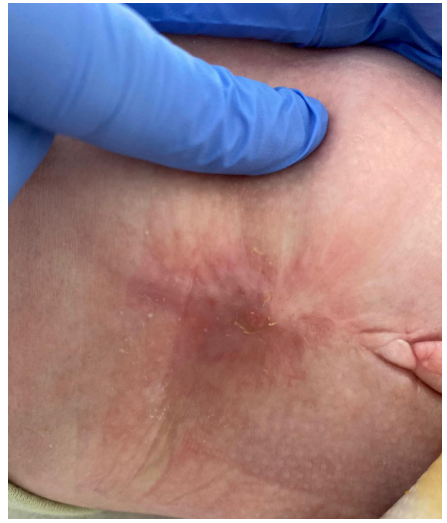




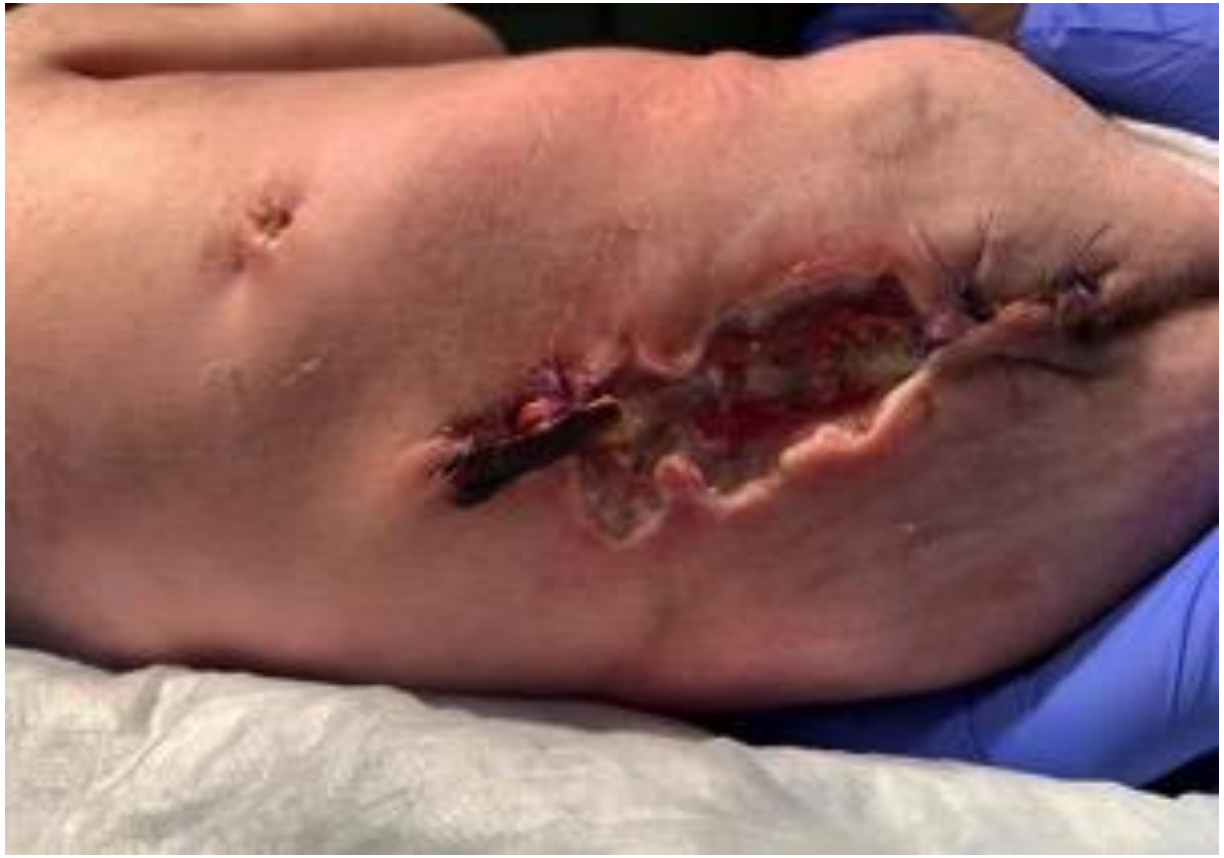


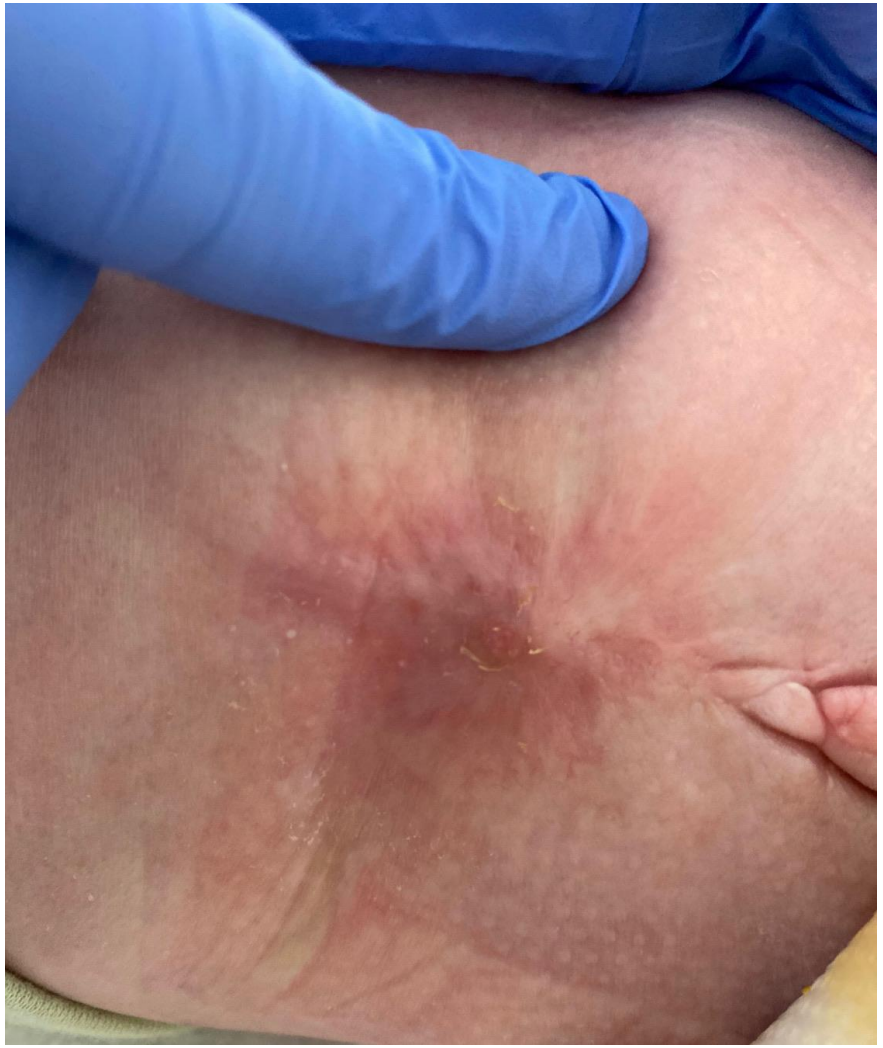






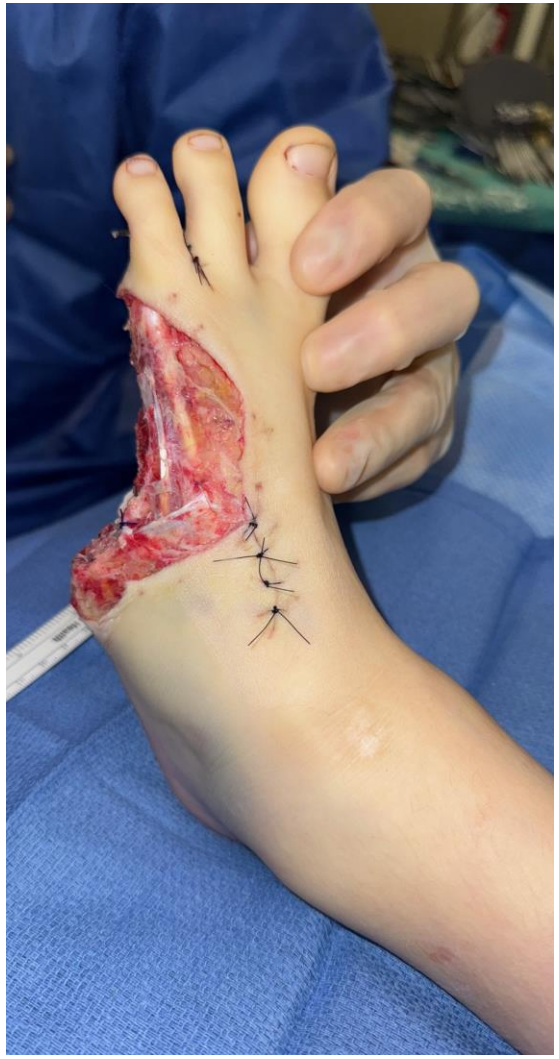
# Bails Me Out of Tough Situations

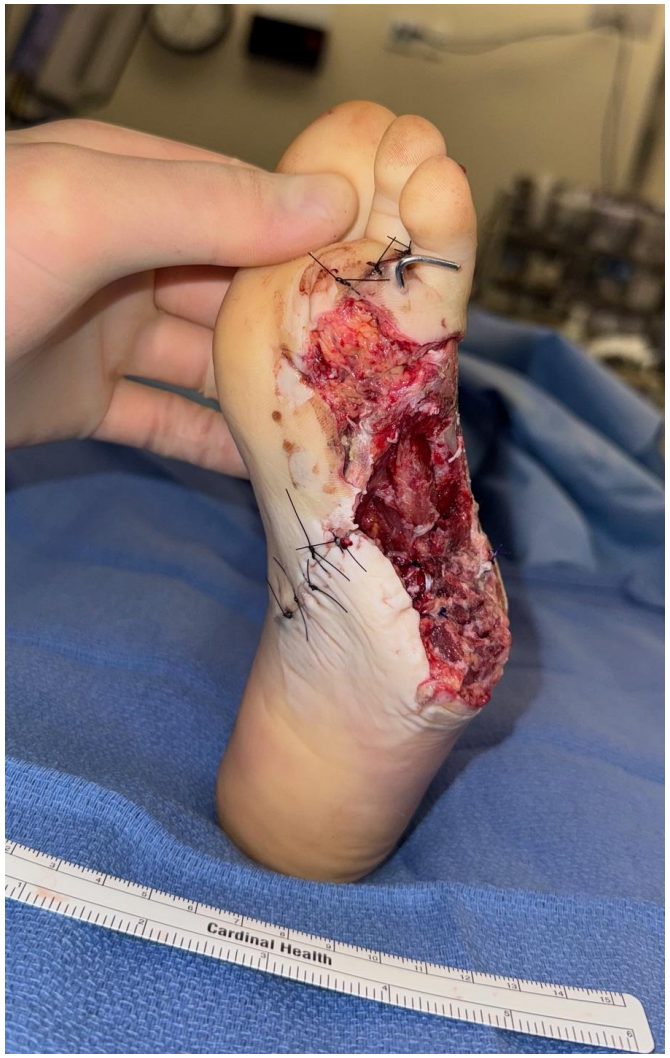


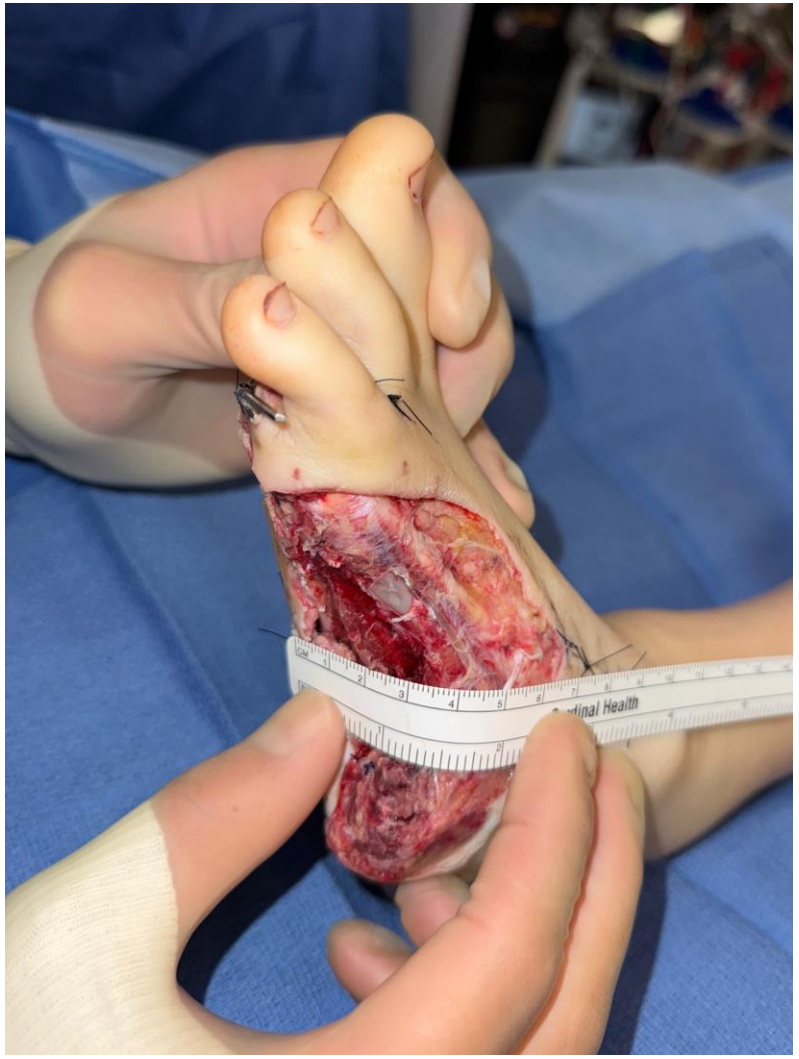


# MTX Case: Indication – Fill Deep Holes and Defects

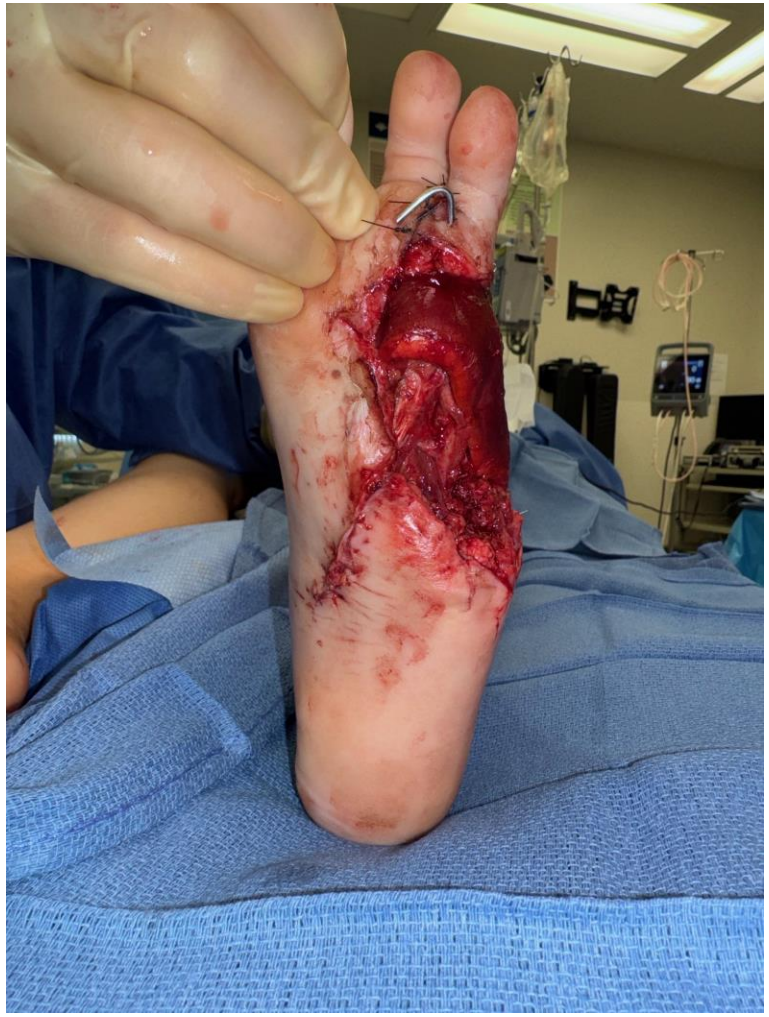
- 10-year-old, firework injury

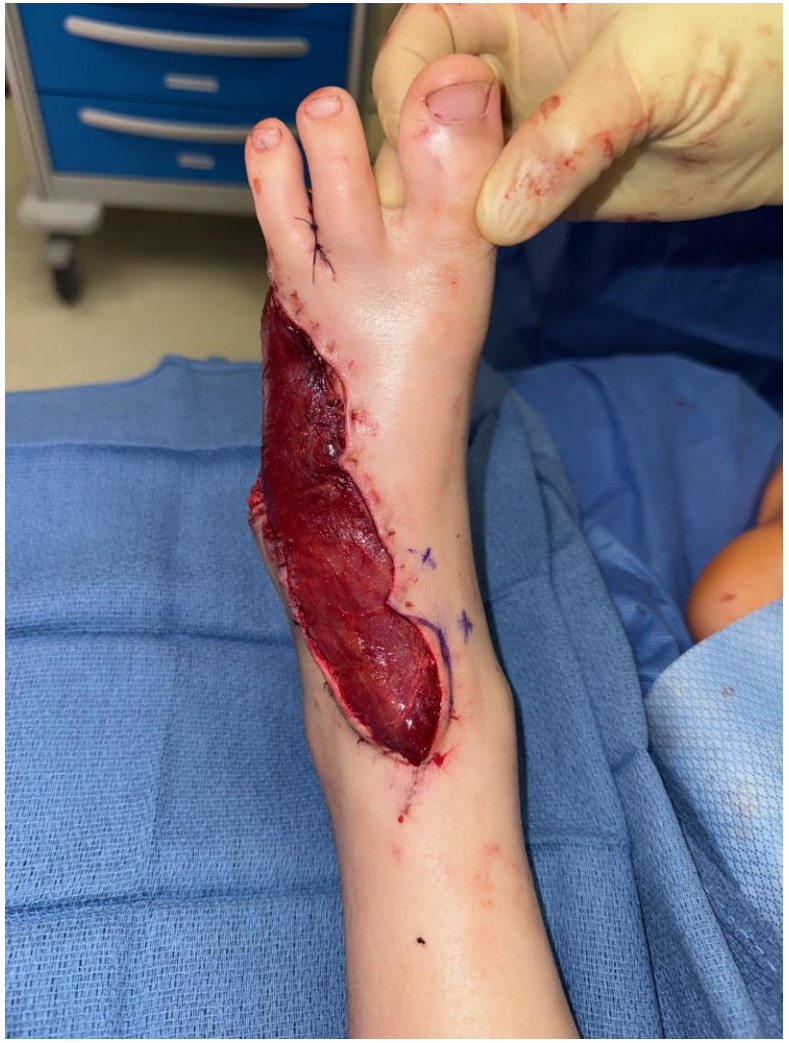


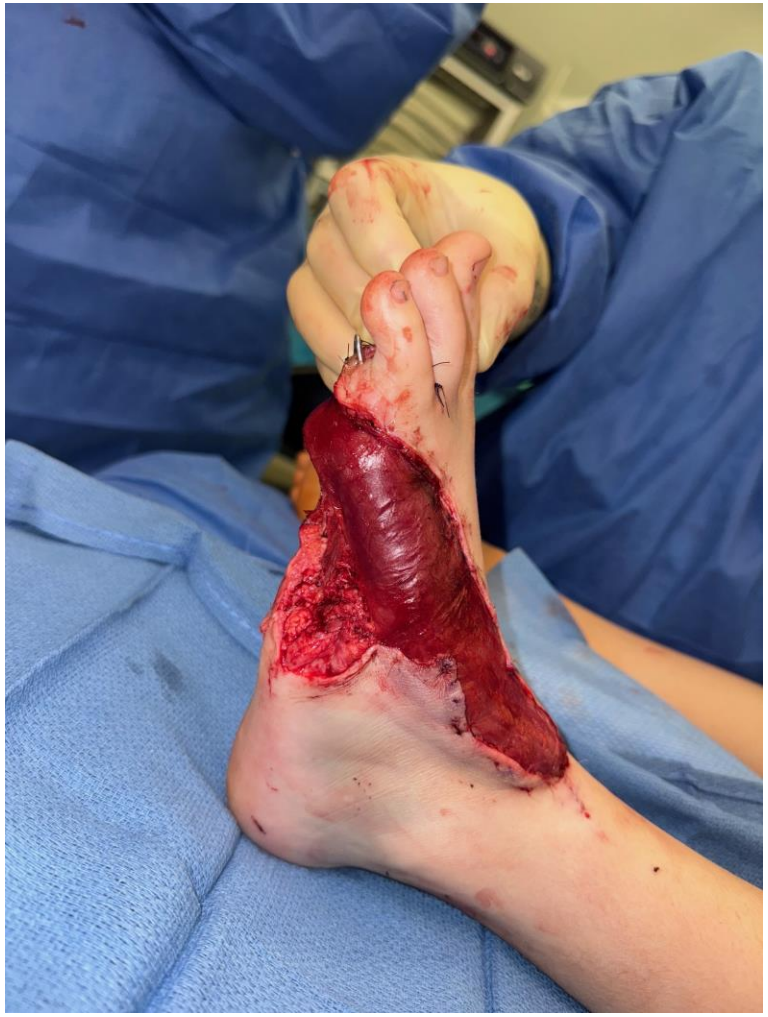


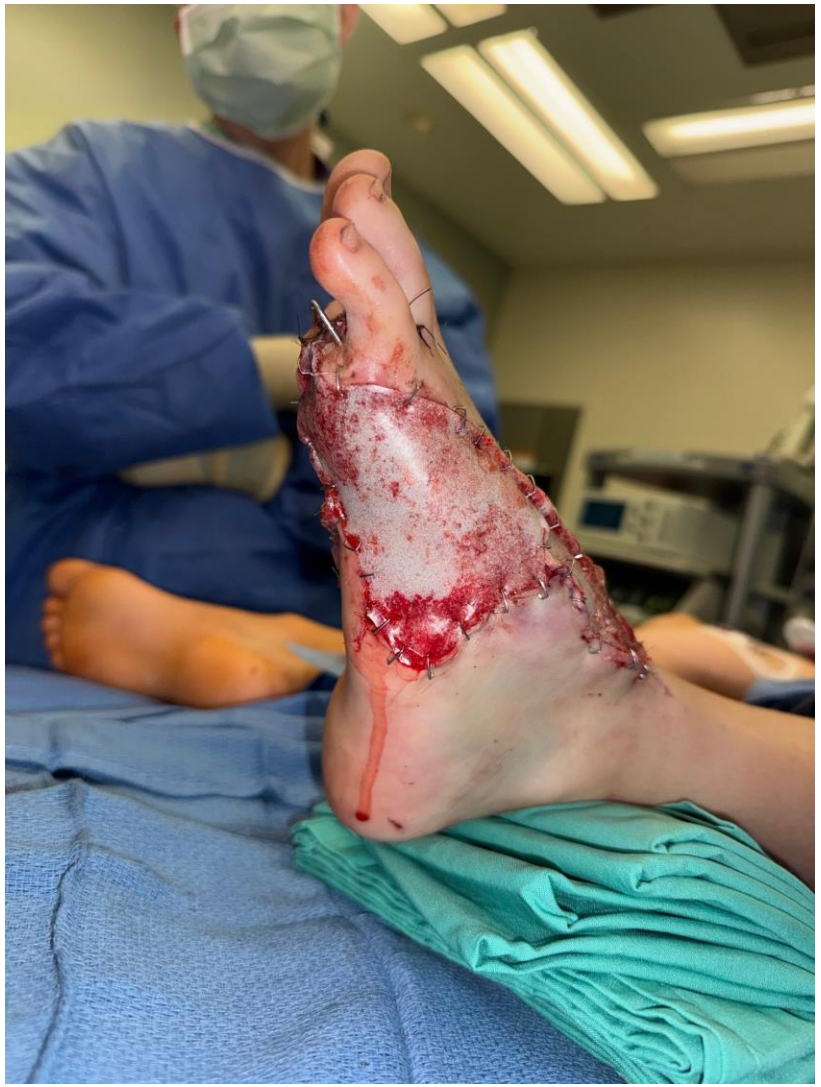
# MTX Case: Indication – Fill Deep Holes and Defects

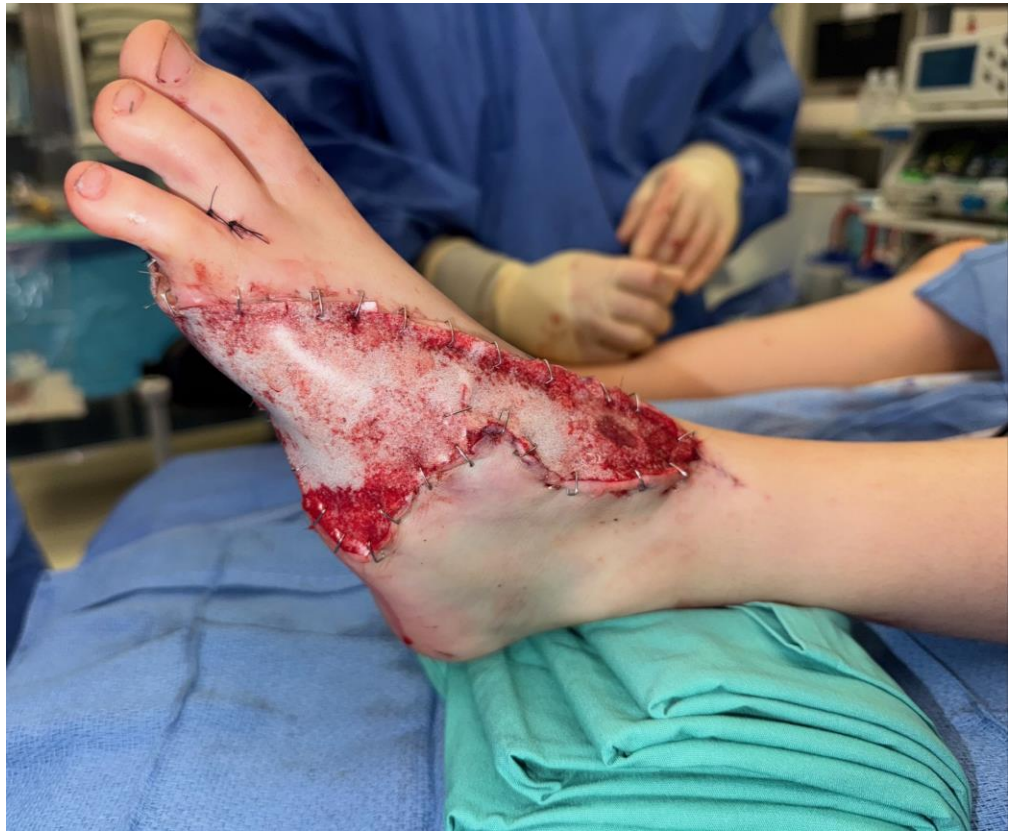


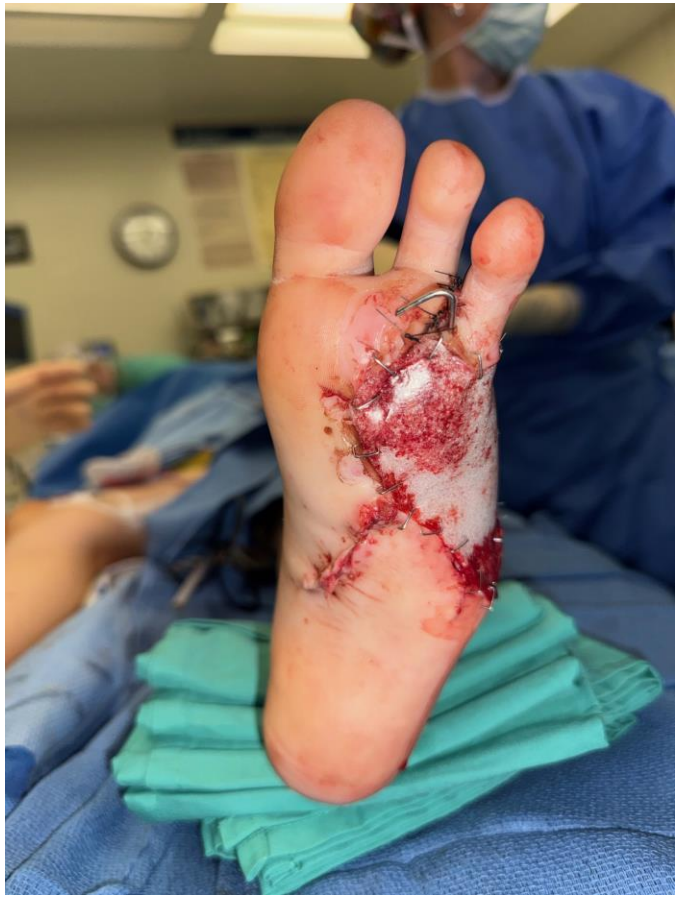




# MTX Case: Indication – Fill Deep Holes and Defects

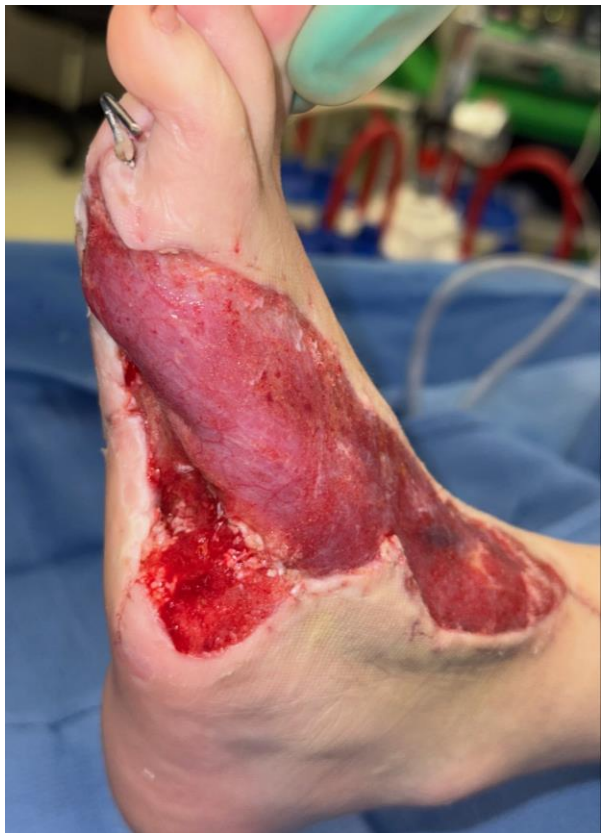


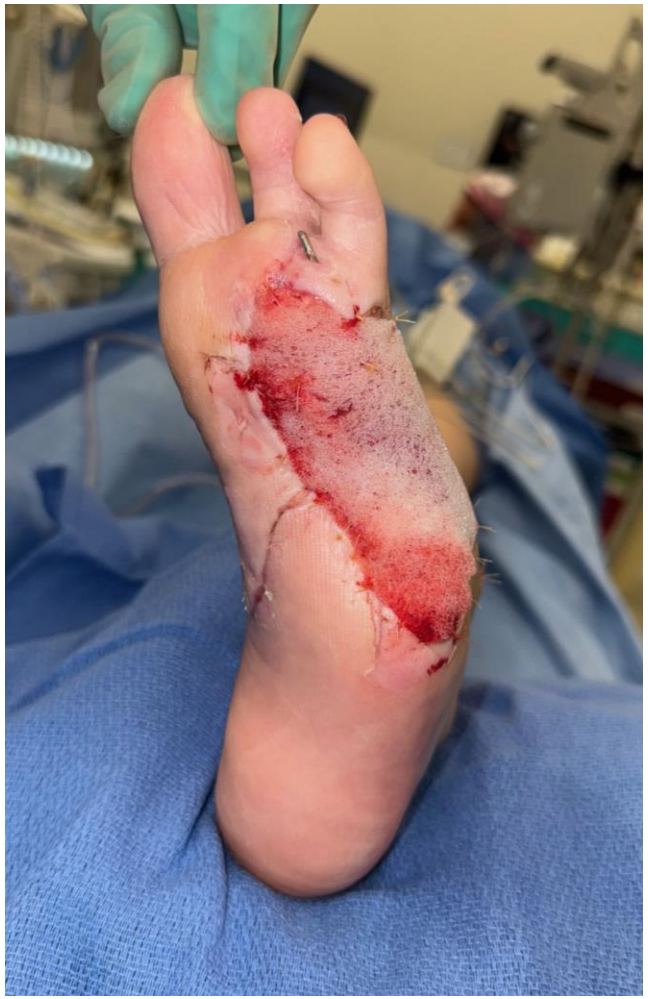


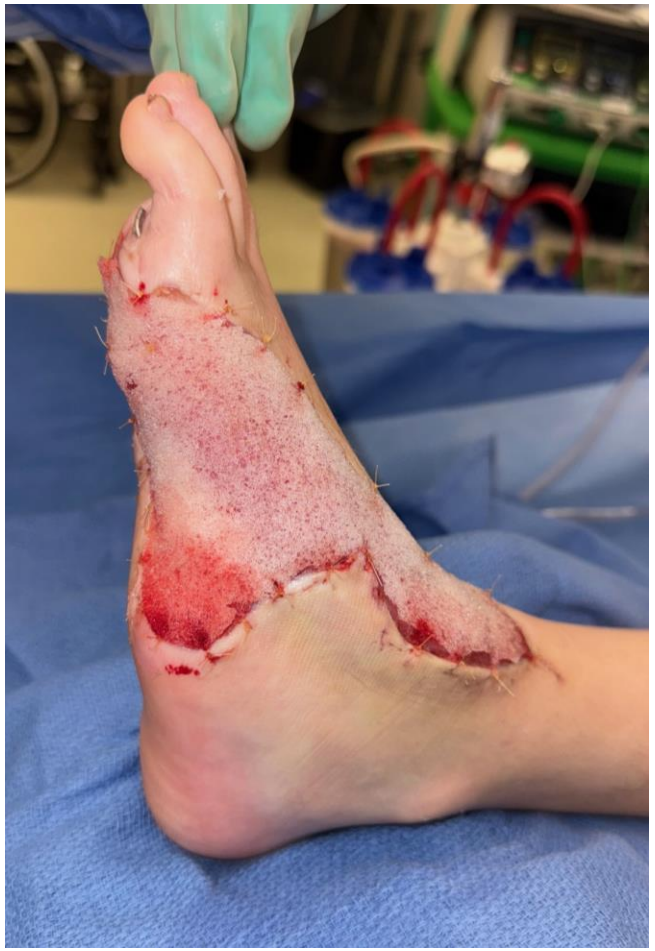


# MTX Case: Indication – Fill Deep Holes and Defects

Still had large defect on bottom of foot so filled and covered with MTX

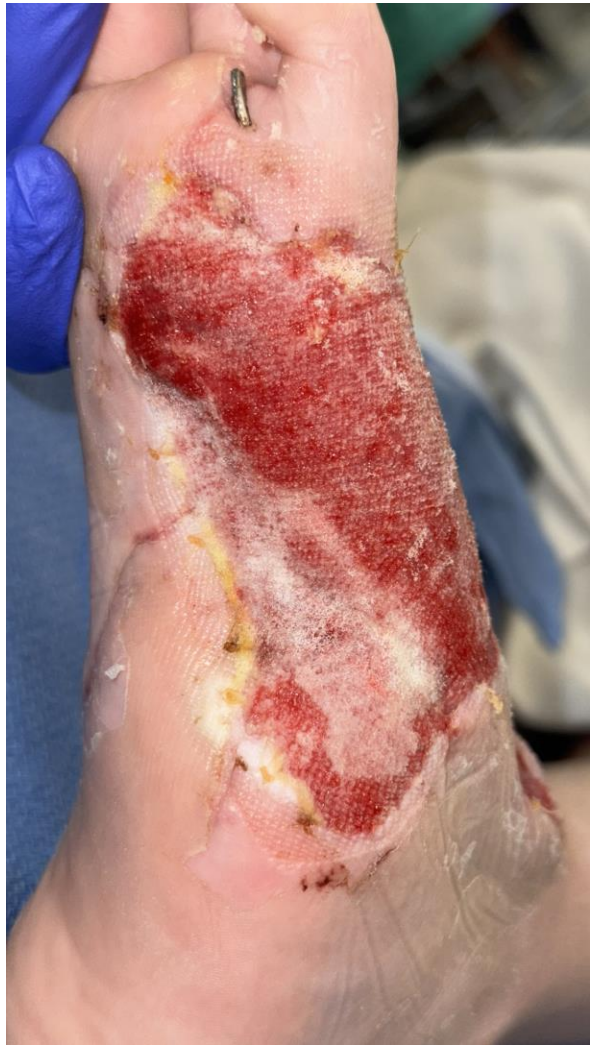


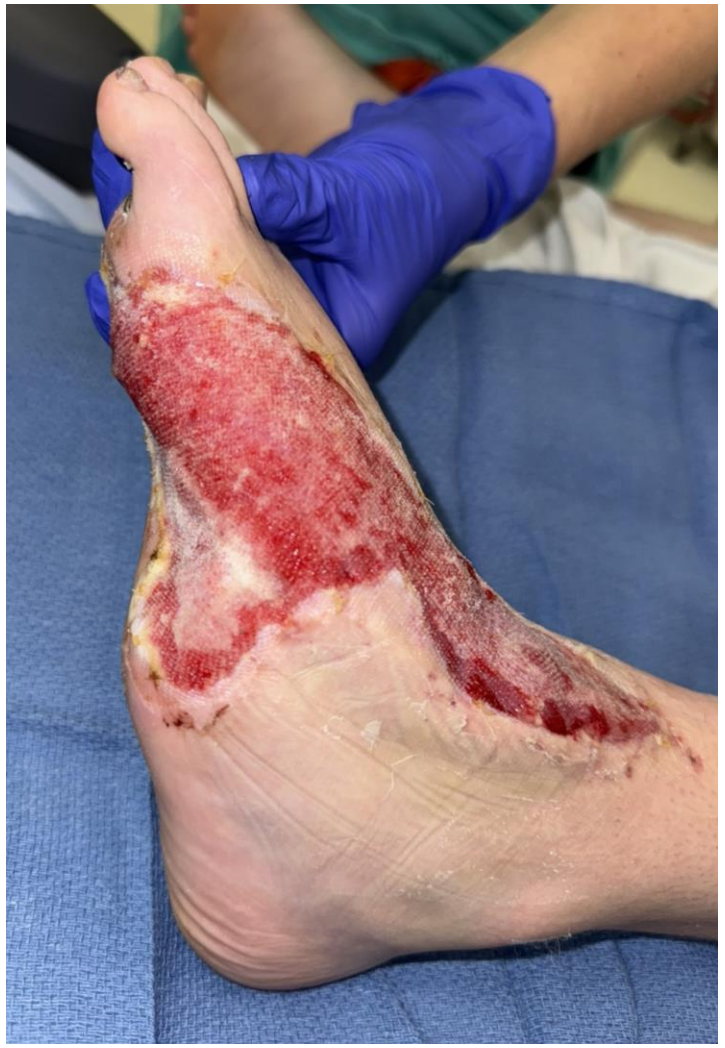


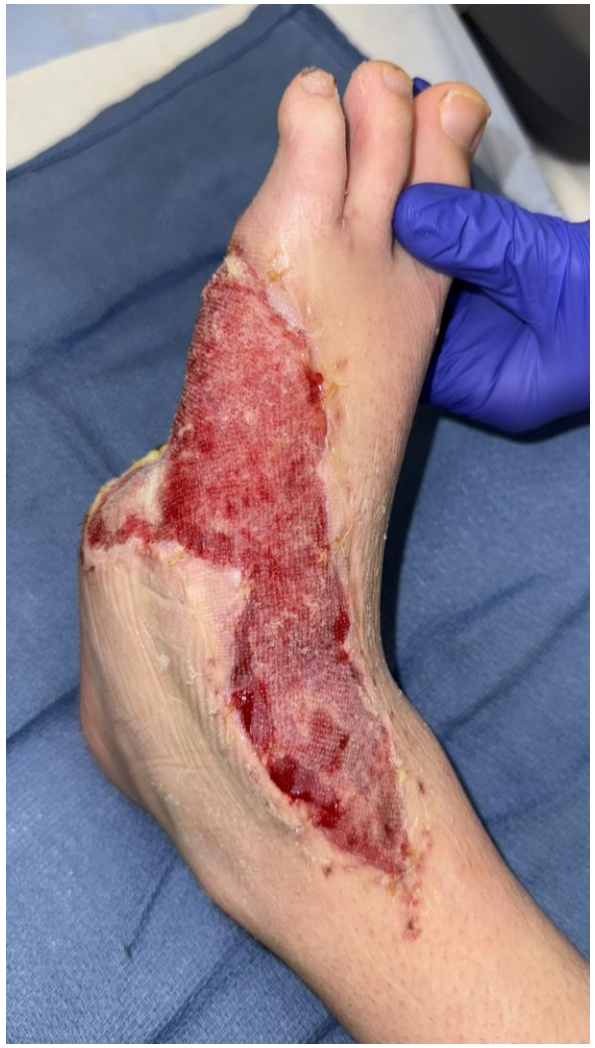


# MTX Case: Indication – Fill Deep Holes and Defects

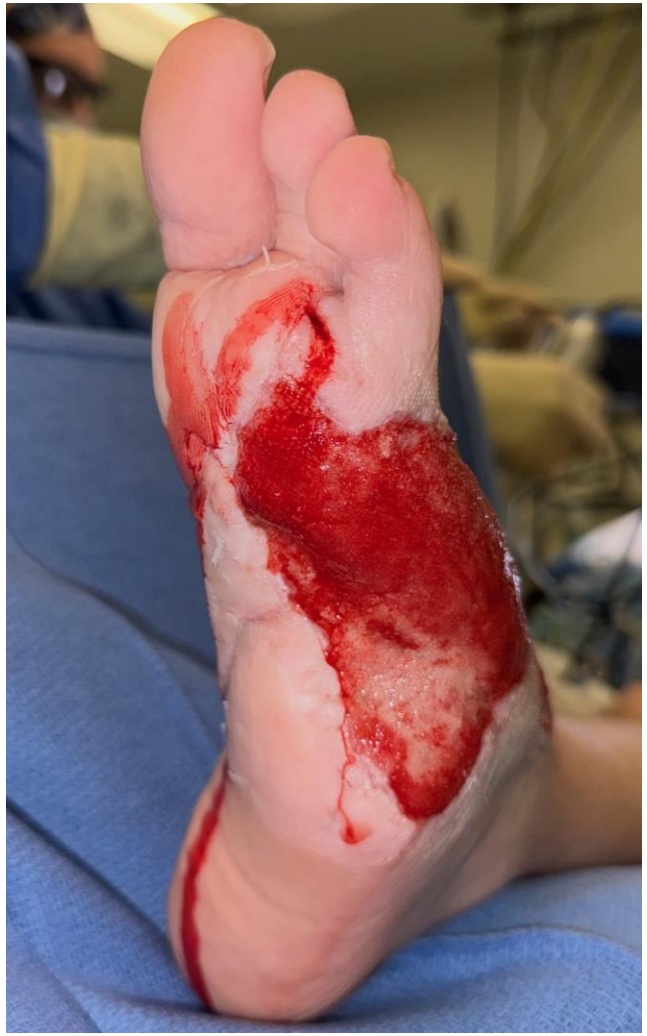
1 week s/p MTX placement

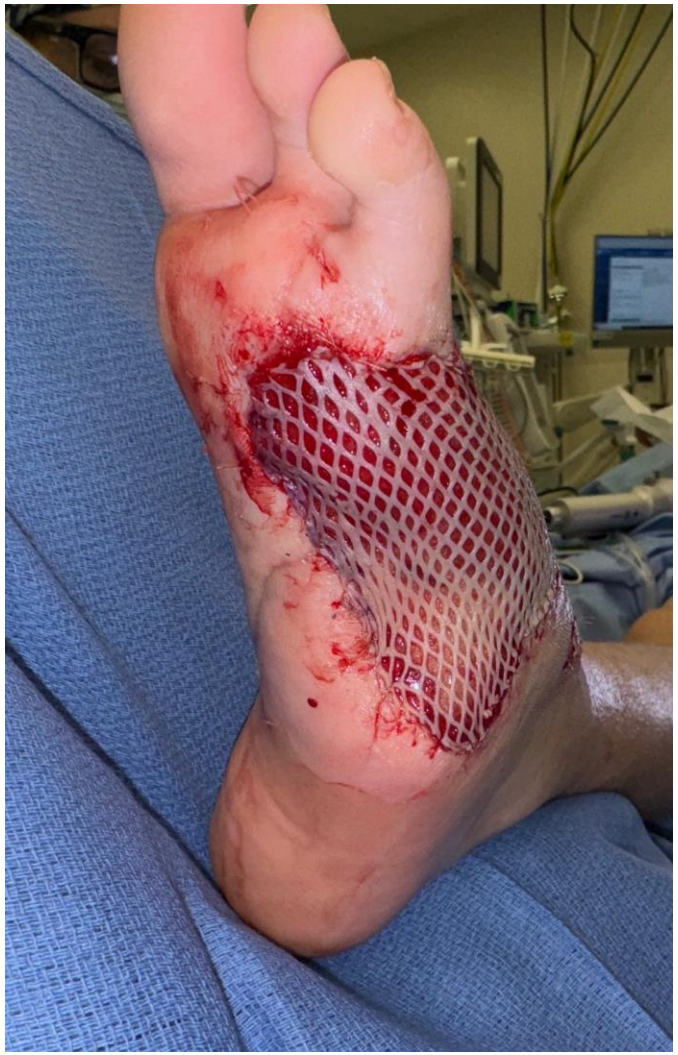


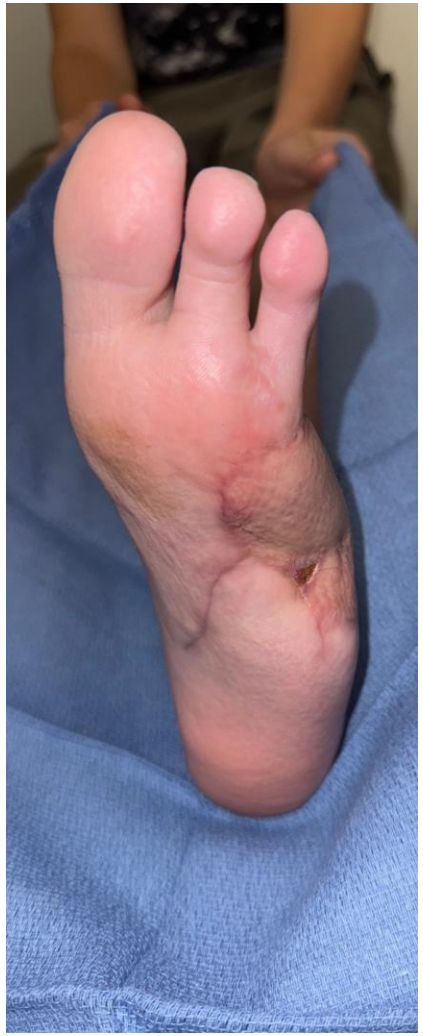


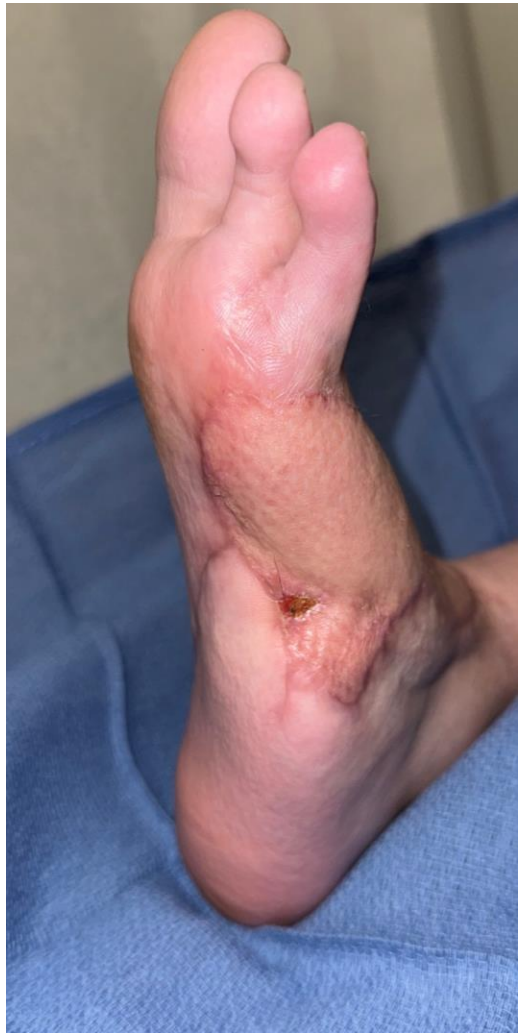


# MTX Case: Indication – Fill Deep Holes and Defects



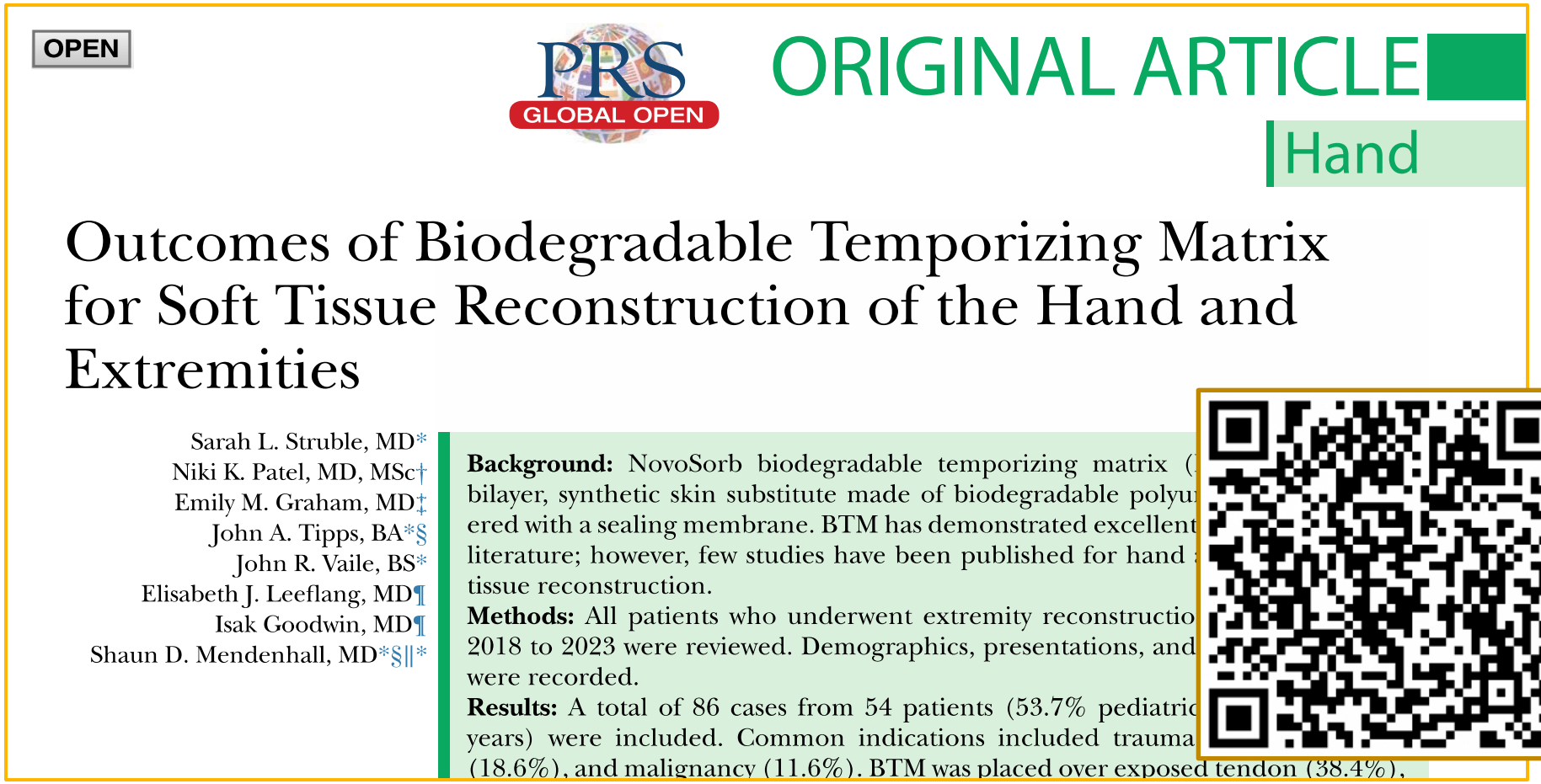






# My Published Case Series

- 88.6% take rate of BTM and 92.1% of skin graft (by $cm^2$)
- 93.3% of reconstructive success, 4 failures (required flap or dressings)
- 5.4% infection rate



OPEN

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ORIGINAL ARTICLE

Hand

## Outcomes of Biodegradable Temporizing Matrix for Soft Tissue Reconstruction of the Hand and Extremities

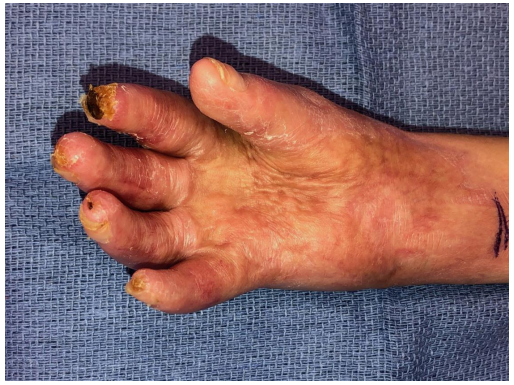
Sarah L. Struble, MD*
Niki K. Patel, MD, MSc†
Emily M. Graham, MD‡
John A. Tipps, BA*§
John R. Vaile, BS*
Elisabeth J. Leeflang, MD¶
Isak Goodwin, MD¶
Shaun D. Mendenhall, MD*§||*

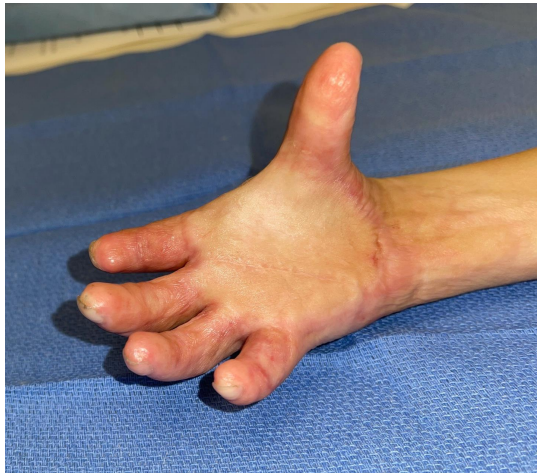
**Background:** NovoSorb biodegradable temporizing matrix (
bilayer, synthetic skin substitute made of biodegradable polyu
ered with a sealing membrane. BTM has demonstrated excellent
literature; however, few studies have been published for hand
tissue reconstruction.
**Methods:** All patients who underwent extremity reconstructio
2018 to 2023 were reviewed. Demographics, presentations, and
were recorded.
**Results:** A total of 86 cases from 54 patients (53.7% pediatric
years) were included. Common indications included trauma
(18.6%), and malignancy (11.6%). BTM was placed over exposed tendon (38.4%),

Struble SL, et al. *Plast Reconstr Surg Glob Open*. 2024;12(7):e5956.

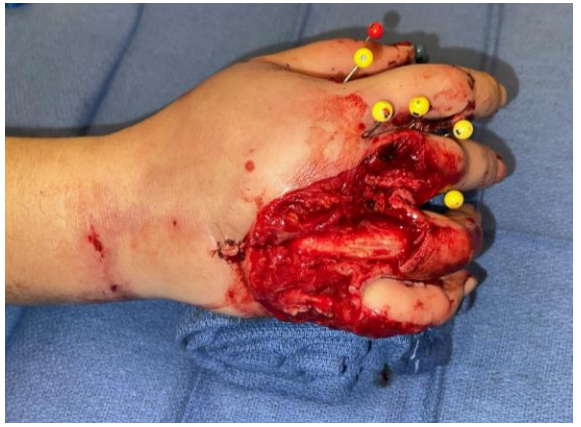
# Conclusions

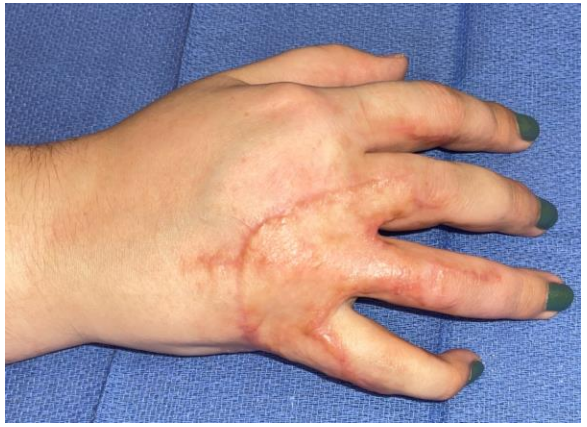
- BTM has a high reconstructive success rate for complex wound reconstruction
- Robust in setting of infection
- Favorable complication profile
- Buys me time, tissue thickness, and bails me out
- Buys patients pain relief and simplifies wound care
- Saves hospitals $$$





BTM





# Q&A