Defining the Future
of Autologous Wound Care

Clinical Evidence, Reimbursement, and Practice Integration of a Multilayered Leukocyte, Platelet, and Fibrin Patch

Supported by an educational grant from Reapplix

Faculty

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Faculty Disclosures

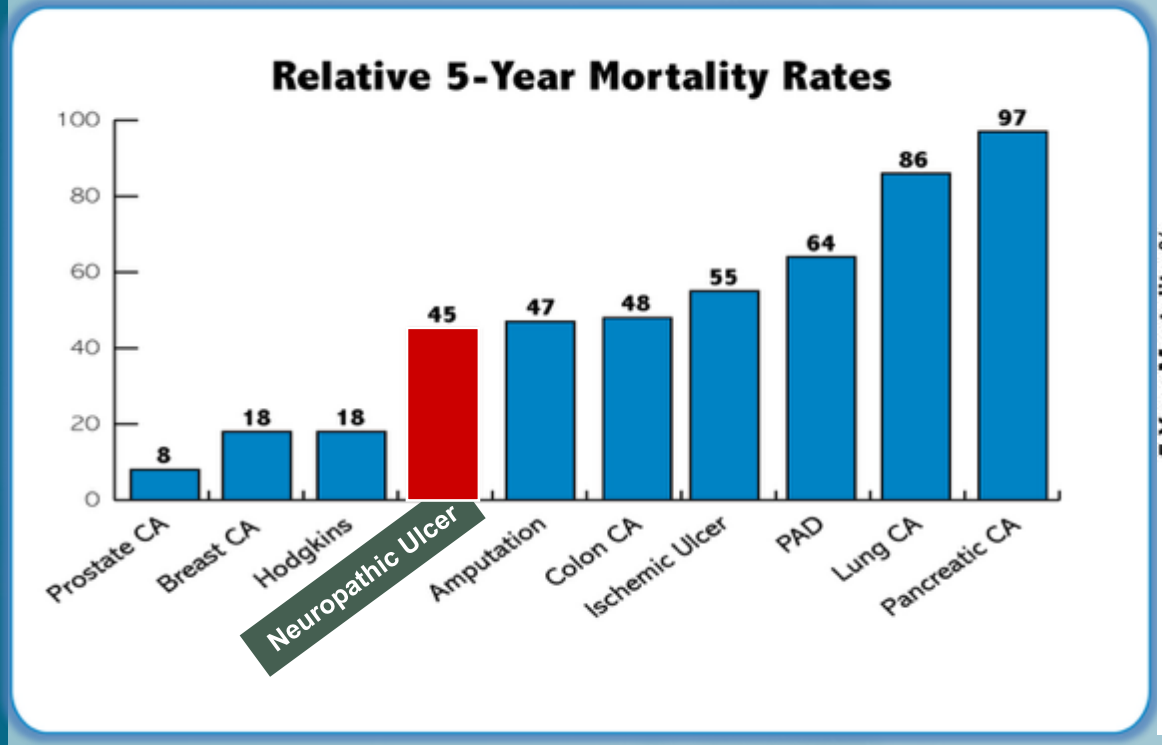
- **Kara Couch, MS, CRNP, CWCN-AP, FAAWC:** Consultant – Integra LifeSciences, Solventum, Reapplix, Urgo Medical North America
- **Michael Stempel, DPM, FACFAS:** Executive board– DCPMA; consultant – Reapplix, MyNerva

Learning Objectives

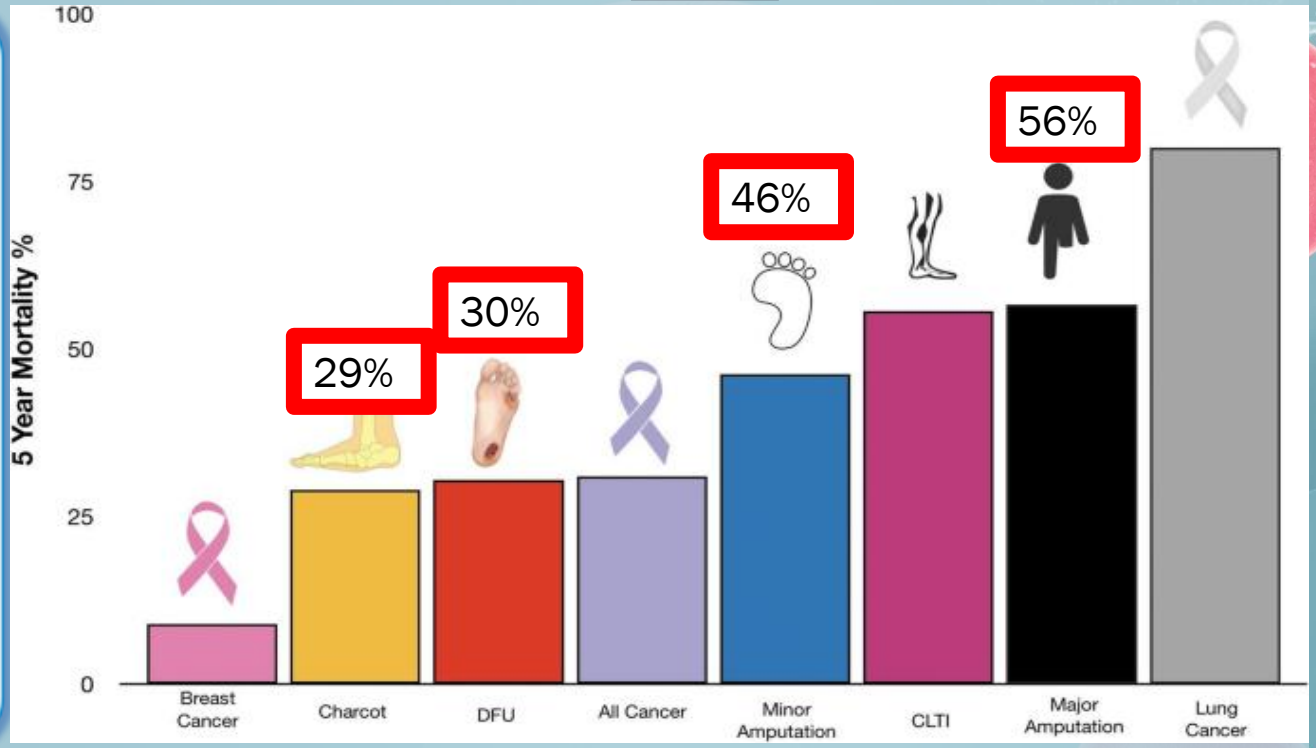
- Interpret clinical evidence and real-world retrospective outcomes data on the use of an autologous multilayered leukocyte, platelet, and fibrin patch for hard-to-heal wounds and differentiate this patient-derived, point-of-care technology from other autologous blood-derived products
- Demonstrate how an autologous multilayered leukocyte, platelet, and fibrin patch can be efficiently incorporated into existing clinic workflows without disruption while maintaining operational efficiency in outpatient wound care practice
- Assess reimbursement pathways, coverage considerations, and documentation requirements for the use of an autologous multilayered leukocyte, platelet, and fibrin patch in the office or outpatient wound care setting
- Evaluate where an autologous multilayered leukocyte, platelet, and fibrin patch fits within the overall wound care treatment armamentarium and consider whether a patient biology-derived therapy should be a first-line option for chronic wounds
- Explore real-world case studies of chronic wounds treated in the office or outpatient wound care setting with an autologous multilayered leukocyte, platelet, and fibrin patch

Consequences of Chronic Neuropathic Ulcers

2007



2020



- Nearly half of all unhealed neuropathic ulcers result in death within 5 years
- Updated 2023: 5-year DFU mortality now 50–70% — rivaling cancer
- Amputation rates rising by up to 50% in some regions despite advances in care

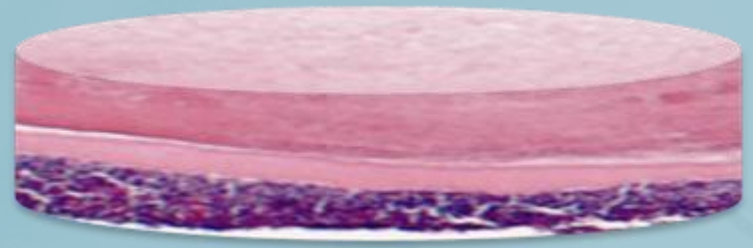
DFU = diabetic foot ulcer; CA = cancer; PAD = peripheral artery disease; CLTI = chronic limb-threatening ischemia.

Armstrong DG, et al. *Int Wound J.* 2007;4(4):286-287. Armstrong DG, et al. *J Foot Ankle Res*. 2020;13(1):16. Everett E, et al. *Diabetes Care*. 2023;46(1):209-221.

What Is the MLPF?

3-layer autologous multilayered leukocyte, platelet, and fibrin patch

Histological image highlighting the 3-layers of the MLPF patch



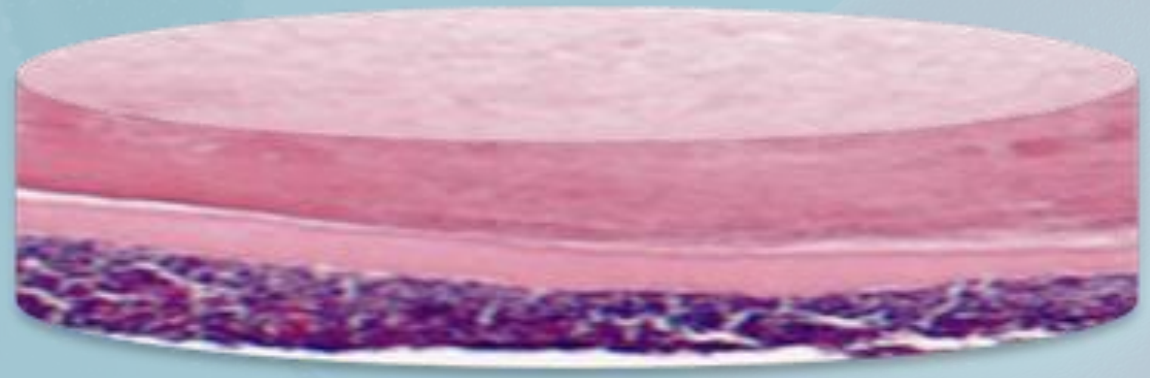
Actual image of the MLPF patch

- MLPF patch is a 100% autologous patch, produced at the point of care from the patient's own blood
  1. Fibrin
  2. Approximately 3 billion platelets
  3. Approximately 50 million leukocytes

MLPF = multilayered leukocyte, platelet, and fibrin.

Lundquist R, et al. *Wound Repair Regen*. 2013;21(1):66-76.

Clinical Effect of the 3-Layer Structure in Wound Healing



Fibrin provides moisture retention and structural integrity

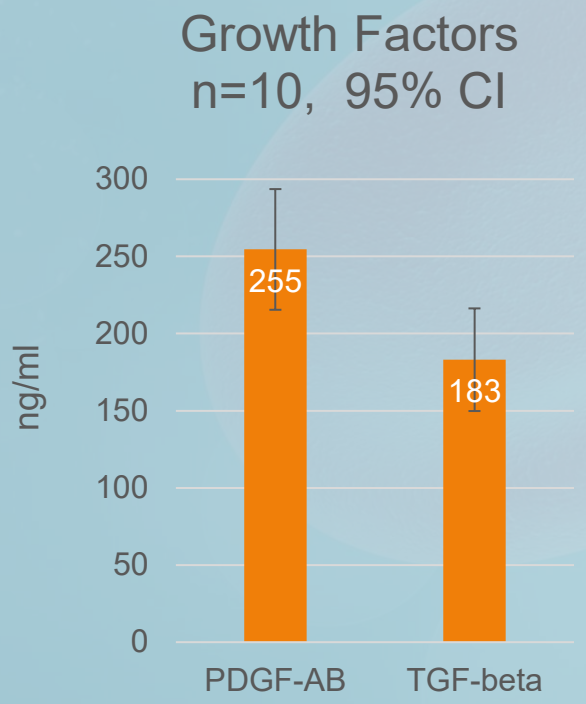
Leukocytes orchestrate healing and fight infection, and are provided directly to the wound surface

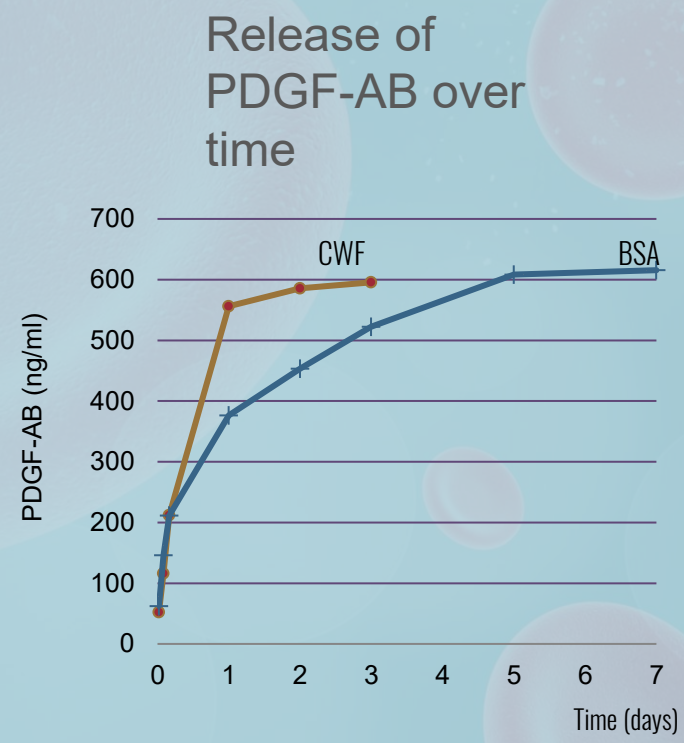
Platelets provide high growth factor levels

Lundquist R, et al. *Wound Repair Regen*. 2013;21(1):66-76.

Role of Platelets in Wound Healing

- PDGF-AB is known to stimulate granulation tissue formation, re-epithelialization, matrix formation, stimulates angiogenesis, wound contraction
- TGF-α known to increase keratinocyte migration and proliferation
- TGF-β known to be involved in collagen production, granulation tissue formation, keratinocytes migration
- VEGF – known to stimulate angiogenesis, granulation tissue formation



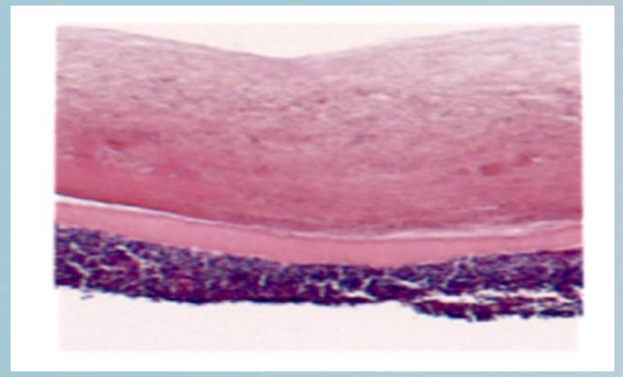


CWF = chronic wound fluid, BSA = bovine serum albumin.
Lundquist R, et al. *Wound Repair Regen*. 2013;21(1):66-76.

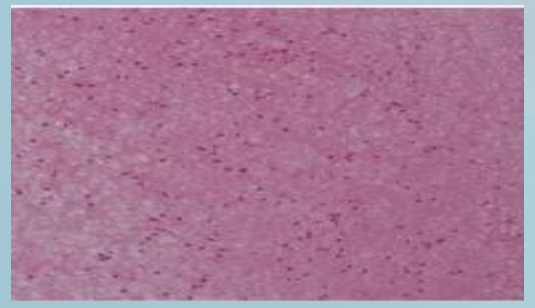
MLPF Is NOT PRP! Composition, Content, and Process Advantage over PRP

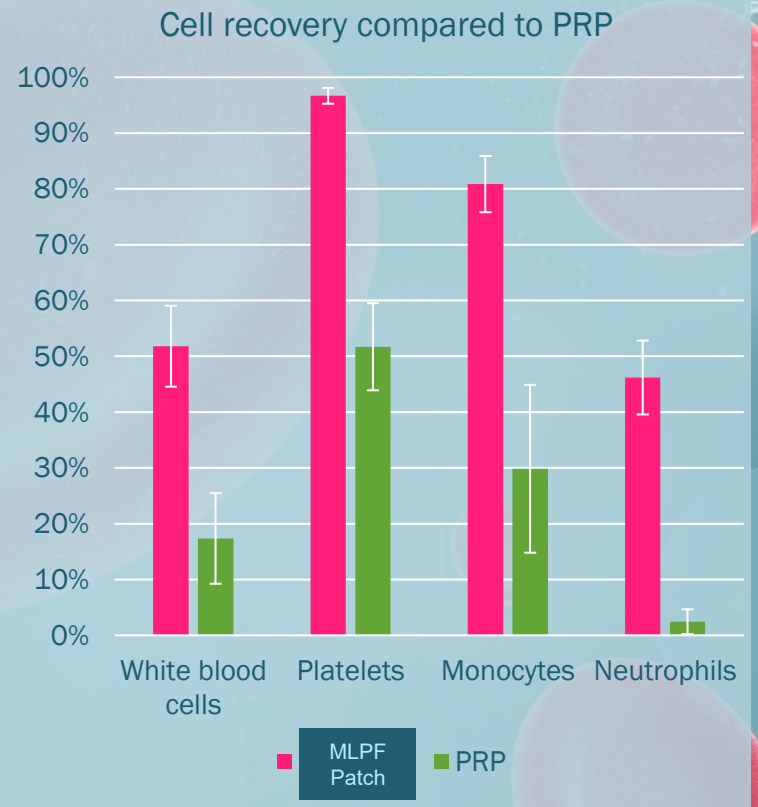
- MLPF vs PRP
  - 3-layer structure vs homogenous
    - Increased cell and growth factor release to the wound bed
    - Release living immune cells key in wound healing
    - Easy application
  - Automated centrifugation process
    - Higher and more consistent cell recovery
    - Less hands-on time
  - Includes growth factors and key signaling molecules from platelets and immune cells
  - Prospective randomized clinical data

MLPF



PRP





PRP = platelet-rich plasma.

Lundquist R, et al. *Wound Repair Regen*. 2013;21(1):66-76.

New 2024 Italian Guideline Meta-Analysis

- Systematically reviewed adjuvant therapies including PRP/fibrin, skin substitutes, NPWT, HBOT, and growth factors across 51 RCTs
- PRP/fibrin class is the ONLY autologous therapy with high-quality evidence for major amputation reduction (MH-OR 0.32, *P*=0.04)
- The MLPF patch represents the highest-evidence product within this class

NPWT = negative pressure wound therapy; HBOT = hyperbaric oxygen therapy; RCT = randomized controlled trial.

Monami M, et al. *Acta Diabetol*. 2025l;62(7):1081-1095.

Clinical Studies of MLPF

A Pilot Study to Evaluate the Safety and Clinical Performance of MLPF patch, an Autologous, Additive-Free, Platelet-Rich Fibrin for the Treatment of Recalcitrant Chronic Wounds

Bo Jørgensen, MD[1], Tonny Karlsmark, MD, DMSci[1], Hanne Vogensen, RN[1], Lone Haase, RN[1], and Rasmus Lundquist, MSc[2]

Abstract

This prospective, uncontrolled pilot study evaluated the safety and clinical performance of Leucopatch an a autologous platelet-rich fibrin in the treatment of recalcitrant chronic wounds. Fifteen patients, with 16 low chronic wounds of varying etiologies were treated weekly with Leucopatch, prepared at the point of care fro of the patients' blood, for 6 weeks, or until healing was complete. The wounds had been present for 2 to (median 24 months) and ranged in size from 0.4 to 15.7 cm^2 (median 2.3 cm^2) and had not responded treatments. Of the 12 wounds (12 patients) included in the per-protocol efficacy analysis, 4 healed completely wound area decreased significantly by 65% (95% confidence interval = 45.4% to 83.8%) resulting in a median of 0.9 cm^2 (range = 0-9.6cm^2). There were no serious adverse events. Two adverse events, one of noncon one infection, were observed; neither was considered to be related to treatment. The results indicate that L easy to prepare and apply in the clinic, is safe, and may be a clinically effective treatment of recalcitrant chron

Keywords

wound healing, autologous transplantation, platelet-rich plasma

Despite greater understanding of the biology of wound healing over the past 20 years, some chronic wounds, such as venous leg ulcers, pressure ulcers, and diabetic foot ulcers, are recalcitrant to healing.[1] In addition to local wound-related factors (eg, ischemia, infection) and patient-related factors (eg, diabetes, old age, obesity, malnutrition) that can impair healing, reduction in tissue growth factors, an imbalance between proteolytic enzymes and their inhibitors, and the presence of senescent cells seem to be particularly important in chronic wounds.[2] For chronic wounds that fail to heal, a number of advanced treatments are available to stimulate wound healing, including negative pressure, dermal matrix equivalents, growth factors, and platelet-rich concentrates.

Chronic ulcers are known to have reduced levels of platelet-derived growth factor, basic fibroblast growth factor, epidermal growth factor, and transforming growth factor β compared with acute wounds. It has been suggested that growth factors may become trapped by extracellular matrix molecules or may be degraded by proteases to an excessive degree, resulting in nonhealing.[3] growth factors released from platelets play role in the wound-healing process,[4] and topica of concentrated activated platelets can stim healing in situations where standard wound ca are ineffective.

Use of platelet concentrates, and in partic rich plasma, as an effective treatment is well chronic wound care, especially for wounds that difficult to heal by other means.[5,6] Platelets pl tant role in the natural healing process, in add well-known function in hemostasis. On activ release a range of biologically active substa

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practice

Use of an autologous leucocyte and platelet-rich fibrin patch on hard-to-heal DFUs: a pilot study

• **Objective:** Leucopatch is a leukocyte and platelet-rich fibrin patch that provides concentrated blood cells and signal substances to the surface of an ulcer. It is produced by centrifugation of the patient's own venous blood. The aim of this pilot multicentre cohort study was to evaluate effects of the leucocyte patch in patients with hard-to-heal diabetic foot ulcers (DFUs).
• **Method:** Non-ischaemic Wagner grade 1 or 2 DFUs with a duration of more than 6 weeks and a maximal area of 10cm^2 were included. Patients with >40% ulcer area change during a two-week run-in period were excluded. The treatment was applied once a week for up to 19 treatments or until the foot ulcer was completely epithelialised. The primary endpoint was healing within 20 weeks.
• **Results:** Of the 60 patients who gave consent 16 were excluded during run-in period, 44 patients initiated study treatment and 39 were included in the per-protocol analysis. Complete epithelisation was achieved in 34% (per-protocol analysis 36%) at 12 weeks and 52% (59%) at 20 weeks. In patients with ulcer duration less than 6 months, 73% of ulcers healed within 20 weeks. Patients with healed ulcers had larger ulcer area reduction during the first two treatment weeks compared to non-healers. Adverse events were mild and rare.
• **Conclusion:** The leucocyte patch is well-tolerated, easy to use and has potential in the armamentarium of the DFU treatment, provided this outcome is confirmed in an appropriately powered randomised clinical trial.

• **Declaration of interest:** M.L and L.T have received consultation fees from Reapplix A/S. R.L. is co-inventor of the Leucopatch technology. All other authors declare no duality of interest associated with this manuscript. This study was financed by Reapplix A/S. Time to data analysis and manuscript preparations have been financed by Medical Faculty (ALF), Lund University, Lund Sweden.

diabetic foot ulcer, platelet-rich fibrin, healing, autologous cell therapy

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4 Nordsjælland

A application of growth factors to hard-to-heal ulcers, either using recombinant products such as platelet-derived growth factor (PDGF)-BB or platelet-rich preparations such as platelet-rich plasma and platelet-rich fibrin have been suggested as plausible adjunctive therapies to aid healing.[1-6] However, clinical evidence for the effectiveness of these treatments in the healing of chronic ulcers, including diabetic foot ulcers (DFUs), is limited.[4,5] Leucopatch is a leucocytes and platelet-rich fibrin patch, which provides a way of transferring concentrated blood cells and signal substances, including growth factors, to the surface of an ulcer.[6] It differs from other preparations based on autologous blood as it has a compact, three-layered structure including a layer with a high concentration of fibrin, a layer of concentrated leucocytes and a layer of concentrated platelet.[6] Growth factors in the patch include PDGF, transforming growth factor-ß (TGF-ß), epidermal growth factor (EGF) and vascular endothelial growth factor (VEGF), which together exhibit different chemotactic, mitogenic and proliferative properties.[6] A small study of 14 patients with lower extremity ulcers of varying aetiologies, including three DFUs, has shown encouraging outcomes.[7]

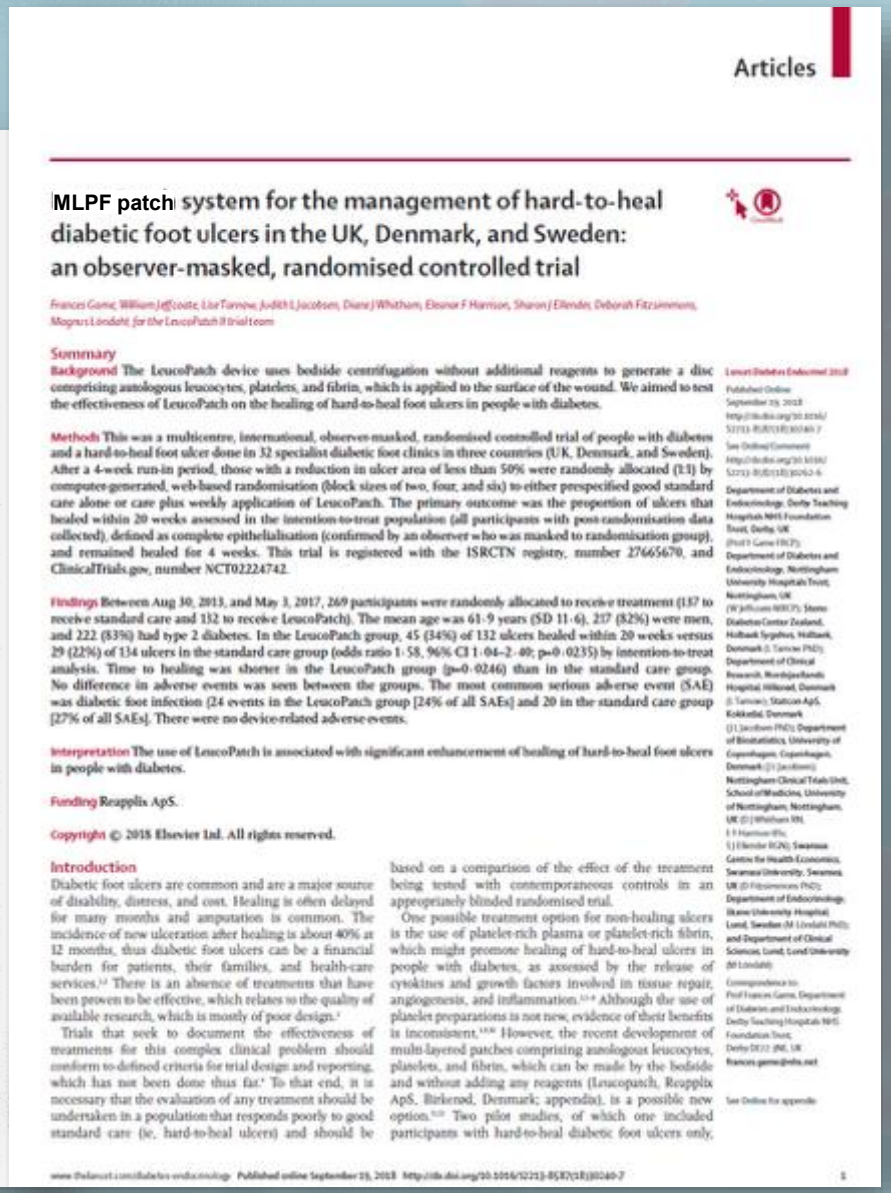
The aim of this study was to evaluate the leucocyte patch in terms of efficacy, safety, and feasibility in patients with hard-to-heal DFUs.

Methods

This prospective, multicentre open, cohort study, designed to evaluate the efficacy, safety, and feasibility of leucocyte platelet fibrin patch treatment in patients with hard-to-heal DFUs without probe-to-bone was initiated, designed, and performed by the authors. The study was performed in accordance with the Declaration of Helsinki, and was approved by appropriate ethic committees and is registered at Clinicaltrials.gov, NCT01454401. All patients provided written informed consent.

Patients

Adult patients (>18) with at least one full-thickness diabetic ulcer, classified by the investigator as Wagner grade 1 or 2, at or below the ankle with a duration of more than 6 weeks and a maximal area of 10 cm^2 were included. All patients had an adequate



MLPF patch system for the management of hard-to-heal diabetic foot ulcers in the UK, Denmark, and Sweden: an observer-masked, randomised controlled trial

Frances Game, William Jeffcoate, Lise Tarnow, Judith L Jacobsen, Diane J Whatham, Eleanor F Harrison, Sharon J Ellender, Deborah Fitzsimmons, Magnus Löndahl, for the LeucoPatch II trial team

Summary

Background The LeucoPatch device uses bedside centrifugation without additional reagents to generate a disc comprising autologous leucocytes, platelets, and fibrin, which is applied to the surface of the wound. We aimed to test the effectiveness of LeucoPatch on the healing of hard-to-heal foot ulcers in people with diabetes.

Methods This was a multicentre, international, observer-masked, randomised controlled trial of people with diabetes and a hard-to-heal foot ulcer done in 32 specialist diabetic foot clinics in three countries (UK, Denmark, and Sweden). After a 4-week run-in period, those with a reduction in ulcer area of less than 50% were randomly allocated (1:1) by computer-generated, web-based randomisation (block sizes of two, four, and six) to either prespecified good standard care alone or care plus weekly application of LeucoPatch. The primary outcome was the proportion of ulcers that healed within 20 weeks assessed in the intention-to-treat population (all participants with post-randomisation data collected), defined as complete epithelialisation (confirmed by an observer who was masked to randomisation group), and remained healed for 4 weeks. This trial is registered with the ISRCTN registry, number 27665670, and ClinicalTrials.gov, number NCT02224742.

Findings Between Aug 30, 2013, and May 3, 2017, 269 participants were randomly allocated to receive treatment (137 to receive standard care and 132 to receive LeucoPatch). The mean age was 61·9 years (SD 11·6), 217 (82%) were men, and 222 (83%) had type 2 diabetes. In the LeucoPatch group, 45 (34%) of 132 ulcers healed within 20 weeks versus 29 (22%) of 134 ulcers in the standard care group (odds ratio 1·58, 96% CI 1·04–2·40; p=0·0235) by intention-to-treat analysis. Time to healing was shorter in the LeucoPatch group (p=0·0246) than in the standard care group. No difference in adverse events was seen between the groups. The most common serious adverse event (SAE) was diabetic foot infection (24 events in the LeucoPatch group [24% of all SAEs] and 20 in the standard care group [27% of all SAEs]. There were no device-related adverse events.

Interpretation The use of LeucoPatch is associated with significant enhancement of healing of hard-to-heal foot ulcers in people with diabetes.

Funding Reapplix ApS.

Introduction

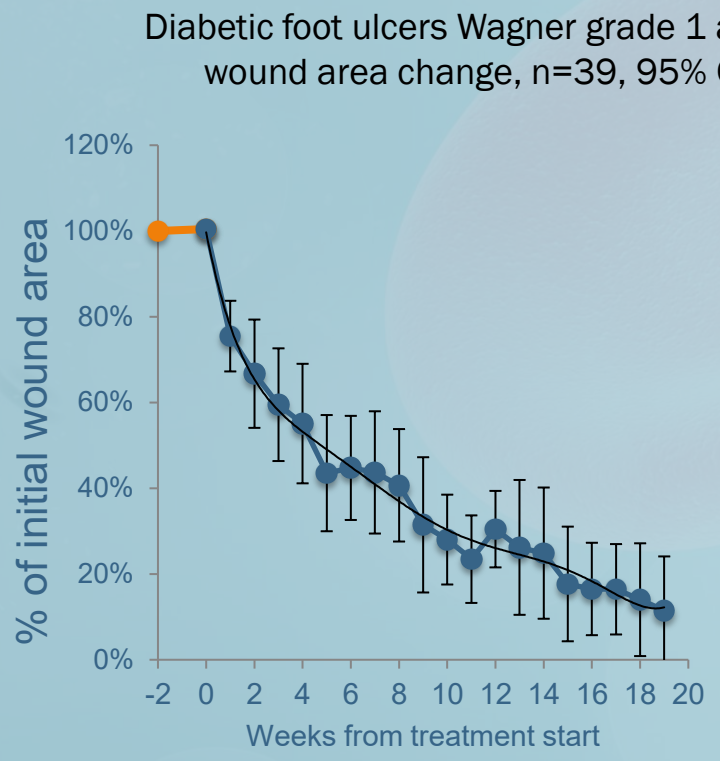
Diabetic foot ulcers are common and are a major source of disability, distress, and cost. Healing is often delayed for many months and amputation is common. The incidence of new ulceration after healing is about 40% at 12 months, thus diabetic foot ulcers can be a financial burden for patients, their families, and health-care services.[1,2] There is an absence of treatments that have been proven to be effective, which relates to the quality of available research, which is mostly of poor design.[3]

Trials that seek to document the effectiveness of treatments for this complex clinical problem should conform to defined criteria for trial design and reporting, which has not been done thus far.[4] To that end, it is necessary that the evaluation of any treatment should be undertaken in a population that responds poorly to good standard care (ie, hard-to-heal ulcers) and should be based on a comparison of the effect of the treatment being tested with contemporaneous controls in an appropriately blinded randomised trial.

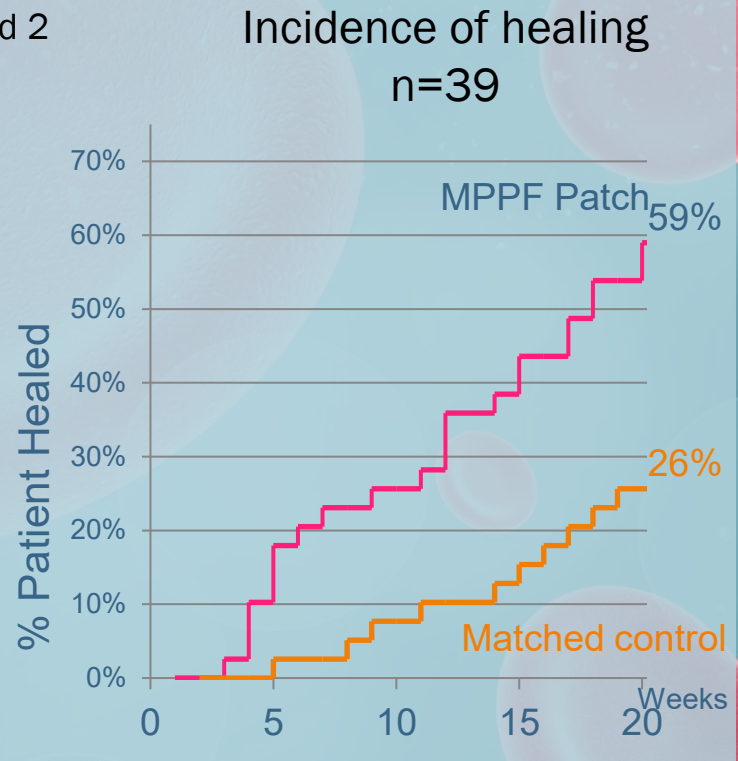
One possible treatment option for non-healing ulcers is the use of platelet-rich plasma or platelet-rich fibrin, which might promote healing of hard-to-heal ulcers in people with diabetes, as assessed by the release of cytokines and growth factors involved in tissue repair, angiogenesis, and inflammation.[5,6] Although the use of platelet preparations is not new, evidence of their benefits is inconsistent.[5,6,8] However, the recent development of multi-layered patches comprising autologous leucocytes, platelets, and fibrin, which can be made by the bedside and without adding any reagents (Leucopatch, Reapplix ApS, Birkerød, Denmark; appendix), is a possible new option.[9,10] Two pilot studies, of which one included participants with hard-to-heal diabetic foot ulcers only,

MLPF on Grade 1 and 2 Diabetic Foot Ulcers

- Prospective multicenter non-randomized pilot study of 39 Wagner Grade 1 and 2 DFU treated with autologous combined leucocyte, platelet and fibrin patch in addition to standard DFU treatment
- Compared to matched control group of patients with Wagner 1 and 2 DFU treated with standard care
- MLPT patch demonstrated a steep reduction in wound area size and favorable healing rates



Dramatic decrease in ulcer area at start of treatment

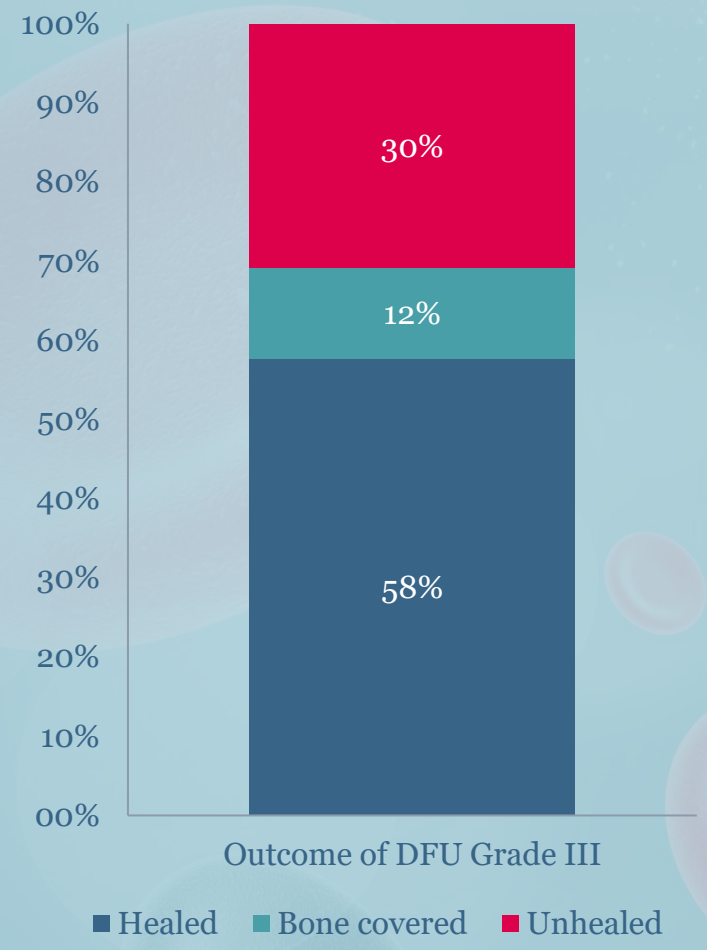


Time to healing:
Mean: 11 weeks, range 3-20 weeks

Löndahl M, et al. *J Wound Care*. 2015;24(4):172-174, 176-178.

MLPF Case Series: Treating Probe to Bone Ulcers

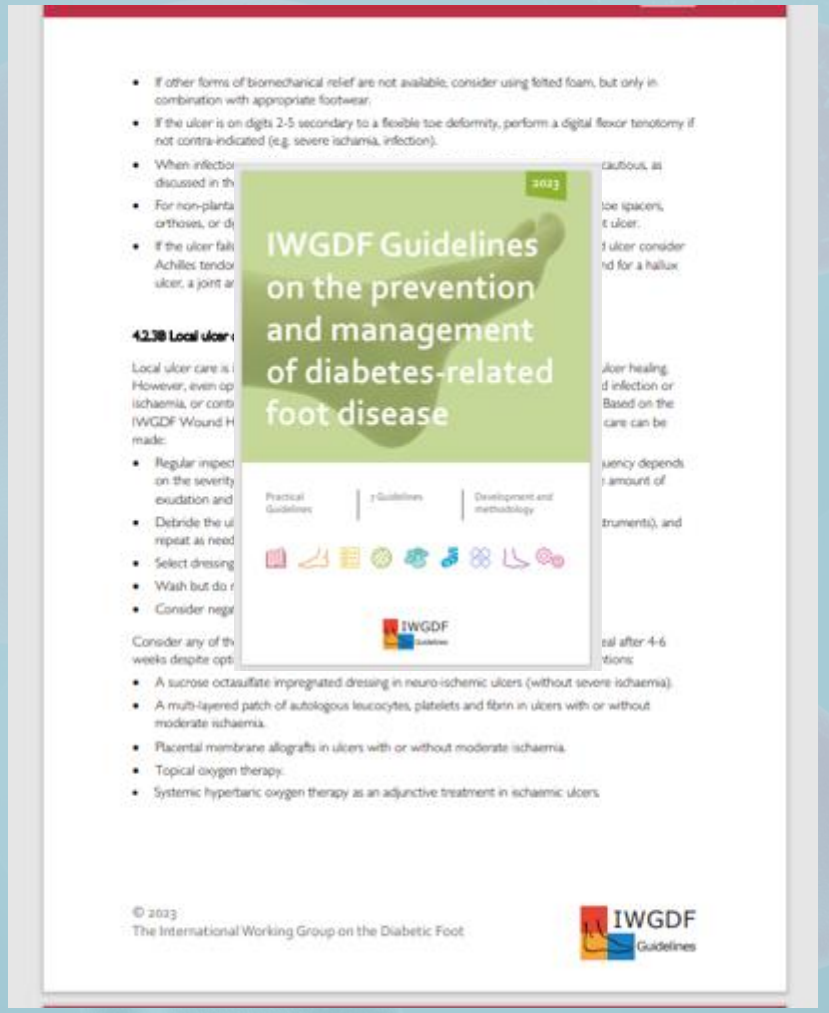
- MLPF has been investigated for use on exposed bone
  - **Purpose:** To evaluate the feasibility of using an MLPF patch in the treatment of diabetic foot ulcers with probe to bone (≥Wagner grade 3)
  - **Method:** The outcome of 3C Patch treatment on 26 ulcers on 22 patients was analyzed
  - **Results**
    - Median ulcer duration was 26 weeks and the median number of treatments was 8
    - **Bone was covered in 18 ulcers of which 15 healed with complete epithelialization**



Katzman P, et al. Presented at: 74th American Diabetes Association (ADA) Scientific Sessions; June 14–17, 2014, San Francisco, CA.

International Working Group of the Diabetic Foot

- **IWGDF GUIDANCE May 25, 2019 and Updated 2023 Guidelines – Wound Healing Interventions Guideline**
  - 19. With the exception of the **autologous leucocyte, platelet and fibrin patch** we suggest not using autologous platelets therapy (including blood bank derived platelets) as an adjunct therapy to standard of care. (Conditional; Low)
  - 20. Consider the use of **autologous leucocyte, platelet and fibrin patch** for diabetes-related foot ulcers as an adjunctive therapy to standard of care, where best standard of care alone has been ineffective, and where the resources and expertise exist for the regular venipuncture required. (Conditional; Moderate)



IWGDF = International Working Group of the Diabetic Foot.
Schaper NC, et al. *Diabetes Metab Res Rev*. 2024;40:e3657.

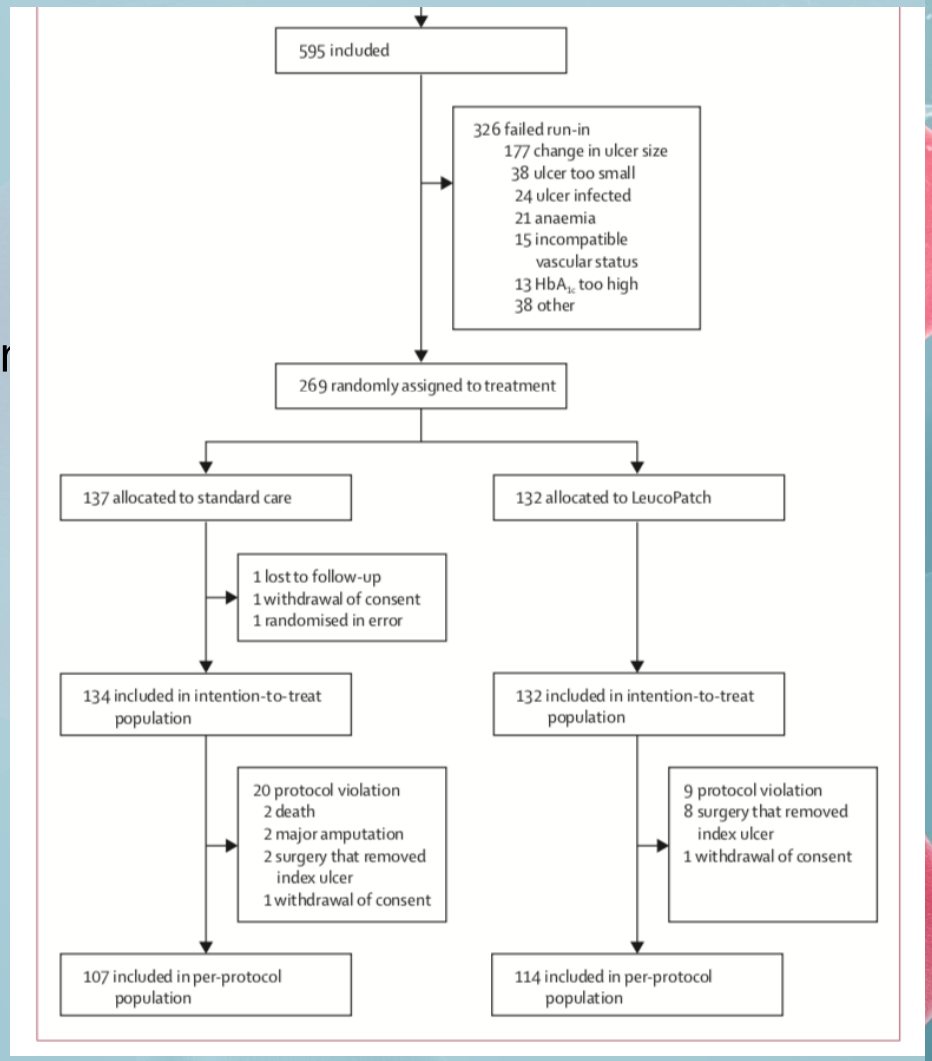
IWGDF

- The 2023 IWGDF Guidelines maintain Conditional / Moderate recommendation specifically for the autologous leukocyte, platelet and fibrin patch — and explicitly advise AGAINST generic PRP
- The MLPF patch remains the only autologous blood-derived product with an IWGDF recommendation

Schaper NC, et al. *Diabetes Metab Res Rev*. 2024;40:e3657.

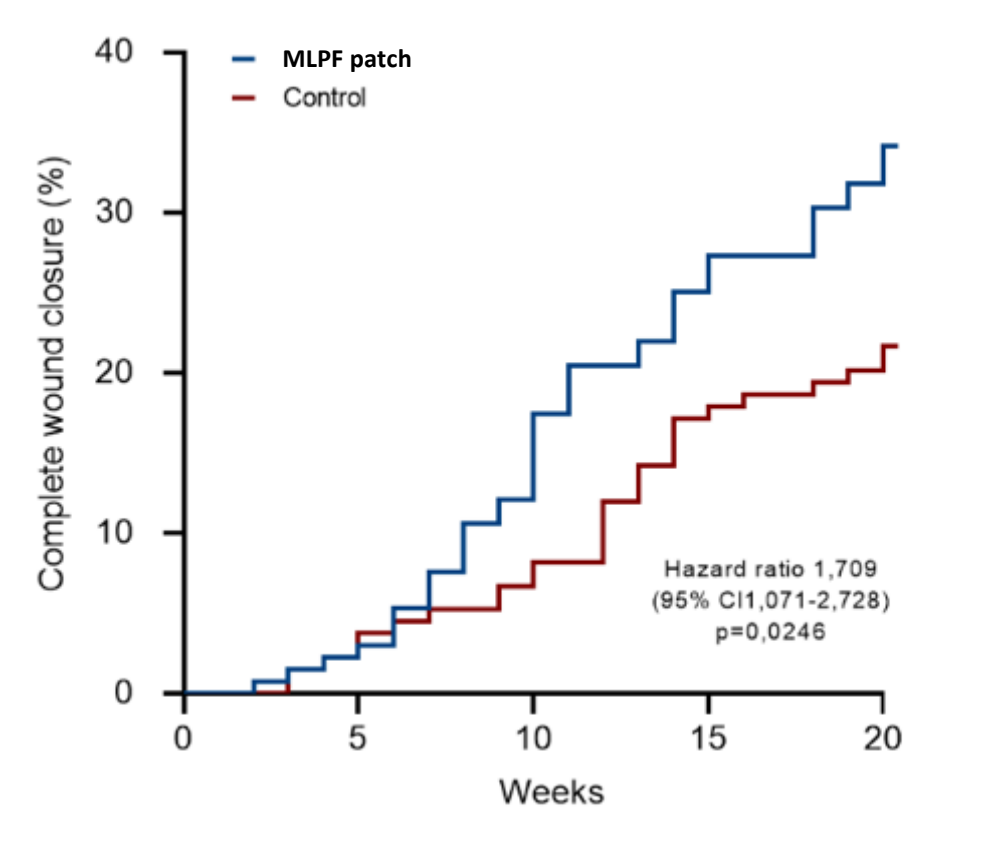
The MLPF Trial

- An investigator driven RCT
- Study details
  - 269 patient randomized across 32 centers in 3 countries
  - **Only study with a full 4-week run-in period**, with <50% wou area reduction
  - Primary endpoint
    - Proportion of pts with complete wound closure within 20 wks
- Hard-to-heal DFUs
  - 595 consented patients
  - 326 excluded during run-in
    - 177 healed >50% in 4 weeks
  - 269 patients randomized
  - Well matched patient populations



Game F, et al. *Lancet Diabetes Endocrinol*. 2018;6(11):870-878.

MLPF Patch Improves Healing of Hard-to-Heal DFUs



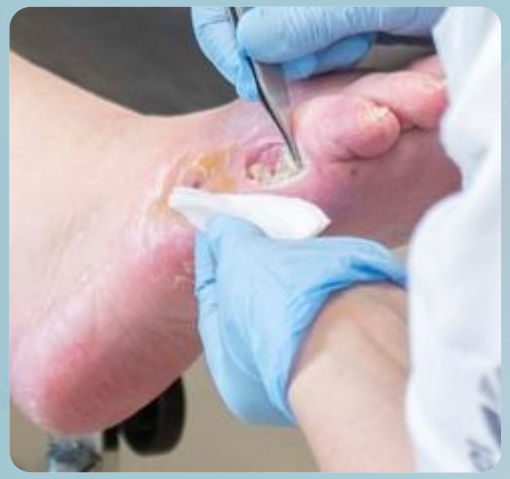
- Graph is demonstrating time to healing
- Healing was defined as complete epithelialization without any drainage for at least 4 weeks
- 58% more patients healed with MLPF
  - The wounds in the MLPF group were larger than the wounds in the control
  - Further data analysis was conducted and it was found that if all things had been equal, the MLPF patch group was 89% more likely to heal
- MLPF group also healed progressively faster in the first 12 weeks

Game F, et al. *Lancet Diabetes Endocrinol*. 2018;6(11):870-878.

MLPF Patch Procedure

Draw blood

Place the device in the centrifuge



Clean and debride the wound

Remove the MLPF patch from the device

Apply the MLPF Patch and dress the wound

Factors that Improve the Treatment Outcome

- The wound is debrided to bleeding before MLPF patch is applied
- Appropriate off-loading modalities are key
- Ensure adequate perfusion for wound healing
- Secondary dressing change frequency depends on exudate (typically decreases after a few weeks of treatment)
- Consider from week-to-week if MLPF patch is effective

Patient and Staff Adoption of the MLPF

- Implementing MLPF
  - Staff training
  - Space requirements
  - Patient scheduling
  - Prior authorization
- Clinical workflow
  - Patients are allowed up to 20 weeks of treatment
- Patients' acceptance
  - Well-adapted to receive weekly blood draws
  - Patient involvement and wound improvement

Blood-Derived Products for Chronic Non-Healing Wounds

Platelet-rich plasma (PRP) is produced in an autologous or homologous manner. Autologous PRP is comprised of blood from the patient who will ultimately receive the PRP. Alternatively, homologous PRP is derived from blood from multiple donors.

Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic, nonhealing cutaneous wounds that persist for 30 days or longer and fail to properly complete the healing process. Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products, and (2) PRP (such as AutoloGel).

The PRP is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, fibrin, stem cells, and fibrocyte precursors.

The PRP is used by physicians in clinical settings in treating chronic, non-healing wounds, open, cutaneous wounds, soft tissue and bone. Alternatively, PDGF does not contain cells and was previously marketed as a product to be used by patients at home.

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for services performed on or after April 13, 2021, the Centers for Medicare & Medicaid Services (CMS) will cover autologous PRP for the treatment of chronic non-healing diabetic wounds under section 1862(a)(1)(A) of the Social Security Act (the Act) for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers.

C. Nationally Non-Covered Indications

Autologous PDGF for the treatment of chronic, non-healing cutaneous wounds, and,

Becaplermin, a non-autologous growth factor for chronic, non-healing subcutaneous wounds, and,

Autologous PRP for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision, or for dehiscent wounds.

D. Other

Effective for services performed on or after April 13, 2021:

Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by the local Medicare Administrative Contractors (MACs).

Coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by the local MACs under section 1862(a)(1)(A) of the Act.

Centers for Medicare & Medicaid Services. Accessed April 6, 2026. https://cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=217.

Documentation of MLPF Application

- Blood draw: Pt prepped for blood draw per guidelines for infection control in the [location of blood draw]. Venipuncture performed by [name of person] using a (21 gauge) needle, collecting a sample of (18 ml) of the patient's blood. Once drawn, the blood sample was placed in centrifuge within infection control guidelines for approximately (# minutes) until an autologous blood-derived product (MLPF) was created
- Procedure: Pre-procedure verification/time-out taken: [time] Start time: [time]. Autologous blood-derived product used: (MLPF) placed on wound [number and location of wound] with (forceps) without complication. Instruments used: [listed]. End Time: [time]. Secured with: (Silicone mesh adhesive dressing, and any additional dressings like sterile-strips, secondary dressings) Peri wound prep: (skin prep or barrier creams may be listed). Patient tolerated procedure well. Application number: Week (#/20 weeks)
- Post-procedure plan: Do not get wound wet. Protect the wound and dressing during shower/bathing. Secondary dressing may be changed between visits if strikethrough is visible. Do not change the silicone layer or below

First Patch, March 2023

Patient Education and Preparation

We will draw a small sample of your blood at each visit to make the patch.

Please make sure to **HYDRATE** with at least 8-16 ounces of water before coming to your appointment- this will help with drawing your blood to make a patch.

Once we have enough blood, we will need about **20-30 minutes** to make a patch.

If you are on blood thinners, please **CONTINUE** to take your blood thinners unless told otherwise by your prescribing doctor.

Once we have a patch, the provider will place it on your wound, and we will put on a dressing that will need to stay on for a week.

Please keep your dressing **clean and dry** until your next appointment.

If you notice **REDNESS, SWELLING, HEAT ON OR AROUND YOUR WOUND, EXTRA or DIFFERENT PAIN THAN USUAL**, please call our office

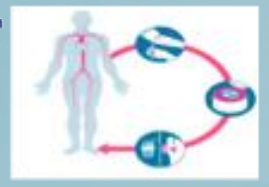
The Use of an Autologous Multilayered Leukocyte, Platelet, and Fibrin Patch for Diabetic Ulcers: Does It Make a Difference?

PURPOSE AND BACKGROUND

33% of DFUs do not heal in a timely manner and ultimately become "chronic" wounds. Approximately 20% of moderate to severe DFUs lead to some form of amputation and patients with diabetes are up to 25 times more likely to have an amputation than non-diabetics. In a busy wound center located in a major metropolitan area, many products have been tried on these chronic wounds with varying degrees of success. When evaluating the adoption of the autologous MLPF patch, providers were initially skeptical. The results however demonstrated the efficacy of the MLPF patch, facilitating wound healing in patients who had failed at least 10 applications of cellular tissue products (CTPs) and/or other advanced modalities.

WHAT IS THE MLPF PATCH?

MLPF patch is produced from the patient's own blood by a unique procedure consisting of a fully automated centrifugation, coagulation, and compaction process.



The resulting patch is 100% autologous, easily transferable to the patient, and consists of a three-layered structure of leukocytes, platelets, and fibrin resulting in the sustained release of living cells and growth factors.

SUPPORT FOR MLPF PATCH

Game et al. evaluated the clinical effect of the MLPF patch on hard-to-heal DFUs in a multi-centered (32 clinics), observer masked, randomized clinical trial (RCT, n=269)[1]. Weekly applications of MLPF patch resulted in significantly more ulcers healed and a shorter time-to-healing compared to best standard of care alone. As a result, the International Working Group on the Diabetic Foot (IWGDF) has twice recommended MLPF Patch as an adjunctive treatment for non-infected DFUs that are difficult to heal.

METHODS

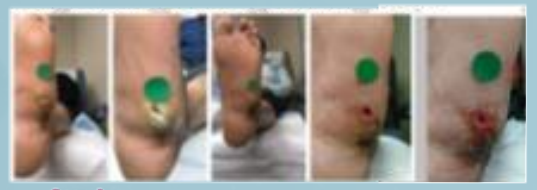
24 patients with DFUs were included in this trial; all of whom had multiple comorbidities and had failed at least 10 applications of CTPs and/or other advanced modalities. All patients underwent weekly sharp debridement as well as adequate offloading and edema control. 6 of these patients are highlighted here.

Case 1

44-year-old male. Type 2 DM with neuropathy and HIV. Large Grade 3 ulcer extending from left posterior calf to plantar heel. Initial wound area was 67.2 cm^2 and within 13 weeks, area decreased to 9.1 cm^2 (86% reduction) with posterior wound almost healed. Due to several setbacks and development of new dorsal wound, wound is not yet completely closed.

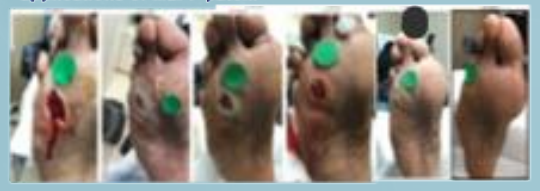
Case 2

56-year-old female. Type 2 DM with neuropathy, anemia, and CKD. Patient with chronic Grade 1 on left plantar foot that was present 8 weeks with no improvement despite offloading and compression. Initial wound closed with 4 MLPF patches within 12 weeks but then recurred. After 6 more MLPF Patch applications, wound closed and remained closed.



Case 3

65-year-old male. Type 2 DM. History of surgical debridement on 3/21/23 of an infected plantar ulceration with application of collagen graft. Pt presented for follow-up evaluation after 1-month nursing facility stay for IV antibiotics of underlying osteomyelitis. Pt had protective weightbearing in a CAM boot. Pt achieved full closure after weekly debridements and 5 weekly applications of MLPF patch.

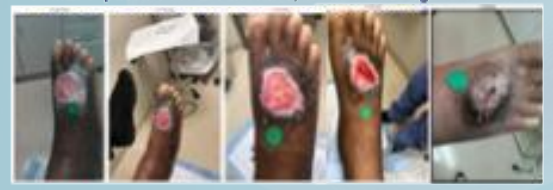


Case 4

89-year-old male. Type 2 DM and history of PAD. Pt presented with a left dorsal great toe wound for over 4 months. Initial wound volume was 4.9 cm^3 and within 6 weeks, volume decreased to 0.25 cm^3. Total area decreased by 89% with 5 weekly MLPF patch applications and subsequent wound closure was achieved in 7 weeks.

Case 5

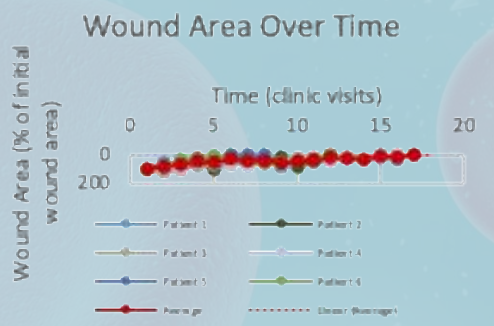
58-year-old male. Type 2 DM. Initially seen 10/16/23 with a wound on dorsal aspect of his foot for at least 1 month. Presented with eschar and colonized wound that was treated topically. Full closure achieved in 5 applications of MLPF patch over 2.5 months; wound healing



Case 6

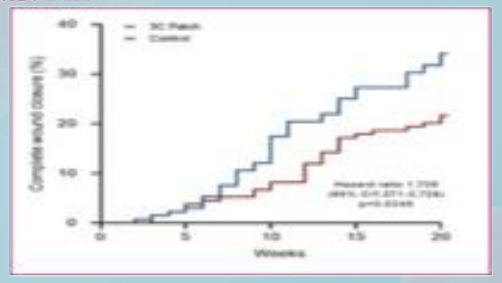
46-year-old male. Type 2 DM. History of partial 1st ray amputation due to osteomyelitis. After initial period of successful healing utilizing NPWT and antibiotics, osteomyelitis returned requiring further revision of the 1st metatarsal as well as 2nd metatarsal head. Continued NPWT and IV antibiotics. The tissue flaps remained viable and the underlying bone infection was resolved with granulation covering the bone. MLPF patch initiated on 1/3/24 and full closure achieved with 7 weekly applications.

RESULTS



Of the total 24 patients in this trial, 45.8% healed (11 total patients). This outperformed the Lancet data of 34% healed over a similar timeframe.

RCT Data



CONCLUSIONS

In this case series, the use of the MLPF patch, in conjunction with diabetes management, sharp debridement, appropriate offloading and edema control, contributed to significant improvement in the wounds. No amputations or infections were seen in this trial group and wound healing was almost 46% with an average of 10 MLPF Patch applications. In a complex patient population that had failed at least 10 applications of cellular tissue products and/or other advanced modalities., the use of the MLPF patch is now considered a first line option in this clinic.

First US Cost-Effectiveness Analysis for PRP in DFU (2025)

- A 2025 US Markov model confirms autologous blood-derived therapy is cost-effective vs standard of care (SOC), with cost savings accumulating over 5 years through reduced complications and amputations — consistent with clinic outcomes data showing 40% fewer 30-day re-admissions and 72% shorter admission duration
  - PRP gel is cost-effective vs SOC — lower care costs over 1 year despite higher initial treatment cost
  - Cost savings demonstrated over 5 years via reduced complications, fewer hospitalizations, and amputation prevention
  - Fewer total clinic interventions required with PRP vs conventional dressing regimens

Russo S, et al. *Clinicoecon Outcomes Res*. 2025;17:157-169.

Wound Healing and Limb Preservation Center
MLPF Patch Experiences

Case 1

- 44-year-old male
- Type 2 DM with neuropathy and HIV. Large Wagner Grade 3 ulcer extending from left posterior calf to plantar heel
- Initial wound area was 67.2 cm^2 and within 13 weeks, area decreased to 9.1 cm^2 (86% reduction) with posterior wound almost healed
- Due to several setbacks and development of new dorsal wound, wound is not yet completely closed

DM = diabetes mellitus.

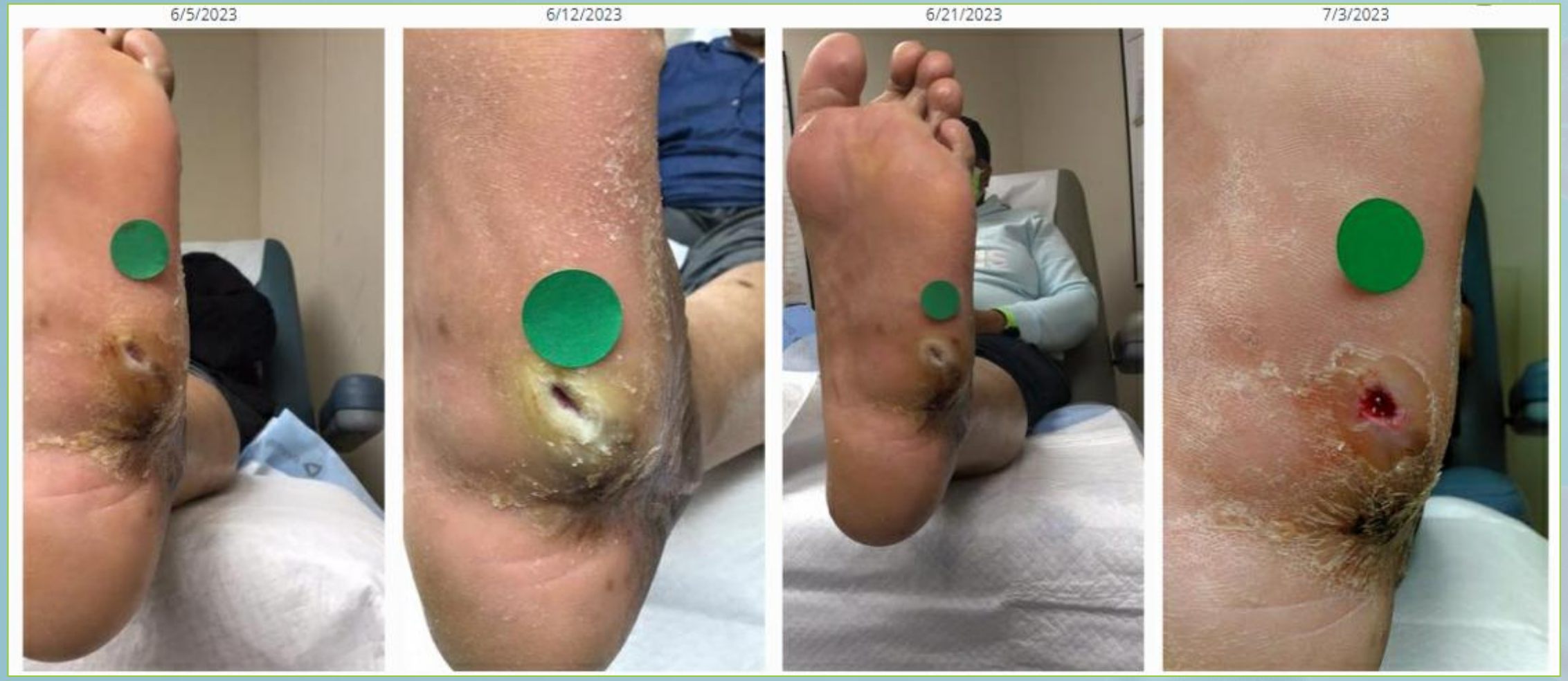
Complex Limb Salvage Case

Case 2

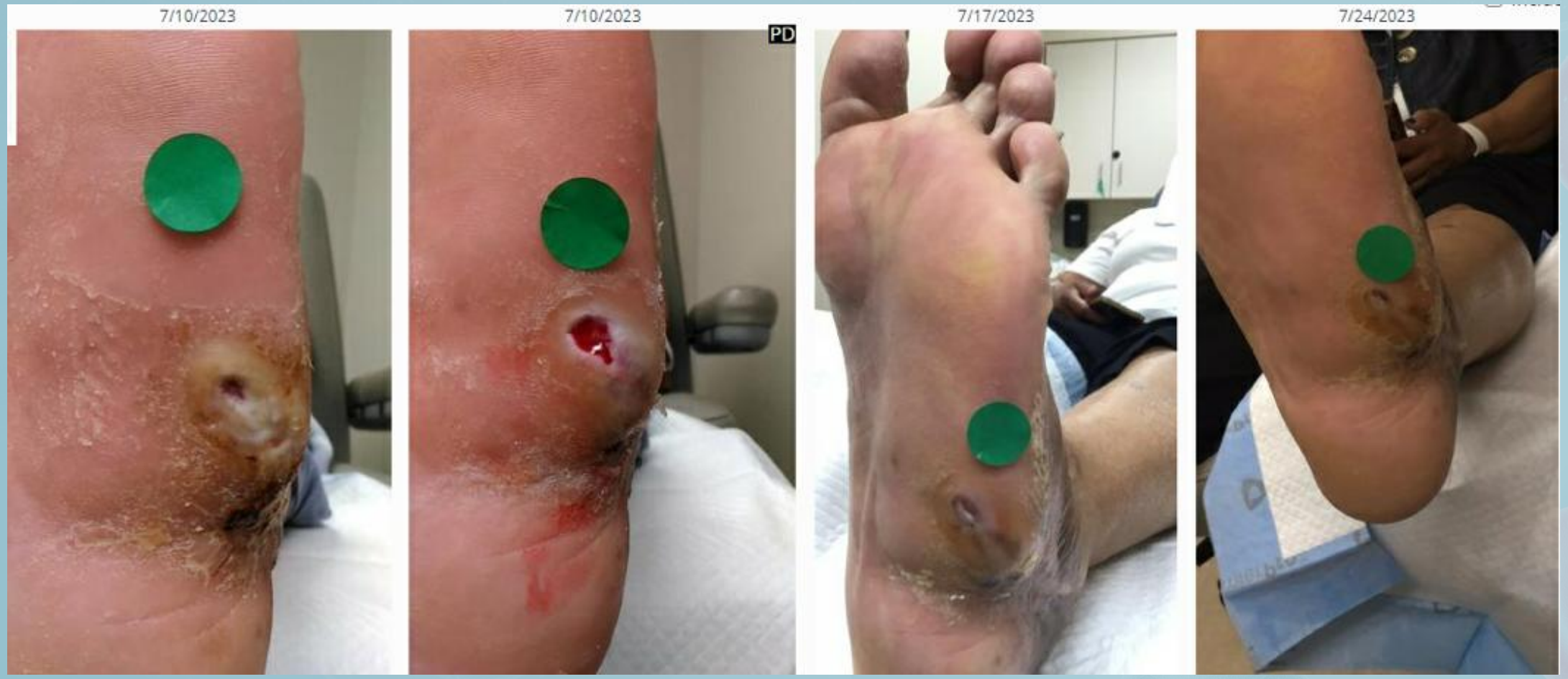
- 56-year-old female
- Type 2 DM with neuropathy, anemia, and chronic kidney disease
- Patient with chronic Grade 1 on left plantar foot that was present 8 weeks with no improvement despite offloading and compression
- History of massive tissue loss from infection, wound plantar and lateral cuboid
- Initially healed that with VAC and antibiotics. Then ulcerated underneath the cuboid initially treated with amniotic membrane. With lack of progress was started on MLPF patch
- Initial wound closed with 4 MLPF patches within 12 weeks, but then recurred
- After 6 more MLPF patch applications, wound closed and remained closed

VAC = vacuum assisted.

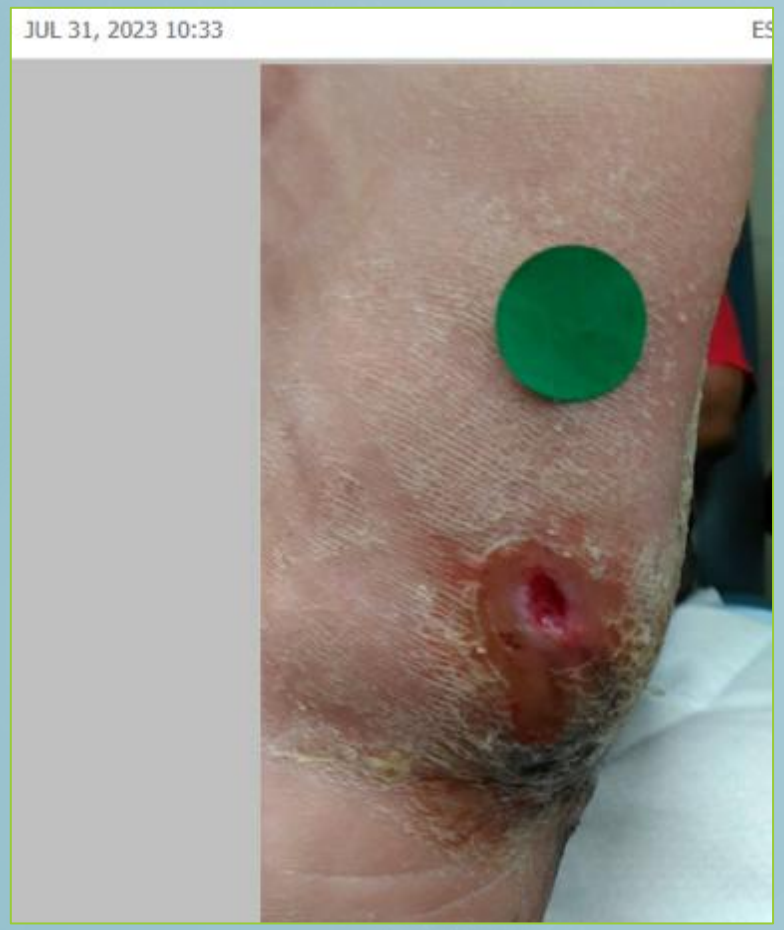
Case 2

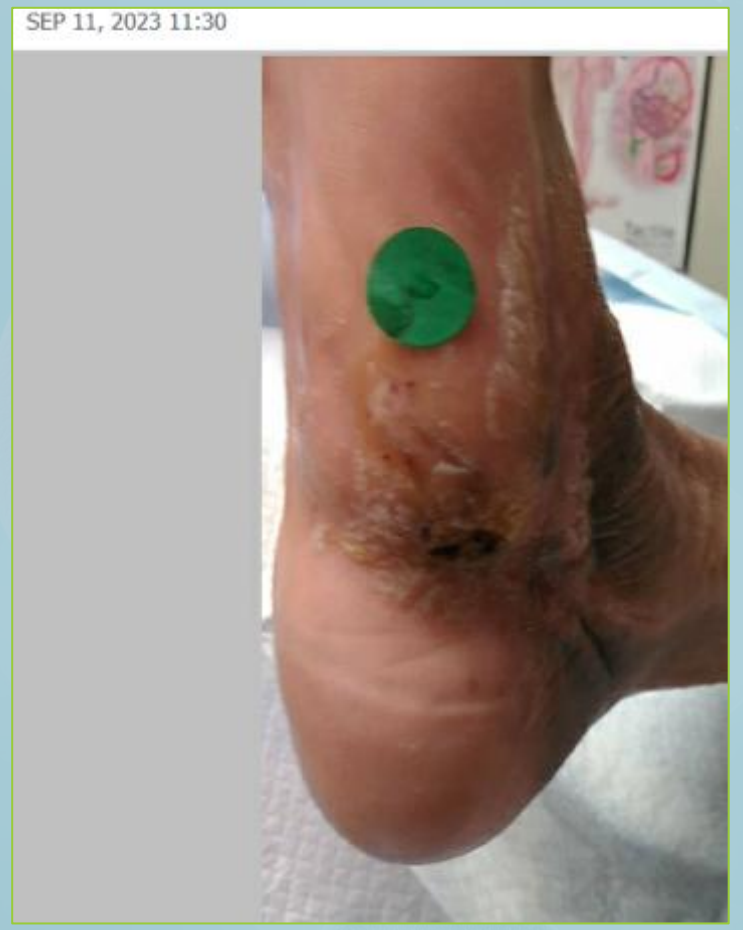


Case 2



10 Applications: 5/22/23–9/11/23





Wound Healing

		Δ 5/15/2023
Total Area	0.04 cm²	-85.03%
Length	0.24 cm	-64.55%
Width	0.2 cm	-63.63%
Perimeter	0.86 cm	-60.44%
Total Tunneling	0 cm	0%
Total Undermining	0 cm	0%

Case 3

- 89-year-old male
- Type 2 DM and history of PAD
- Has foot drop
- Sandal strap rubbed open the wound
- Pt presented with a left dorsal great toe wound for over 4 months
- Initial wound volume was 4.9 cm^3 and within 6 weeks volume decreased to 0.25 cm^3
- Total area decreased by 89% with 5 weekly MLPF patch applications and subsequent wound closure was achieved in 7 weeks

Patient 3

Patient 3

Final Measurements

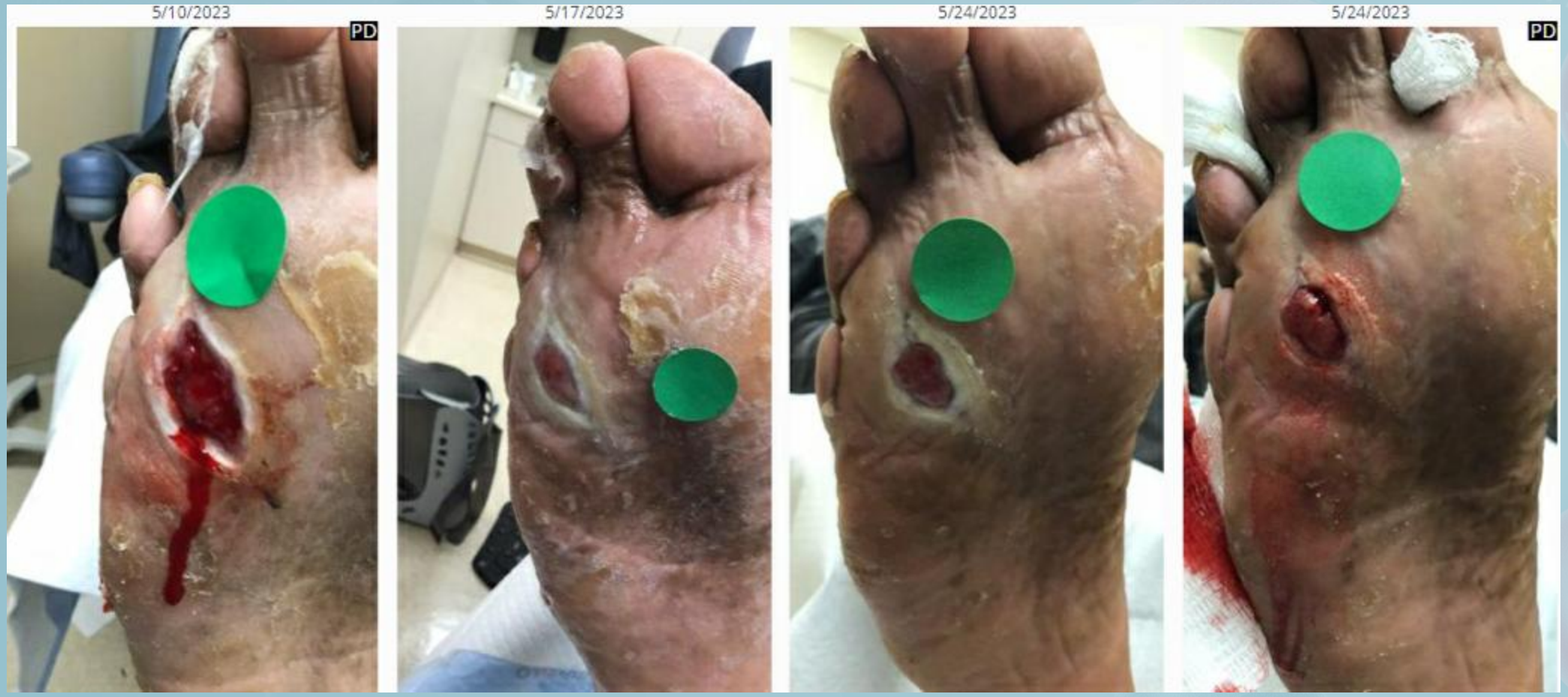
		Δ 6/26/2023
Total Area	0.21 cm²	-87.77%
Length	0.53 cm	-59.02%
Width	0.48 cm	-72.32%
Perimeter	1.77 cm	-67.93%
Total Tunneling	0 cm	0%
Total Undermining	0 cm	0%
Maximum Depth	0.1 cm	-50%

Case 4

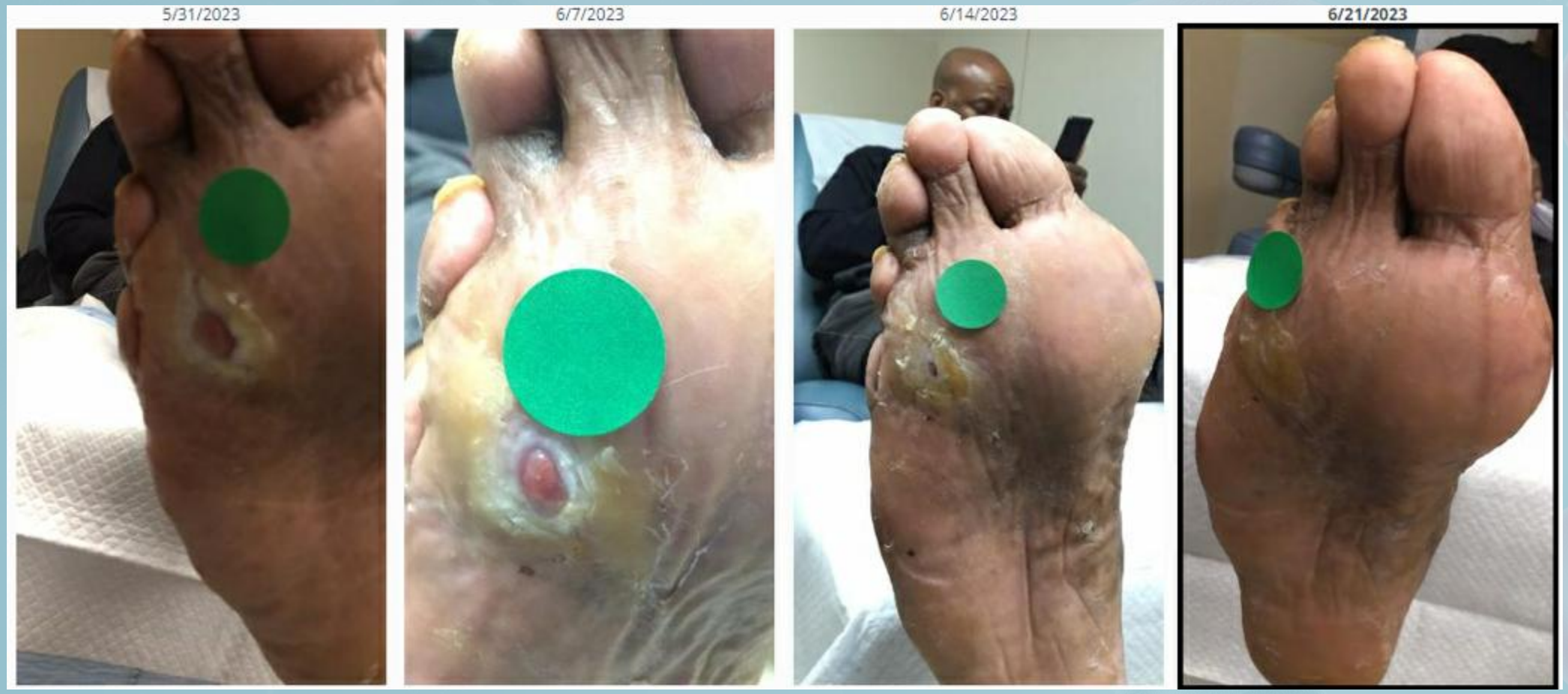
- 65-year-old male
- Type 2 DM
- History of surgical debridement on 3/21/23 of an infected plantar ulceration with application of collagen graft
- Pt presented for follow-up evaluation after 1-month nursing facility stay for IV antibiotics of underlying osteomyelitis
- Pt had protective weightbearing in a CAM boot
- Pt achieved full closure after weekly debridements and 5 weekly applications of MLPF patch

CAM = controlled ankle movement.

Plantar DFU



Plantar DFU



5/10/23–6/21/23 5 Applications

		Δ 5/10/2023
Total Area	0.21 cm²	-86.01%
Length	1 cm	-49.31%
Width	0.38 cm	-68.52%
Perimeter	2.69 cm	-55.56%
Total Tunneling	0 cm	0%
Total Undermining	0 cm	0%
Maximum Depth	0 cm	-100%

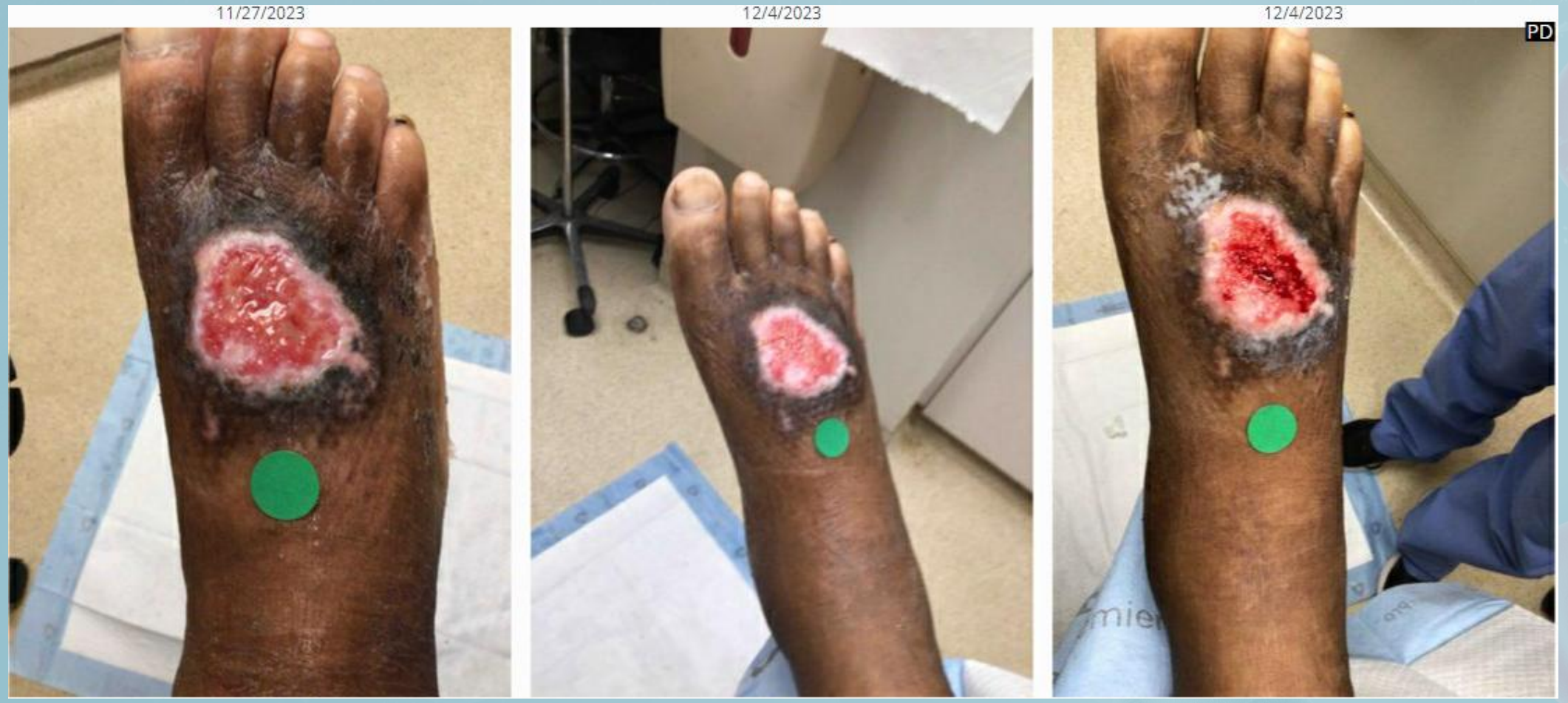
Case 5

- 58-year-old male
- Developed an ulcer due to severe lower extremity edema and resultant blister with full-thickness tissue loss
- Presented with eschar and colonized wound that was treated topically
- Pt was healing well when he suffered a CVA while in wound clinic
- No further grafting done
- Pt returned to clinic 1 month later, healed

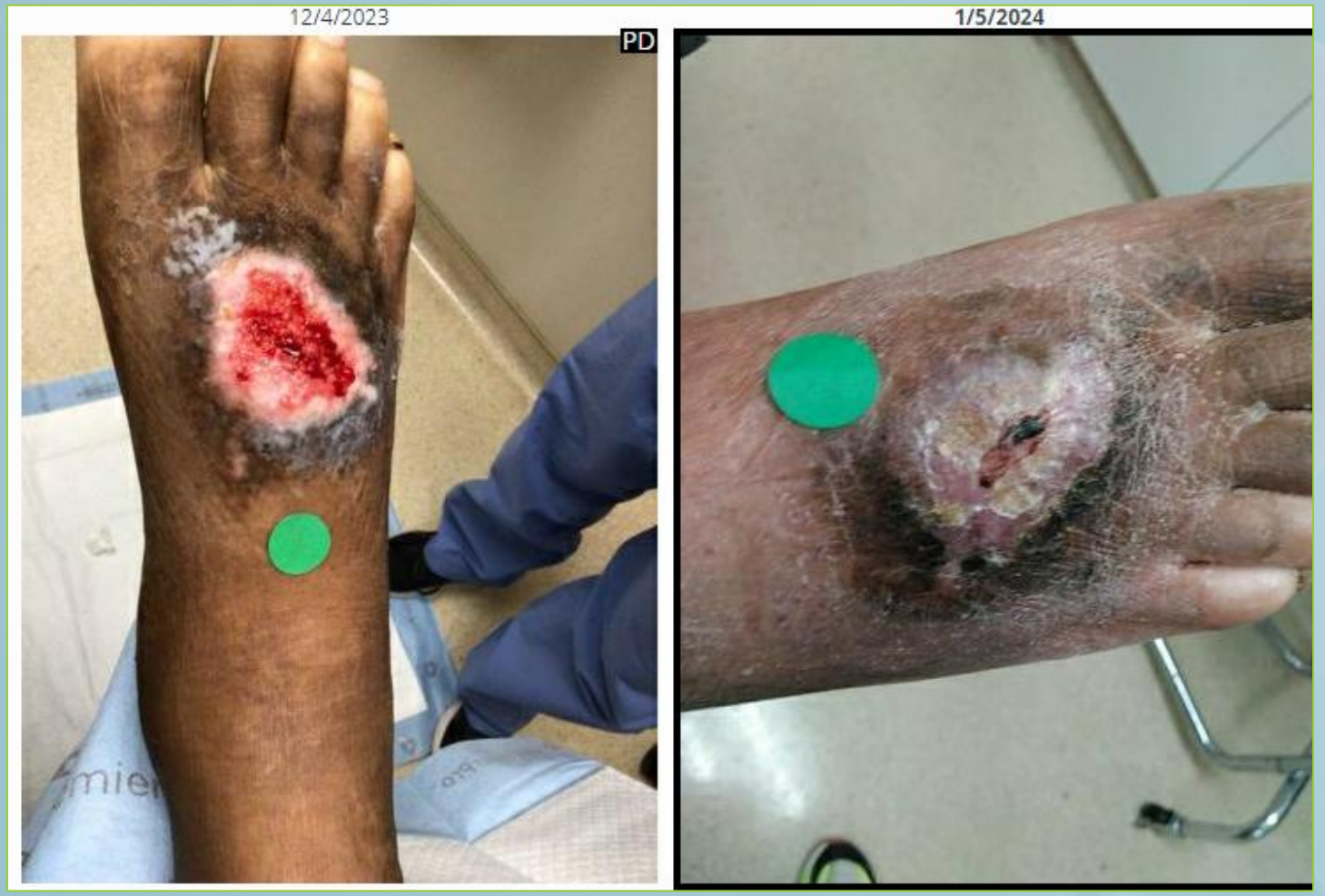
CVA = cerebrovascular accident.

Dorsal Foot Ulcer

Dorsal Foot Ulcer



Patient Was Admitted with CVA and then Sent to SNF. Continued to Heal to Closure



SNF = skilled nursing facility.

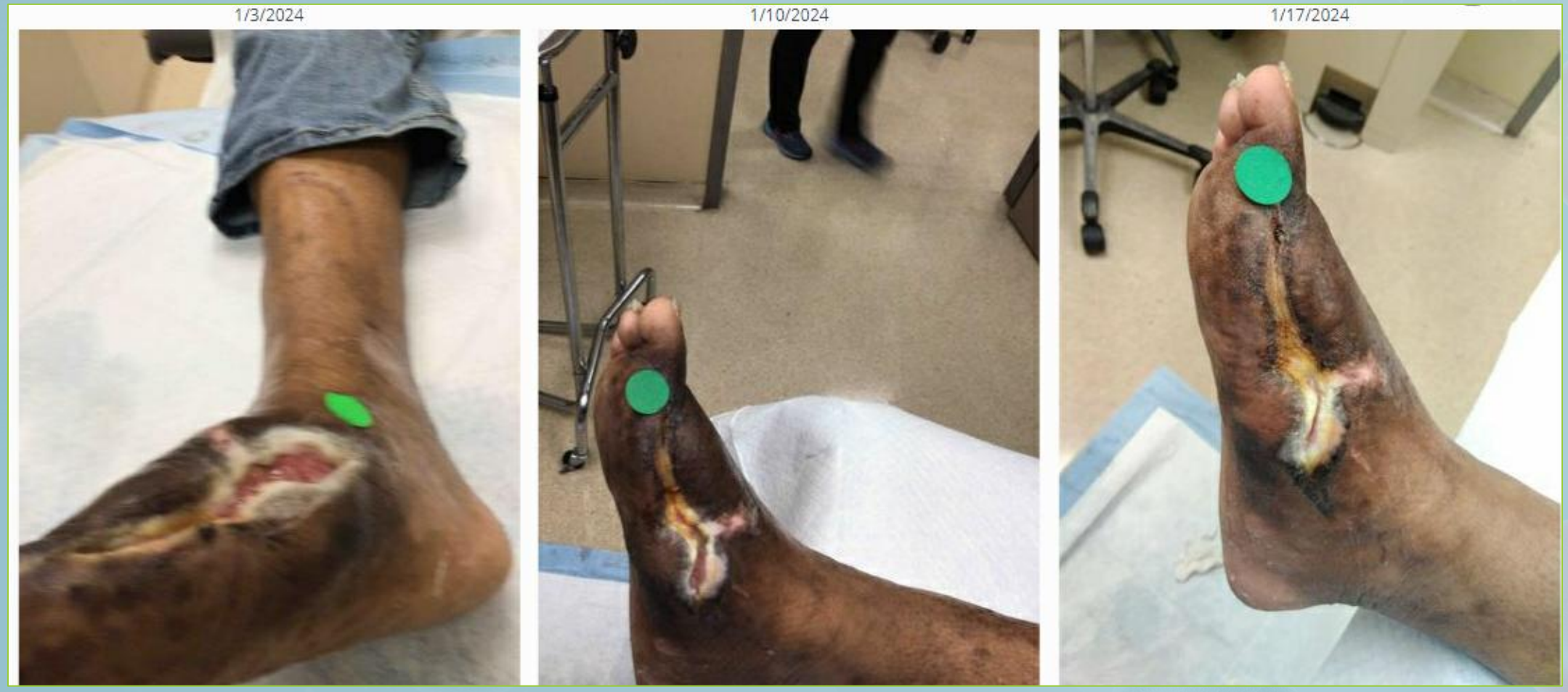
5 Applications, Admitted to Hospital after 5 Apps with CVA, Healed Once Returned to Clinic

		Δ 10/30/2023
Total Area	0.72 cm²	-93.61%
Length	1.24 cm	-65%
Width	1.14 cm	-72.92%
Perimeter	4.75 cm	-66.57%
Total Tunneling	0 cm	0%
Total Undermining	0 cm	0%
Maximum Depth	0 cm	-100%

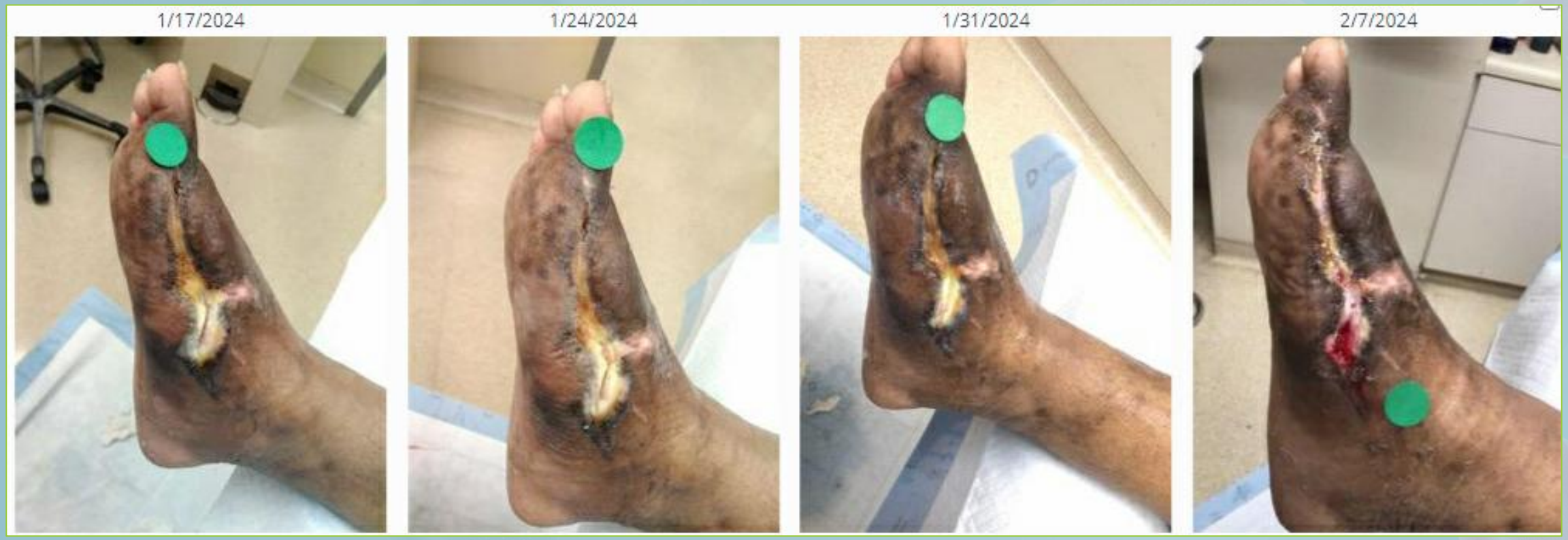
Case 6

- 46-year-old male
- Type 2 DM
- History of partial 1st ray amputation due to osteomyelitis
- After initial period of successful healing utilizing NPWT and antibiotics, osteomyelitis returned requiring further revision of the 1st metatarsal as well as 2nd metatarsal head
- Continued NPWT and IV antibiotics
- The tissue flaps remained viable and the underlying bone infection was resolved with granulation covering the bone
- MLPF patch initiated on 1/3/24 and full closure achieved with 7 weekly applications.

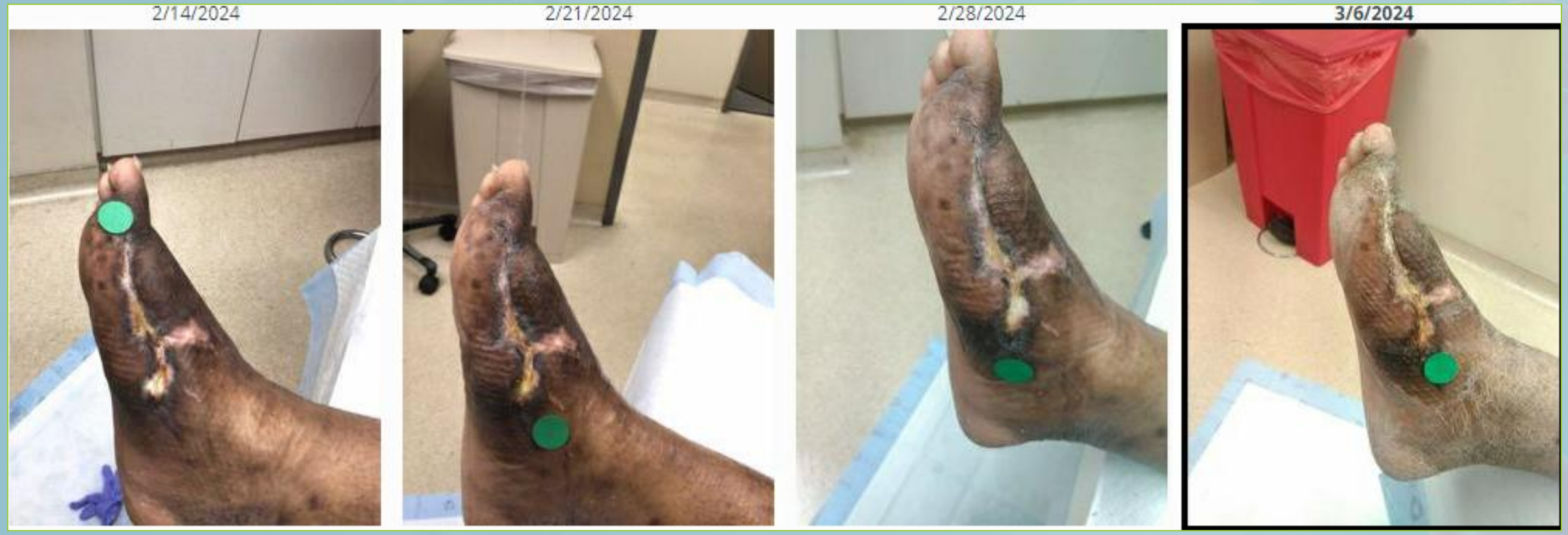
Chronic Neuropathic DFU with Challenging Offloading



Chronic Neuropathic DFU with Challenging Offloading



Chronic Neuropathic DFU with Challenging Offloading

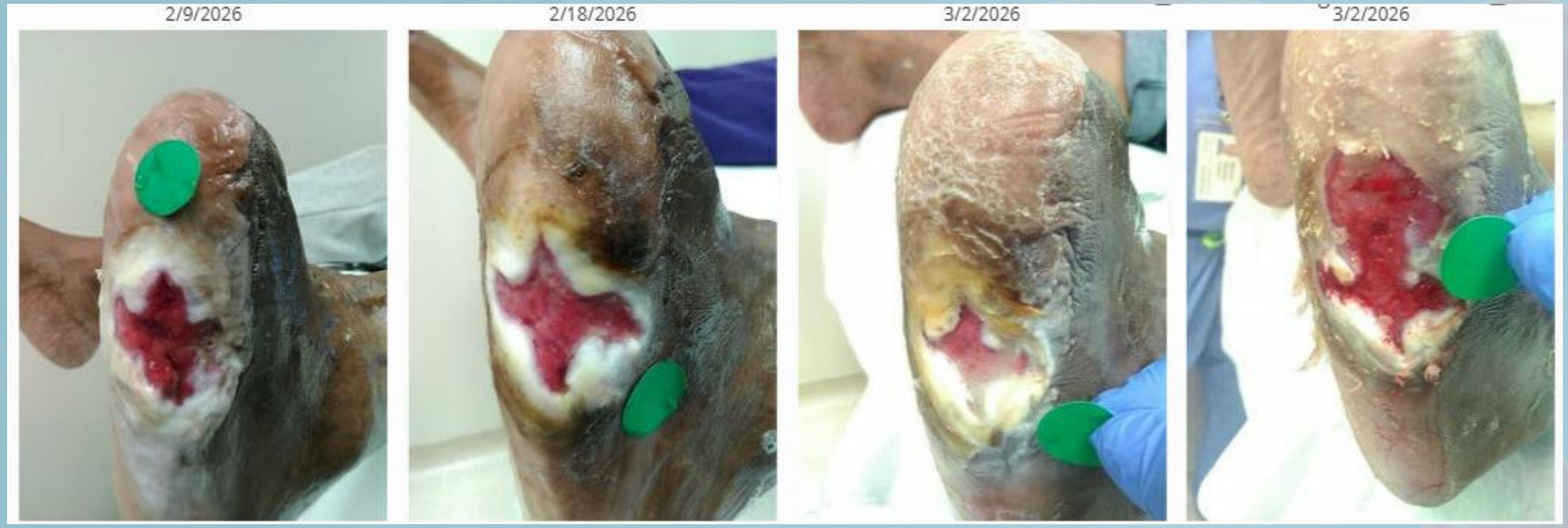


Case 7

- 52-year-old male neuropathic diabetic, PAD, live donor kidney transplant
- History of prior left foot transmetatarsal amputation with wound dehiscence treated successfully with MLPF
- Developed multiple left foot ulcerations after healing prior wounds, receiving his son's kidney after wearing a workboot instead of his prescription shoes and orthoses
- OR debridement 11/18/2025 with synthetic acelluar tissue graft, NPWT and initiation of antibiotics for osteomyelitis
- Removal of acellular grafts and initiation of MLPF 12/15 heel and 12/22 lateral foot
- Heel wound closed 3/23/2026
- Lateral wound nearly closed 3/30/2026

Initial Improvement with MLPF and NPWT

Wound Degradation after Period of Poor Compliance and Need to Stop NPWT



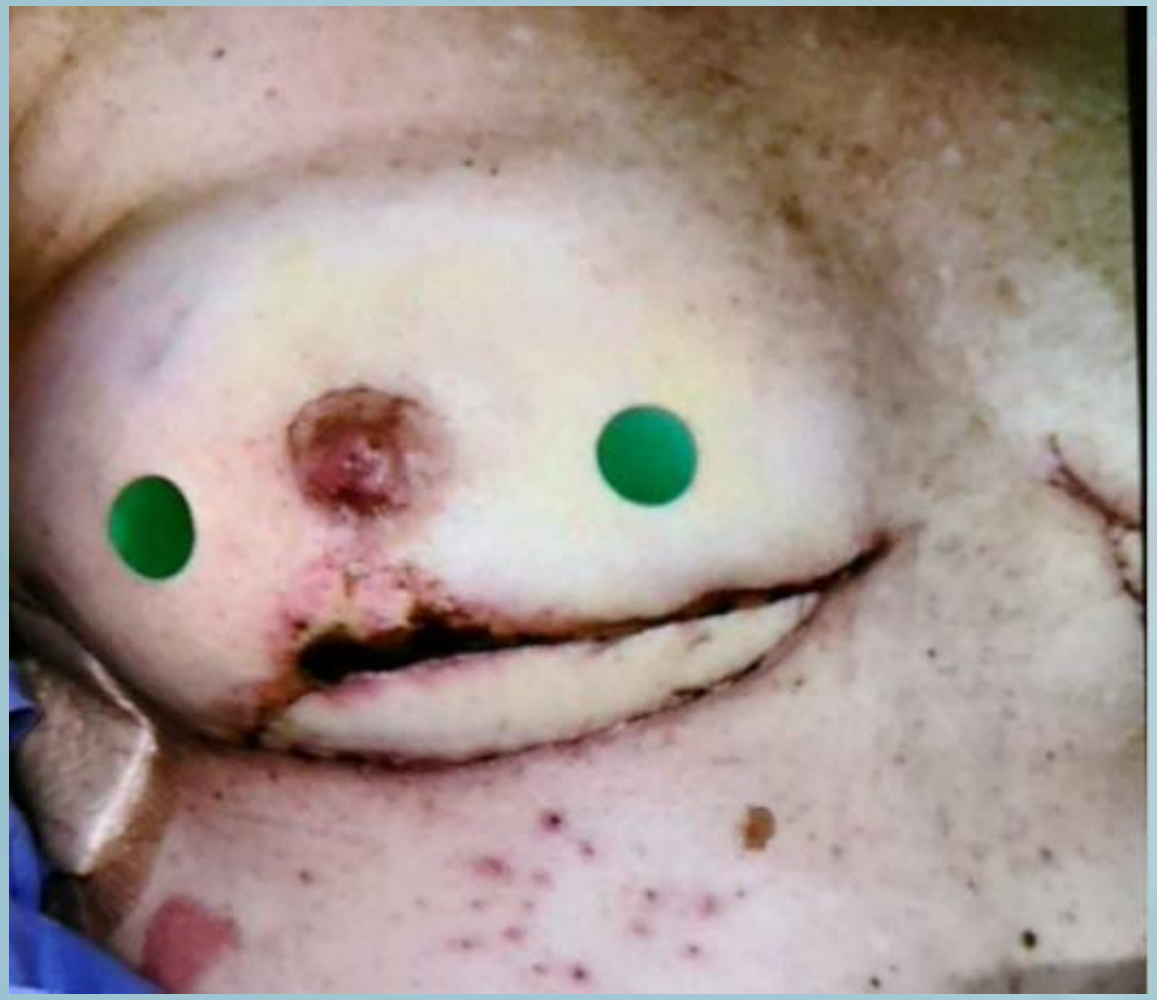
Rapid Recovery with Improved Compliance and MLFP

Non-DFU MLPF Cases

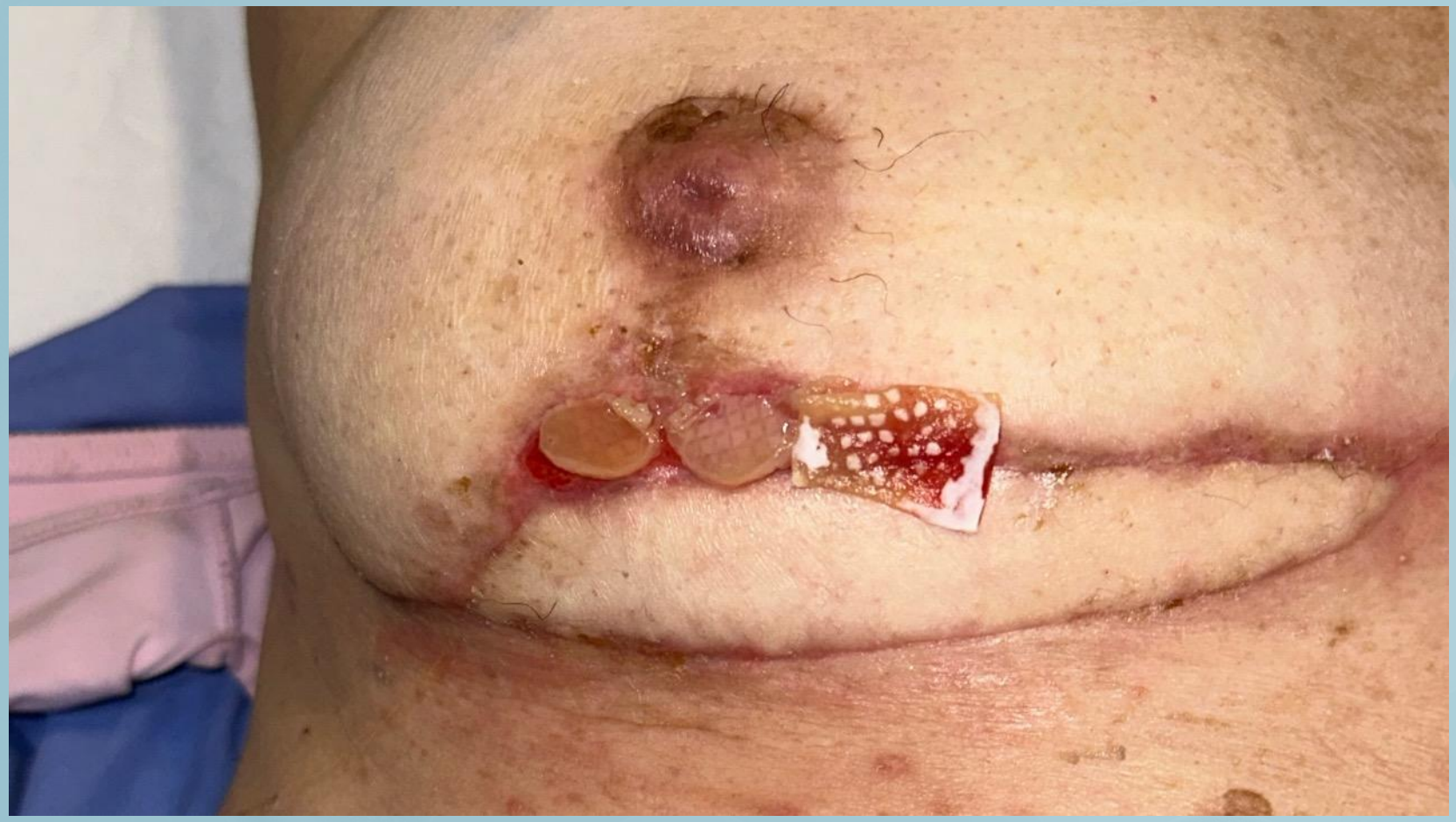
Case 1: Threatened Flap

- 53-year-old female with BRCA gene
- Had preventative bilateral mastectomies with immediate reconstruction using a deep inferior epigastric perforator (DIEP) flap
- During the surgery, SPY angiography showed ischemic insult
- HBOT was started the next day as per hospital protocol

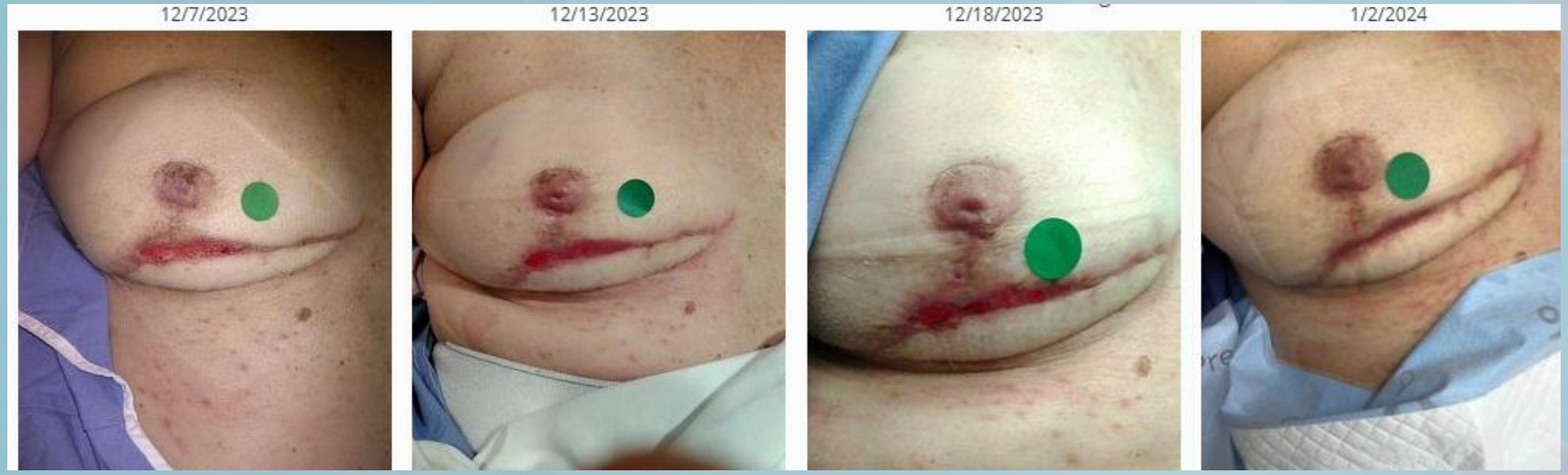
Threatened Flap after DIEP



Initial 4.7 x 2.2 x 0.2cm (11/20/23)



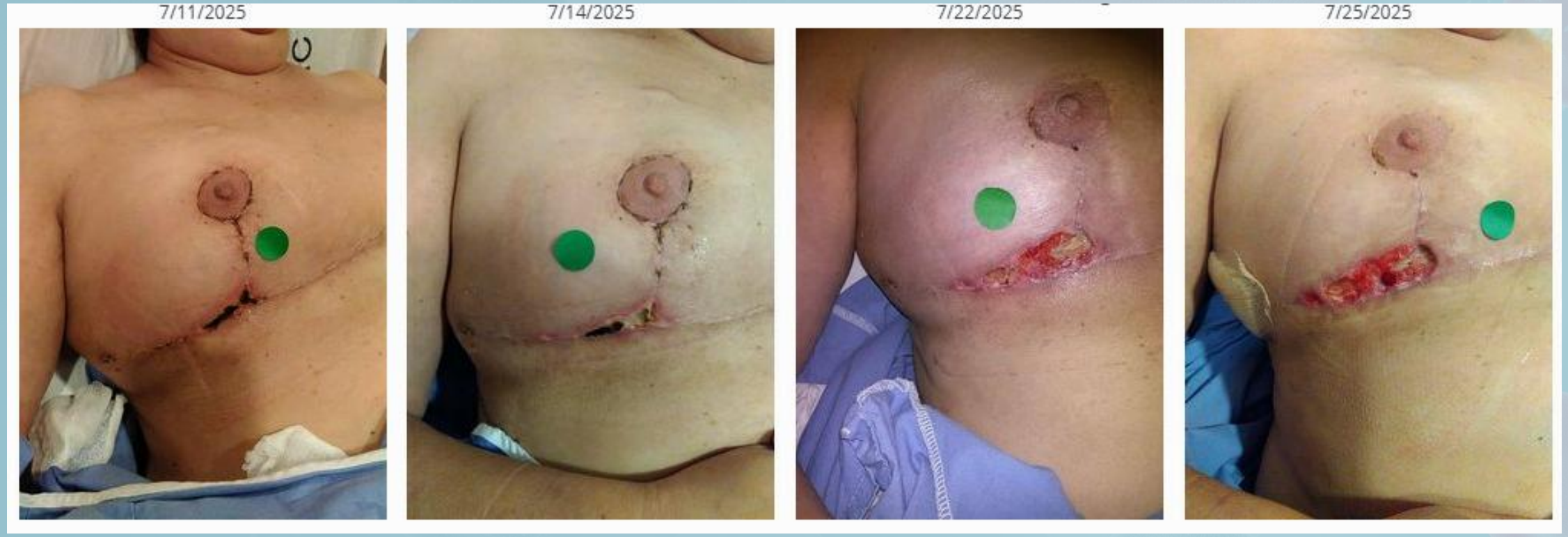
2 Applications



Case 2

- 53-year-old with Stage 3 breast cancer
- Underwent mastectomies with DIEP flap
- Had revision of flap on the left side at outside hospital
- Referred to Faculty's hospital for HBOT
- Awaiting chemo and radiation therapy

Initial Post Debridement: 7.6 x 2.8 x 0.3cm 7/25/25

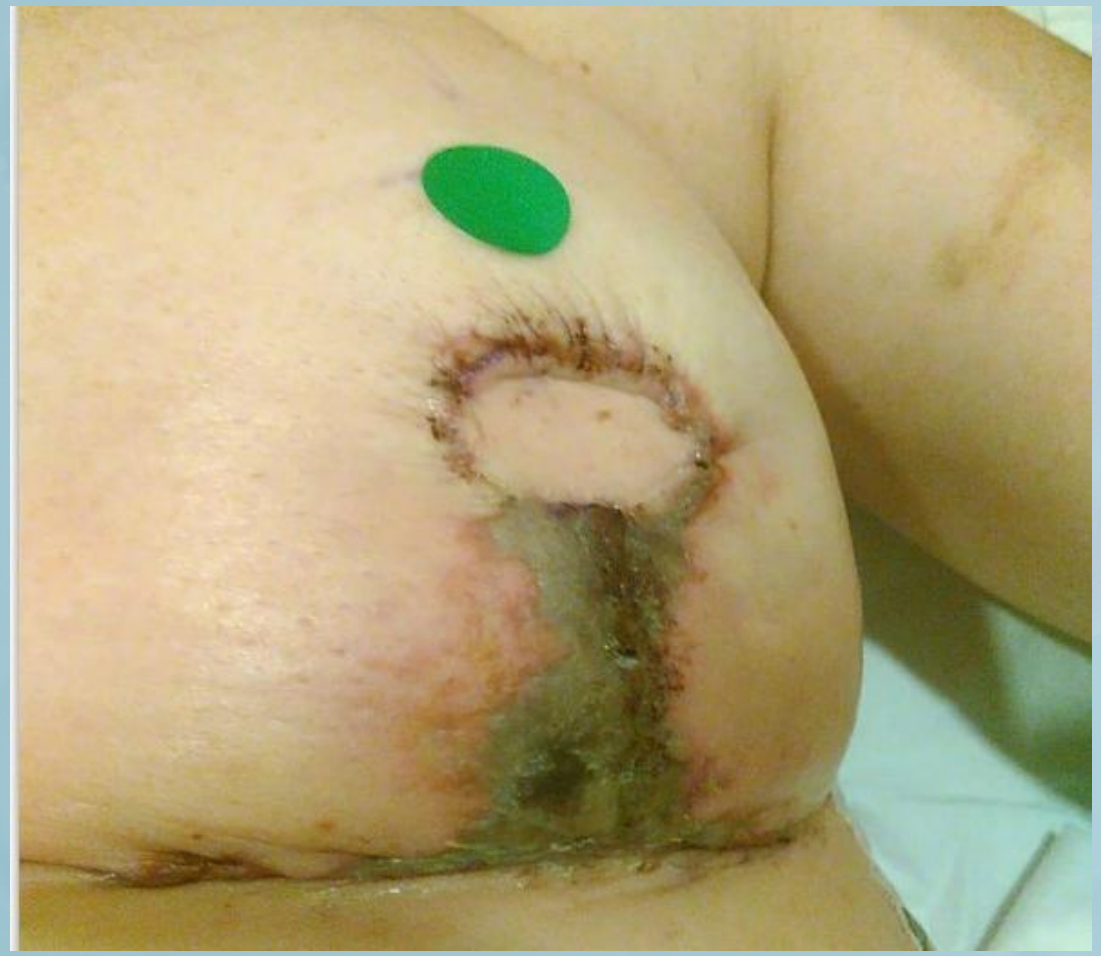


3 Applications

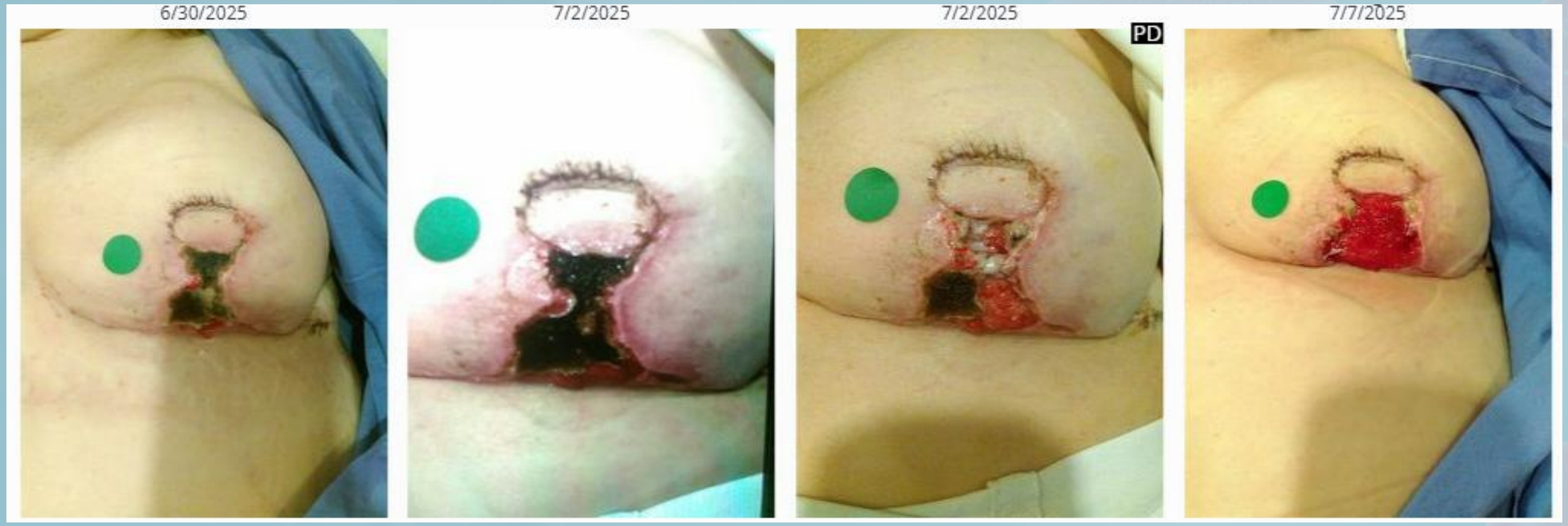
Case 3

- 45-year-old with Stage 3 breast cancer, left breast
- Underwent chemo
- Had bilateral mastectomies with immediate reconstruction using DIEP flaps
- HBOT was started the next day as per hospital protocol
- Patient did not want surgical revision if possible

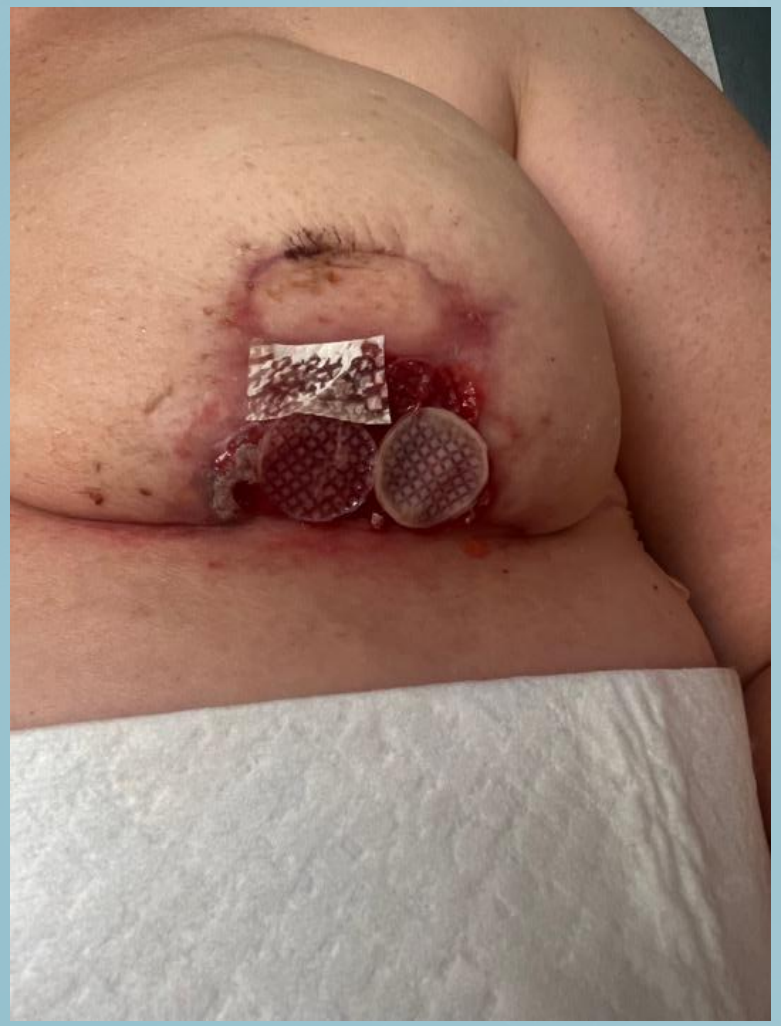
Initial Tissue Ischemia: 6/20/25, 20 Dives HBOT

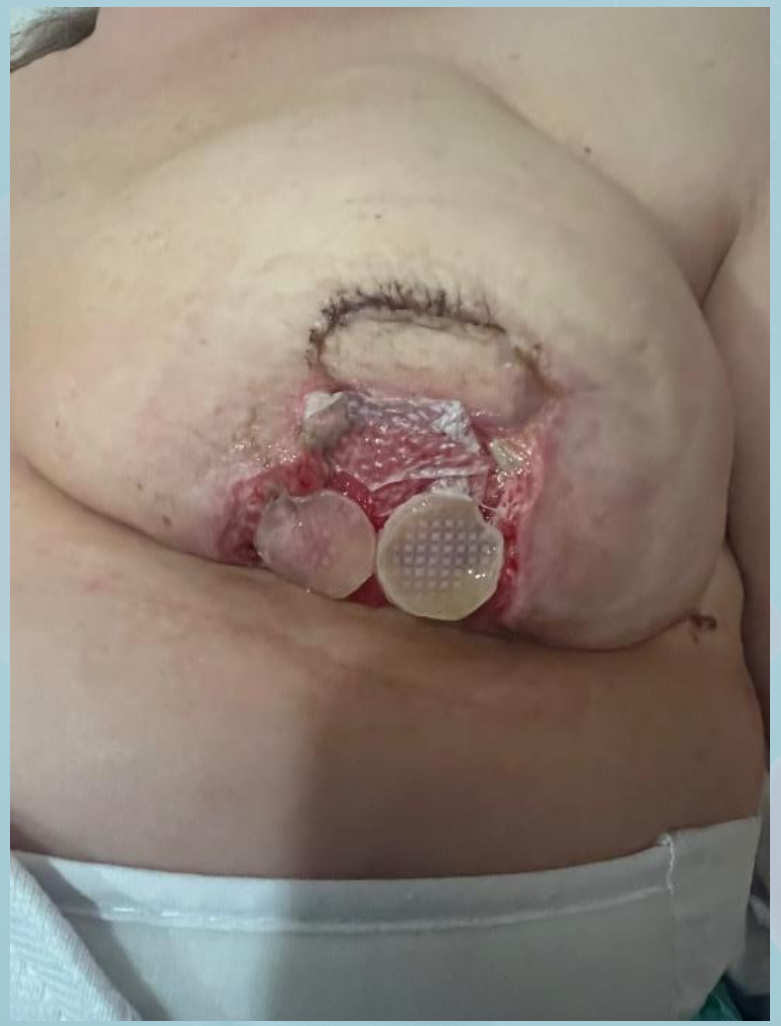


Initial Measurements: 4.7 x 3.8 x 0.3cm 7/7/25

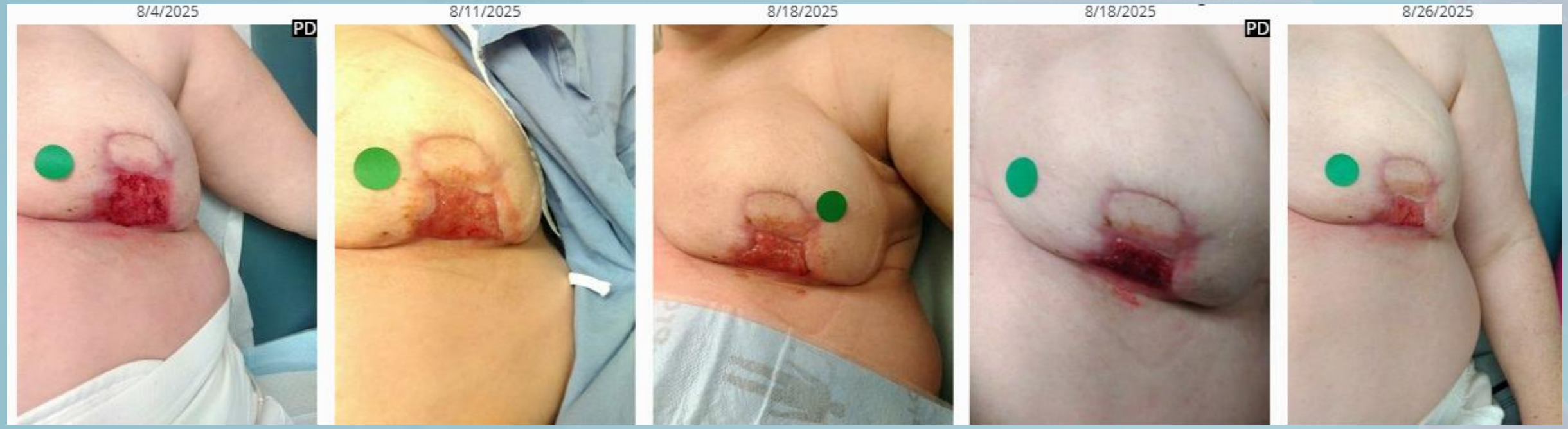


July 2025

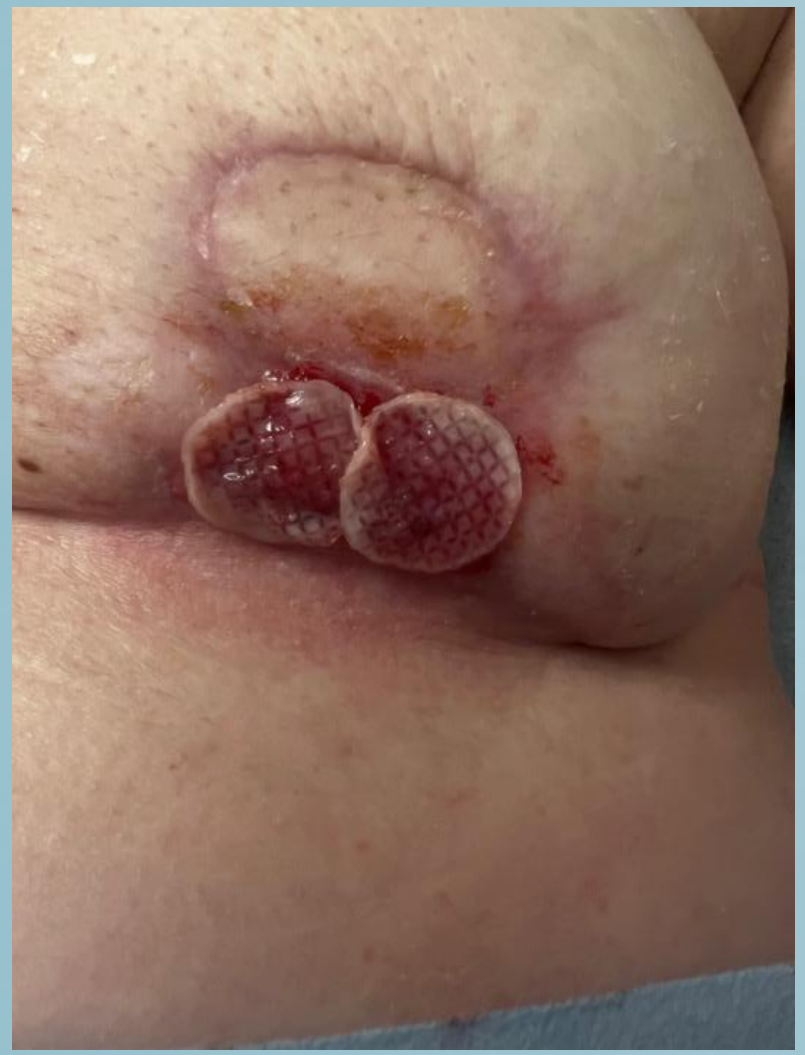


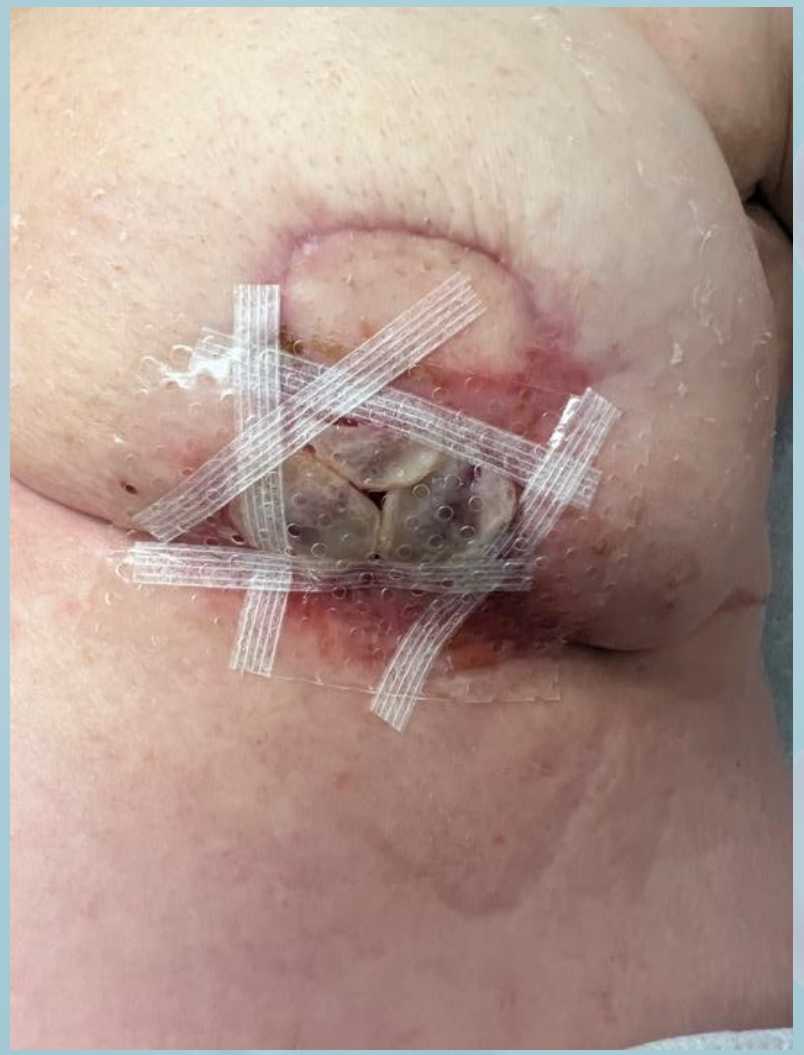


Continued Local Care and MLPF Applications



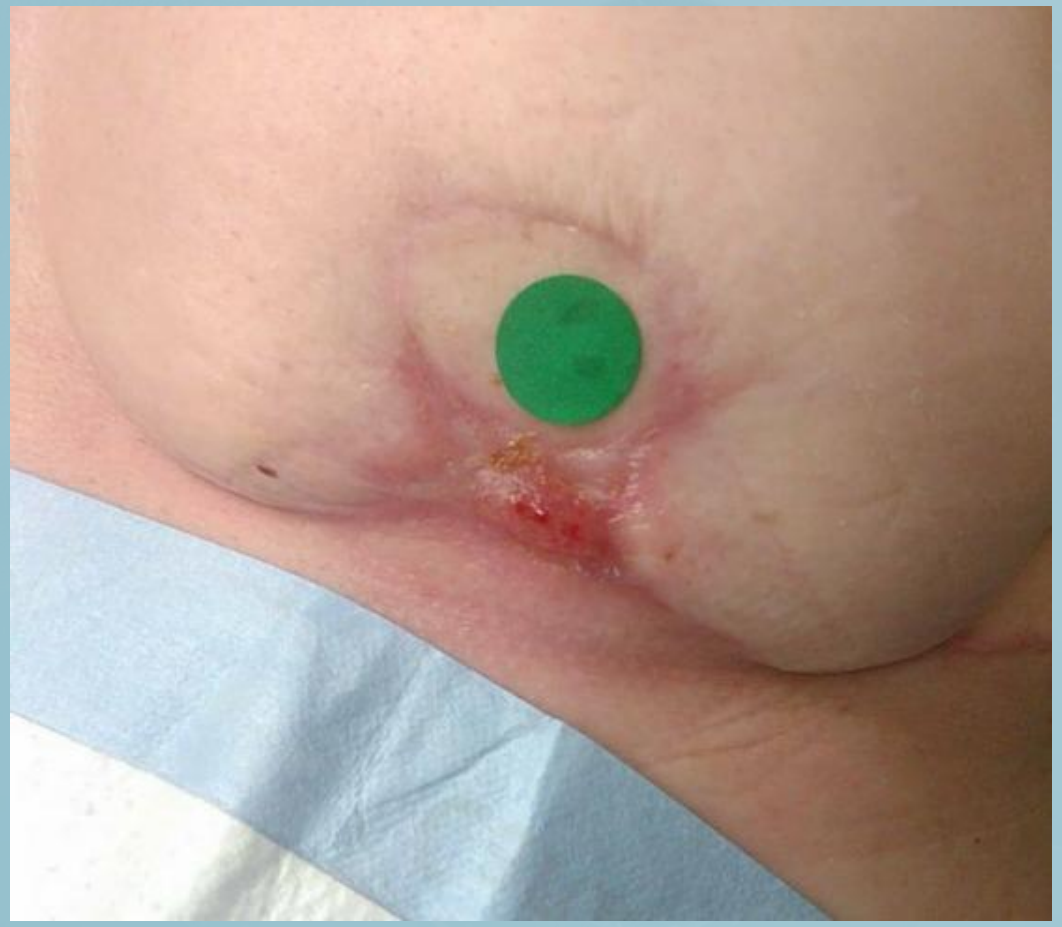
August 2025

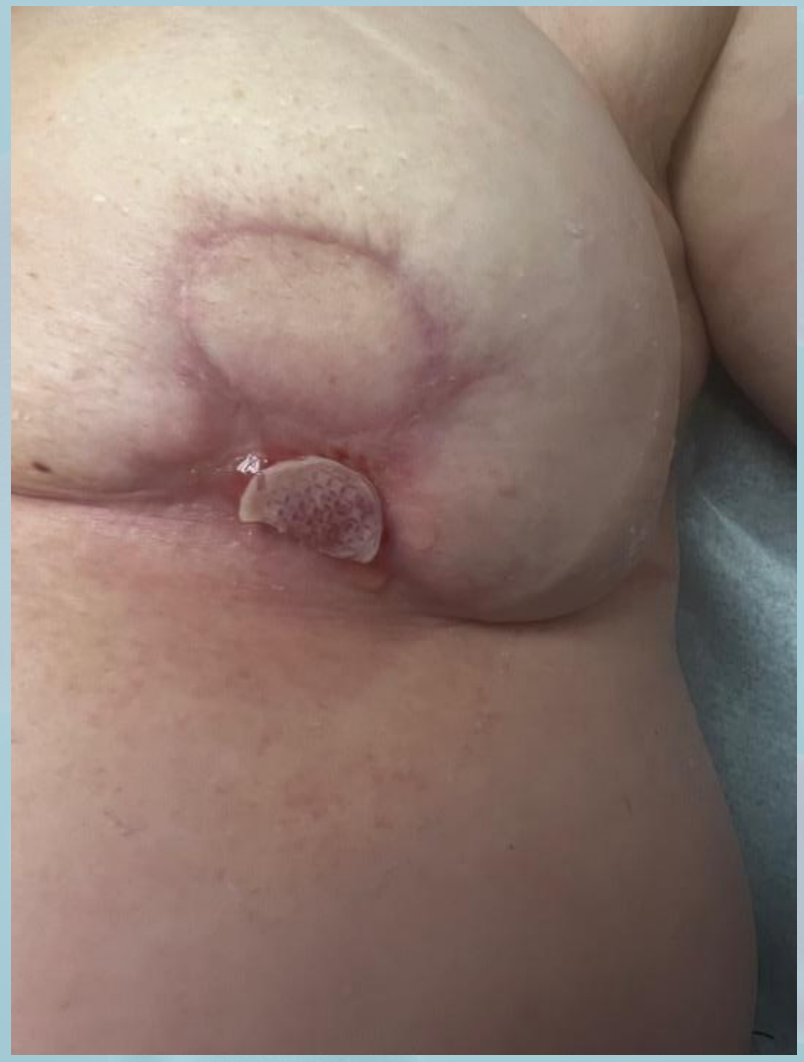




September 2025

September 2025



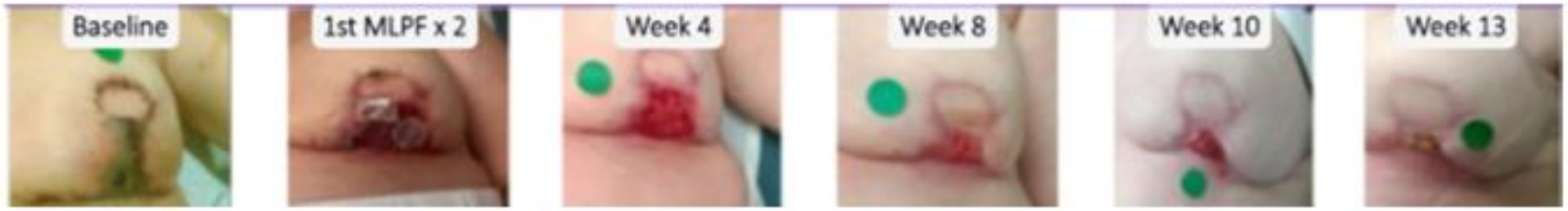


Use of Autologous MLPF Patch in Ischemic Breast Flaps

Three breast cancer patients undergoing mastectomy with DIEP flap reconstruction developed partial flap necrosis. MLPF Patch therapy, combined with 20 HBOT sessions, resulted in wound closure in all patients.

Patient 1— 45 y/o Female

- Initial measurement 4.7 x 3.8 x 0.3cm
- 12 weeks MLPF Patch therapy
- **Wound closed**

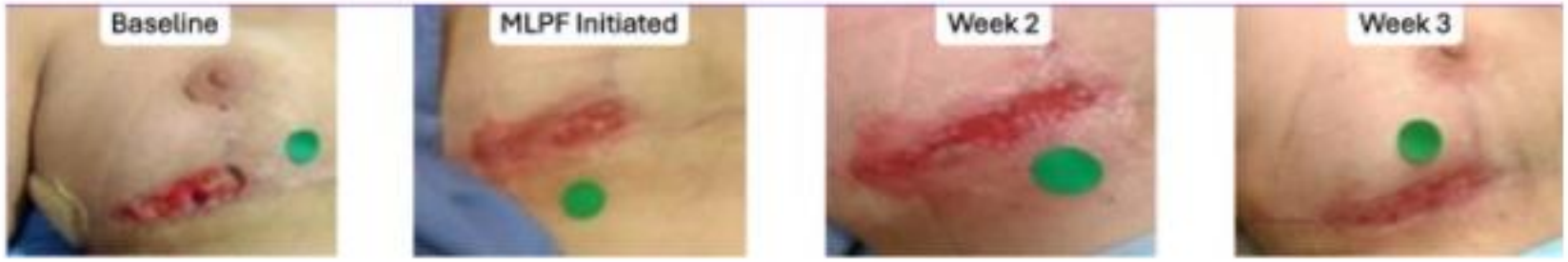


Patient 2 — 53 y/o Female

- Initial measurements 4.7 x 2.2 x 0.2cm
- **2 applications MLPF Patch therapy, wound closed**

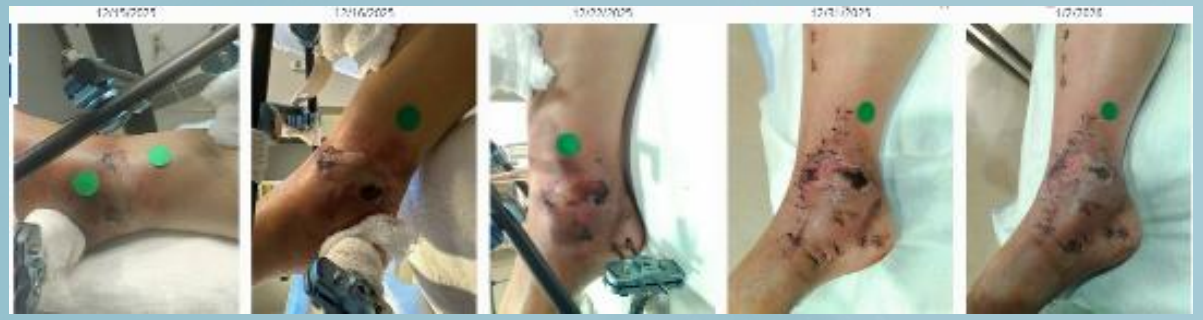
Patient 3— 52 y/o Female

- Initial measurements 7.6 x 2.8 x 0.3cm
- **3 applications MLPF Patch therapy, wound closed**



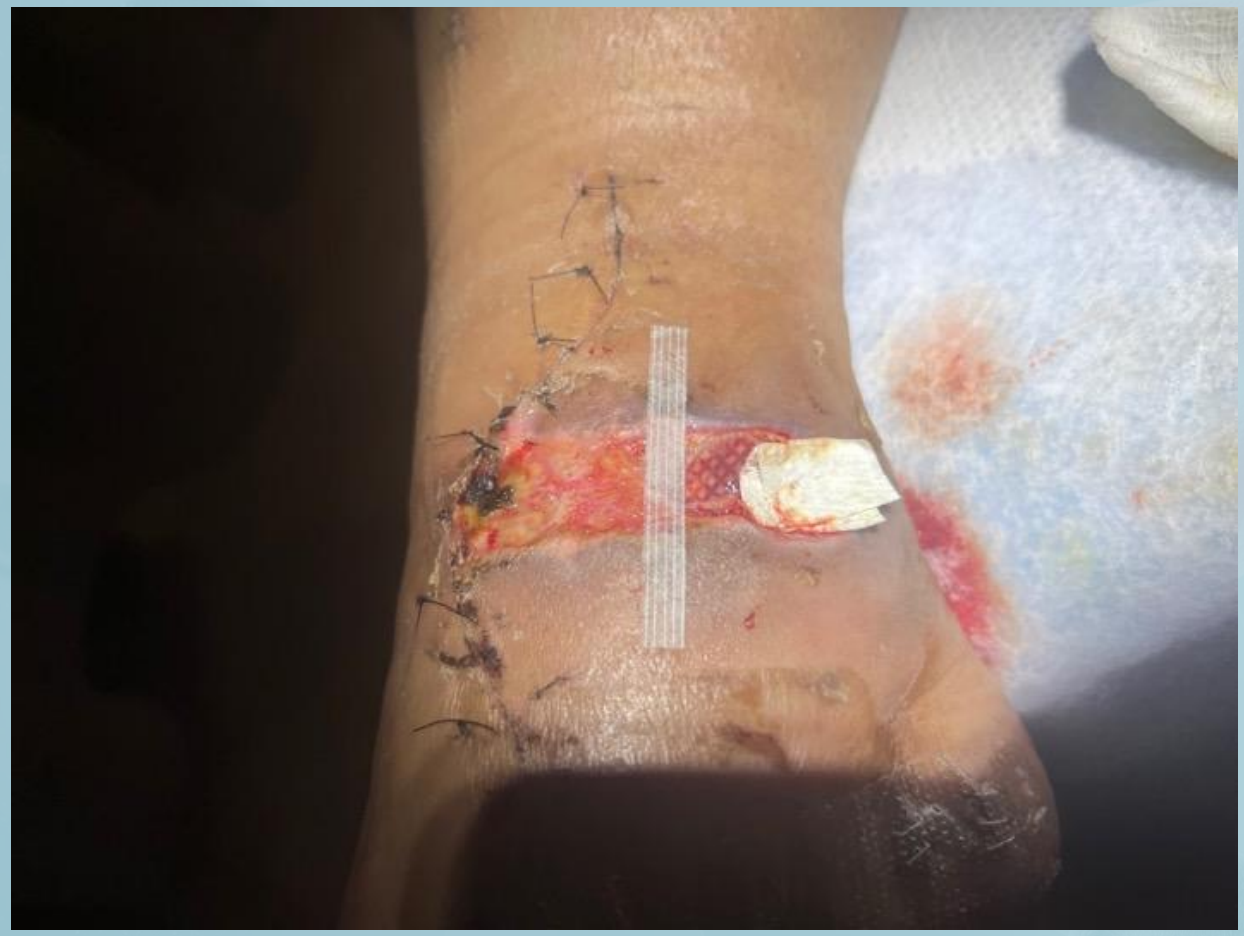
Lower Extremity Crush Injury

- 47-year-old female who fell off a stepladder and sustained a severe tibia-fibula fracture as well as a crush injury
- HBO was started to assist with healing
- ORIF incision needed to pass close to area of ischemic insult

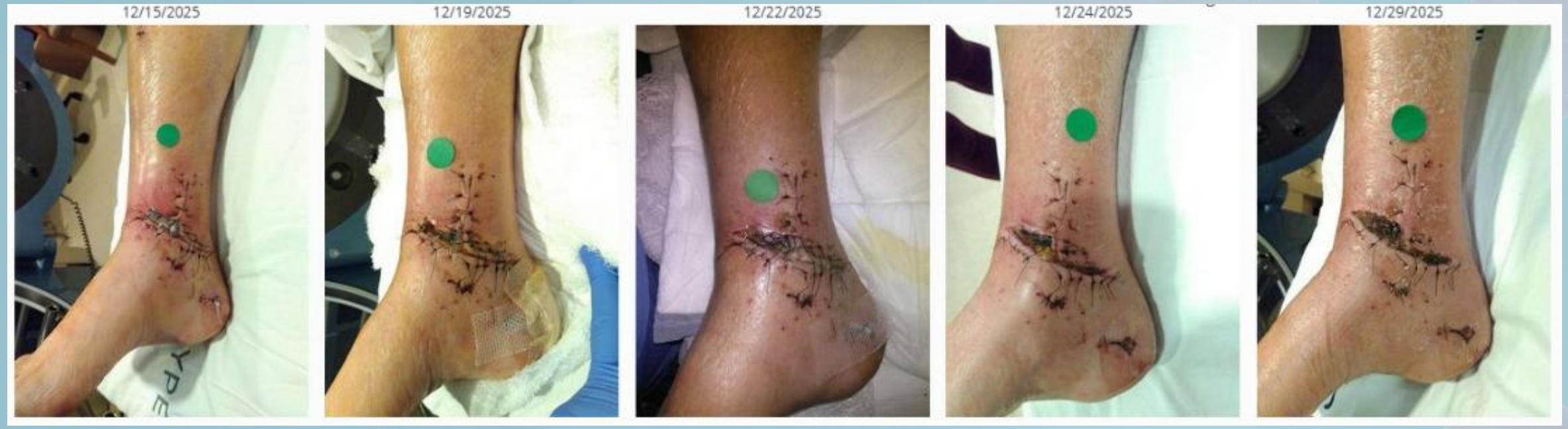


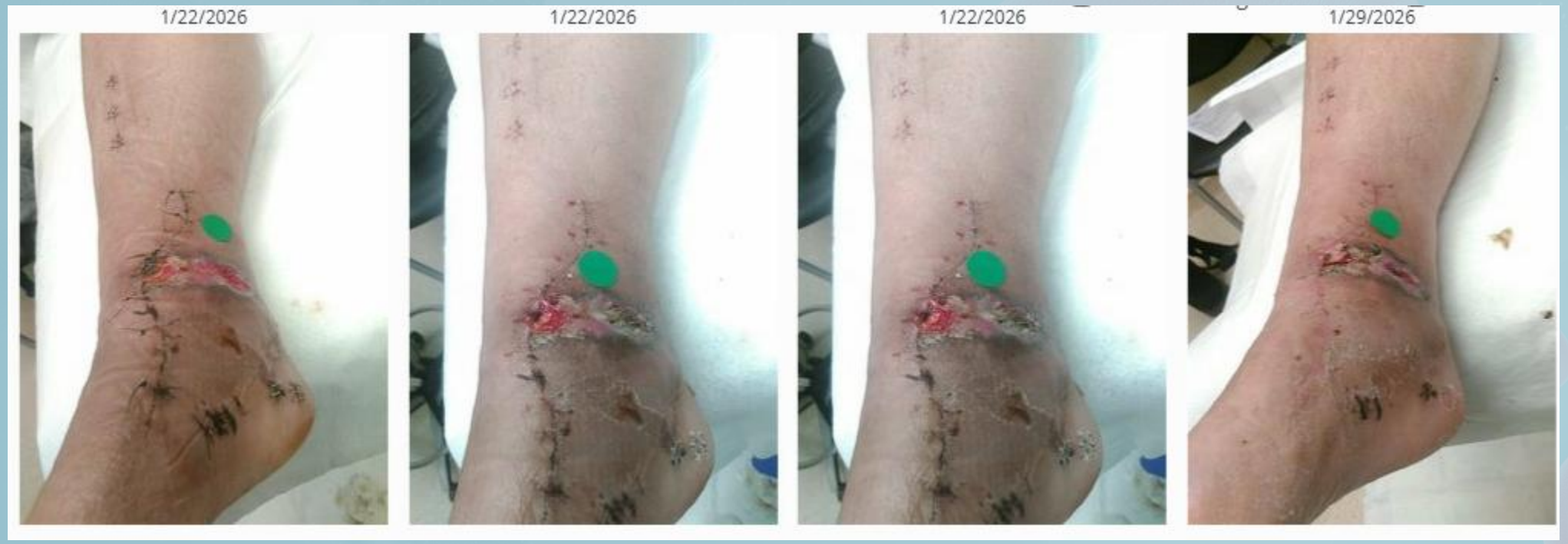
ORIF = open reduction and internal fixation.

First Application



Local Care

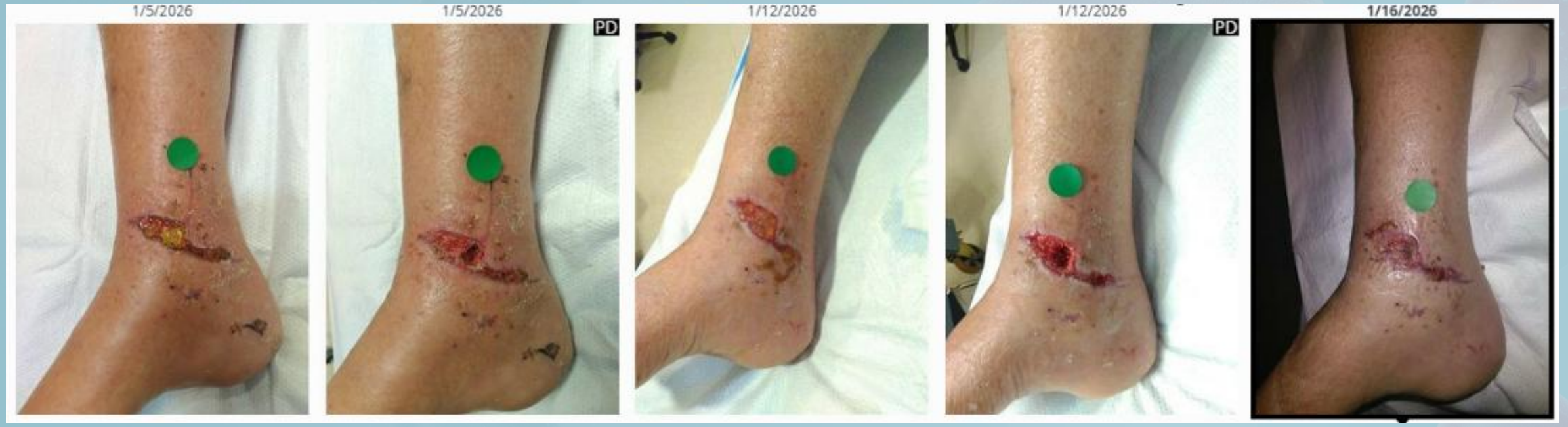



1/22/2026
1/22/2026
1/22/2026
1/29/2026

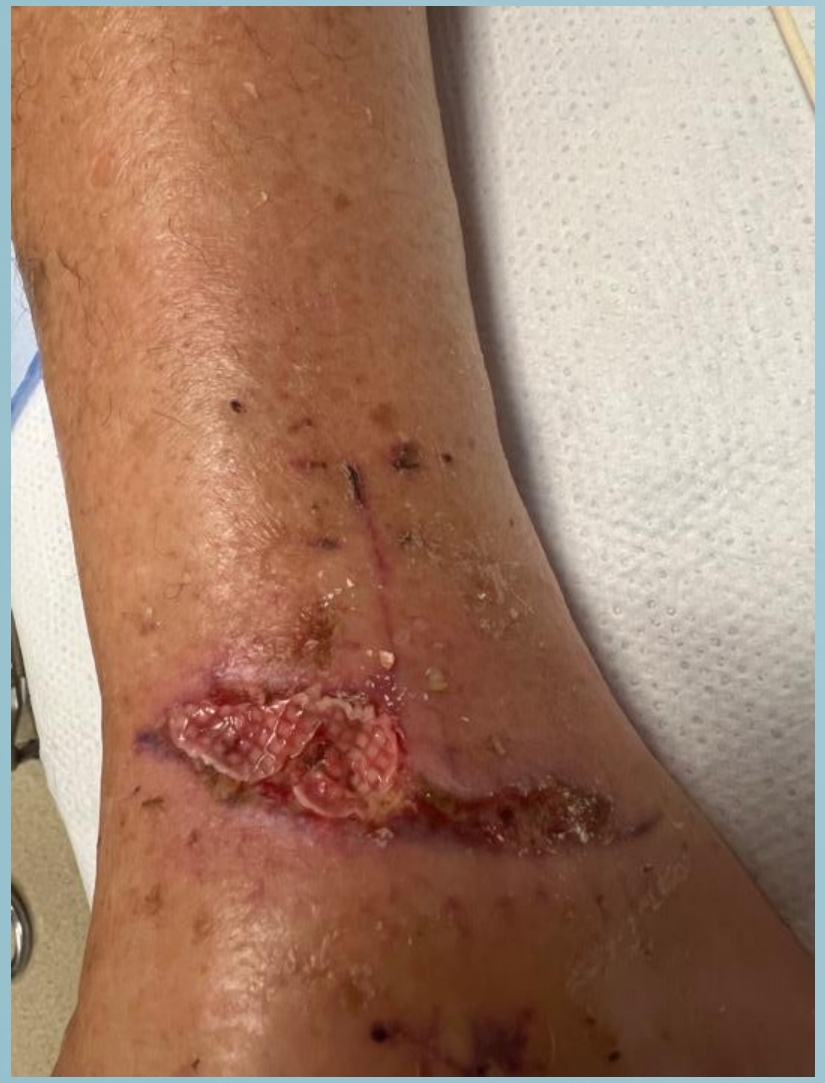
Lower Extremity Threatened Flap

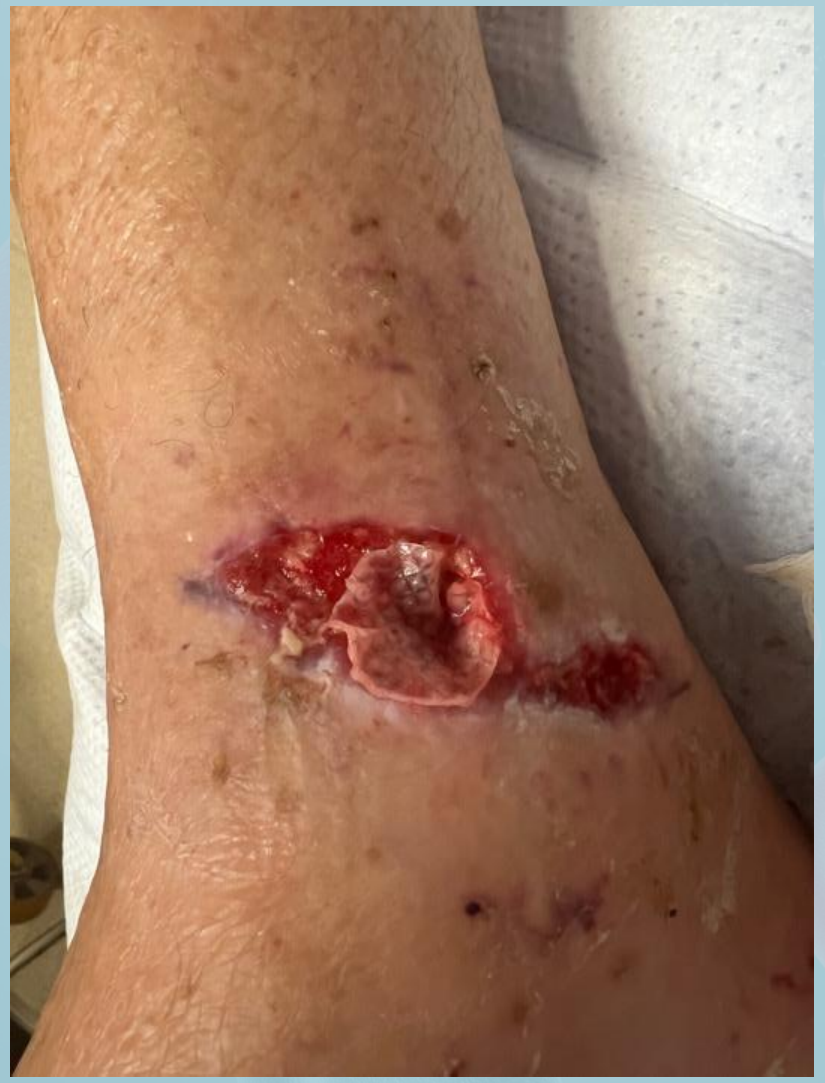
- 67-year-old female visiting from out of state
- Tripped over a scooter when getting out of a car
- Sustained open ankle fracture
- Poor candidate for a free flap for coverage
- HBOT commenced

Initial Images



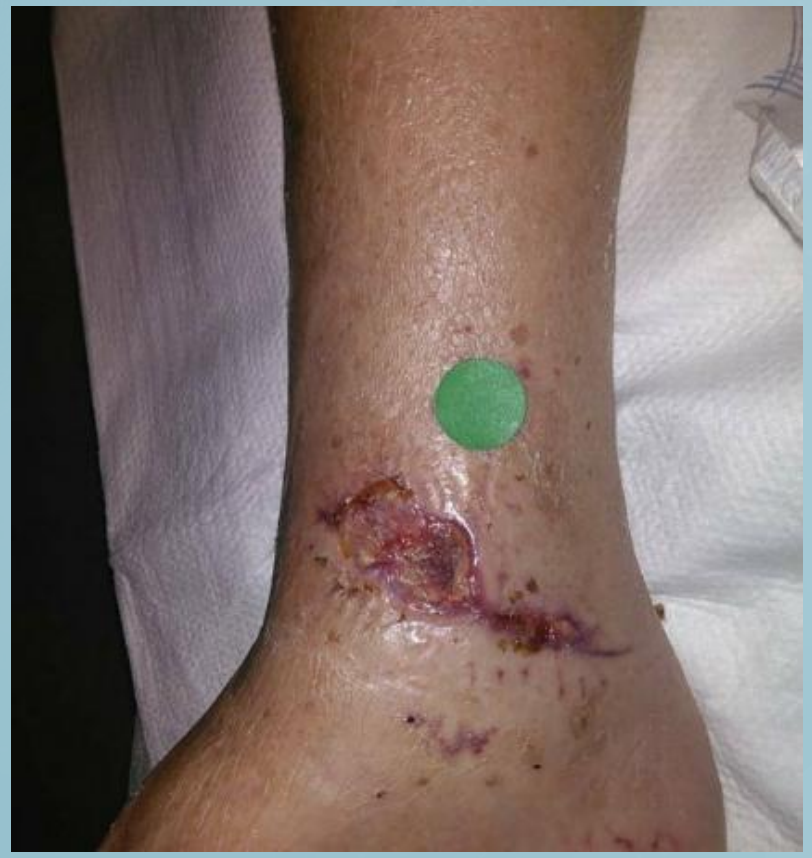
First and Second Applications

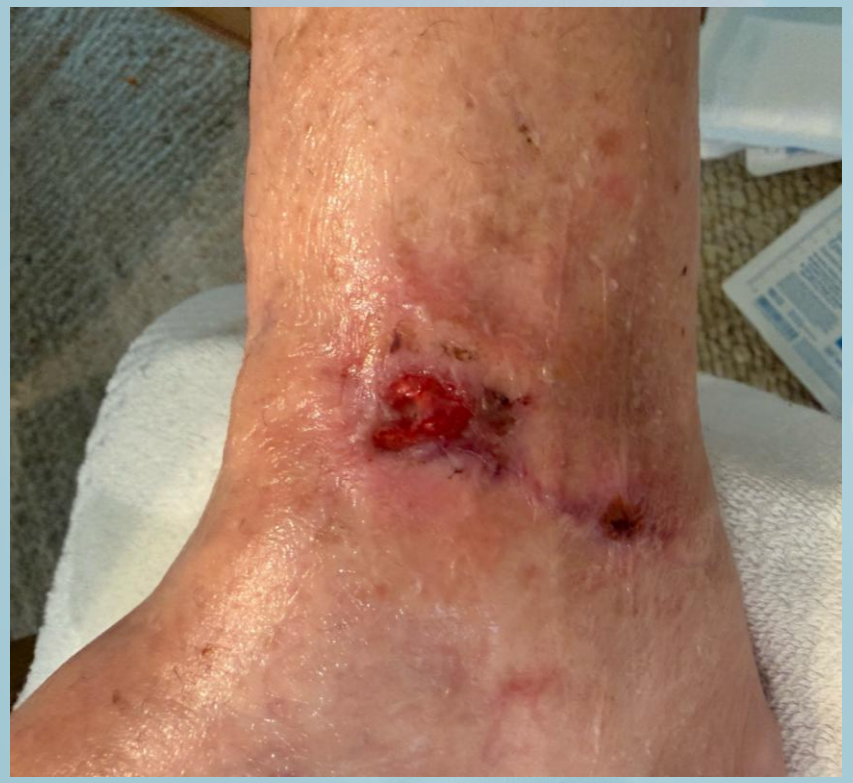




Jan–March 2026

- Patient returned to her home state in early January. She sends updated pictures!

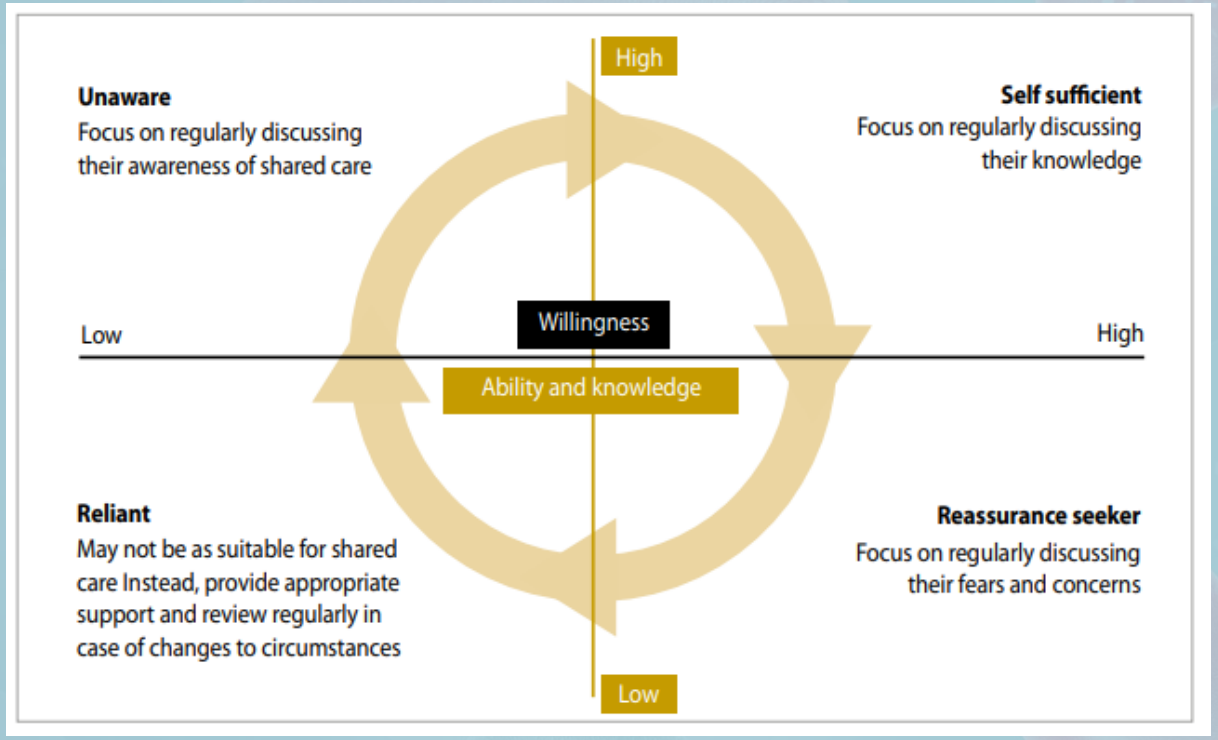




Patient Engagement

- Patient education
- Shared decision making
- Explore new treatment options
- Involve patient and caregiver in the wound care
- Potential of autologous wound care for patient engagement
- Patient-physician trust

Potential levels of patient involvement



Moore Z, et al. *J Wound Care.* 2025;34(10):790-796.

Three Years of MLPF Experience

- Has become our wound center's first preference for patients (as per their insurance coverage) for treatment of both new and chronic DFU wounds, outperforming other advanced CTPs
- Can be utilized in wounds present for less than 4 weeks with comprehensive documentation of necessity
- Effectiveness enhanced and integrates well with other modalities such as NWPT with a once-a-week integrated dressing, especially in acute/postsurgical and open amputation wounds
- Reduced infection risk
- Consistent product between operators and visits, and reduced cost and inventory issues over CTPs

CTP = cellular/tissue-based product.

Summary

- MLPF is an autologous blood product that is proven to heal DFU
- It has the highest levels of evidence to show its efficacy
- None of the patients treated with MLPF underwent any level of amputation nor were admitted to the hospital with a wound infection during the treatment period
- MLPF has efficacy in healing complex wounds that are not DFU
- It can be easily incorporated into a busy wound center flow

Questions?

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