
# Faculty

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## Learning Objectives

- Review clinical evidence on the use of mechanically powered negative pressure wound therapy
- Recognize the importance of an effective wound therapy in minimizing interference with patients' overall activity, enhancing mobility and overall preservation of quality of life
- Explore outcomes of a variety of wounds treated with mechanically powered negative pressure wound therapy through case studies

# Mechanically Powered Disposable Negative Pressure Wound Therapy for the Outpatient Setting

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# Introduction

- NPWT has been studied across multiple care settings and wound types over the past 15 years
- Many types of NPWT are available
  - **Electrical** – Generally considered the original, consider size, weight
  - **Mechanical** – The new kid on the block, generally smaller, less weight
- Similar mechanisms of action

**NPWT = negative pressure wound therapy.**
**Armstrong DG, et al. *Wound Repair Regen.* 2012;20(3):332-341. Lerman B, et al. *Plast Reconstr Surg.* 2010;126(4):1253-1261. Marston WA, et al. *Adv Wound Care.* 2015;4(2):75-82.**

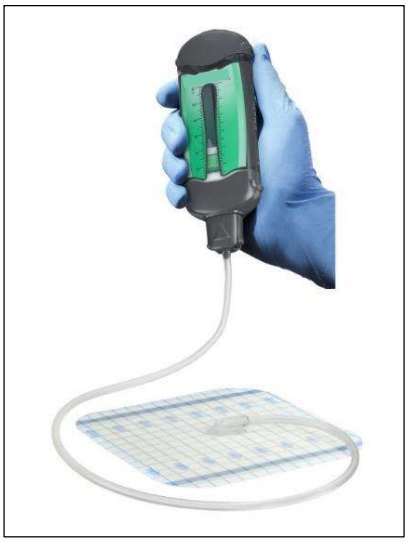
# The MP-NPWT Story

- **Stanford Biodesign and Engineering Program**
  - Students assigned wound care topic
    - Plastics, Engineering, Business
  - Clean sheet design
    - Used survey results to focus on portability
      - QOL – size, weight, noise
  - FDA approval August 2009

**MP-NPWT = mechanically powered NPWT; QOL = quality of life.**

# Introducing the MP-NPWT Wound Care System

- Combines the simplicity of advanced wound dressings with the proven benefits of negative pressure therapy in a discreet design



Armstrong DG, et al. *Wound Repair Regen.* 2012;20(3):332-341.

# NPWT: From Portable to Wearable

# NPWT: From Portable to Wearable

# MP-NPWT Wound Care System
## Value Proposition

### High QOL Scores

- Patient QOL Exit Survey findings:
- MP-NPWT Wound Care System vs NPWT
  - Less noticed in social situations
  - Less noise
  - Less interference with daily activities
  - Less interference with sleep

Armstrong DG, et al. *Wound Repair Regen.* 2012;20(3):332-341.

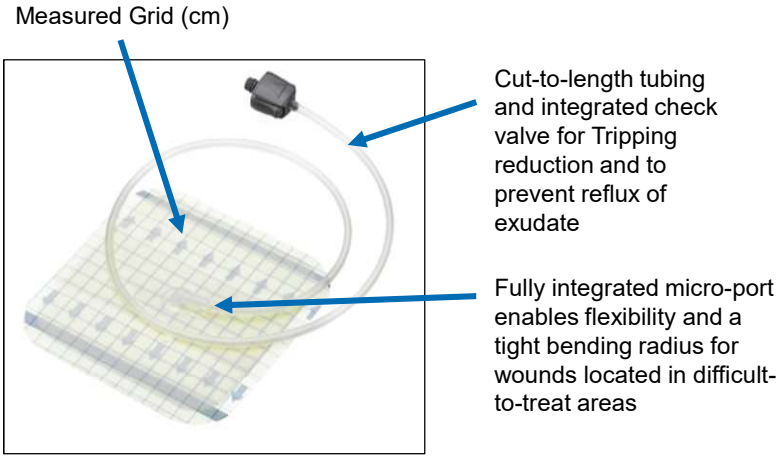
# MP-NPWT Wound Care System
## Cartridge

**Provides 3 vital functions without electrical or battery power**

- **Power Source** – Proprietary spring mechanism generates consistent, even levels of pressure
- **Exudate Management System** – 60 cc fluid capacity with BIOLOCK™ Technology to gel exudate for improved containment
- **Control System** – Visual indicator displays when cartridge is full or discharged

**Small, silent, lightweight design that disappears under clothes**

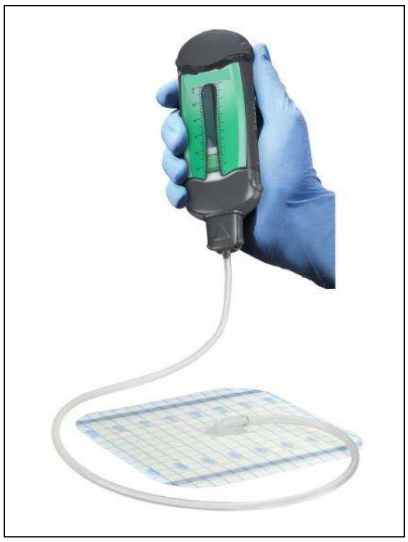
# MP-NPWT Wound Care System
## Proprietary Hydrocolloid with Integrated Tubing



# MP-NPWT Wound Care System
## Features

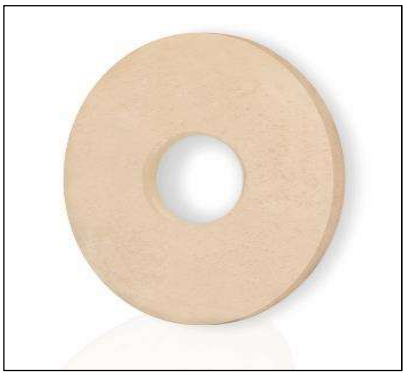
**MP-NPWT Wound Care System is a mechanically-powered, disposable system**

- **Weight:** 0.1 kg
- **Pressure:** -125 mmHg
- **Dressing:**
  - Wound, Interface - Blue ROCF (Blue)
  - Sealant Layer - Proprietary hydrocolloid layer with Integrated Tubing Port
- **Cartridge:** Disposable therapy unit integrated with exudate containment unit, 60 mL
- **Therapy setting:** Continuous only
- **Alarms:** Audible: None. Red visual indicator displays when exudate capacity full or leak



# MP-NPWT Wound Care System
## SecurRing™ Hydrocolloid Accessory

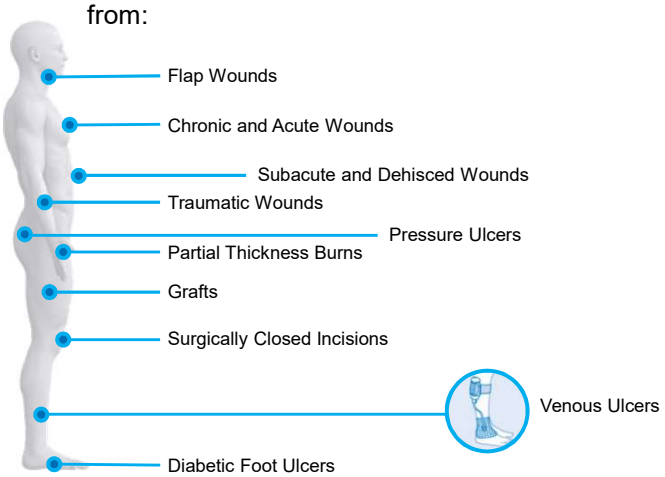
- Fast and easy sealing on uneven skin surfaces and challenging body contours
- Reduces accessories needed to seal and protect the wound from moisture
- Increases adhesion of the MP-NPWT Wound Care System Dressing on dry and uneven skin



**Simplifies Dressing Applications**

# Indicated Wound Types Identical to EP-NPWT

**MP-NPWT Wound Care System is Indicated for Removal of Small Amounts of Exudate** from:




**EP-NPWT = electrically powered NPWT.**

# NPWT Contraindications

- Active bleeding and/or infection (untreated osteoporosis)
- Exposed vessels, nerves, tendons
- Exposed anastomotic sites, organs
- Inadequately drained wounds
- Necrotic tissue such as eschar or adherent slough
- Wound with malignancy

# 3 Key Evidence-Based Articles

- Evaluation of Chronic Wound Treatment with the MP-NPWT Wound Care System Versus Modern Dressing Protocols
  - **Lerman B, et al. *Plast Reconstr Surg*. 2010;126(4):1253-1261.**
- Comparative Effectiveness of Mechanically and Electrically Powered Negative Pressure Wound Therapy Devices: A Multicenter Randomized Controlled Trial
  - **Armstrong DG, et al. *Wound Repair Regen*. 2012;20(3):332-341.**
- A Multicenter Randomized Controlled Trial Comparing Treatment of Venous Leg Ulcers Using Mechanically Versus Electrically Powered Negative Pressure Wound Therapy
  - **Marston WA, et al. *Adv Wound Care*. 2015;4(2):75-82.**

# MP-NPWT vs "Modern"

Evaluation of Chronic Wound Treatment with the MP-NPWT Versus Modern Dressing Protocols

# Clinical Data: Study 1

- 36 outpatient wound care clinic participants with difficult-to-treat lower extremity ulcers were enrolled in the study
- 21 participants completed treatment with the MP-NPWT and were evaluated for wound healing for up to 4 months
- Outcomes were then compared with 42 patient-matched controls treated at the same center with modern wound care protocols that included the use of cell-based tissue regeneration product, platelet-derived growth factor, and skin grafting
- 100% of MP-NPWT treated participants demonstrated improvement in wound size and 86% (18 of 21) exhibited a statistically significant healing trend ($P<.05$)

**Lerman B, et al. *Plast Reconstr Surg*. 2010;126(4):1253-1261.**

# Clinical Data: Study 1 (cont'd)

- Kaplan-Meier wound healing estimates demonstrated that MP-NPWT treated participants healed on average of 74.25 ± 20.1 days from the start of treatment and the matched controls healed on average of 148.73 ± 63.1 days. The 50% absolute time to healing was significantly less for participants treated with MP-NPWT ($P<.0001$)
- Retrospective studies are inherently limited by design
- Patients treated with MP-NPWT may have benefited from the effects of being in an experimental environment
- Study had relatively high dropout rate. More variable follow-up in control

**Lerman B, et al. *Plast Reconstr Surg*. 2010;126(4):1253-1261.**

# EP-NPWT vs MP-NPWT
# Diabetic Foot Ulcer/Venous Leg Ulcer

Comparative Effectiveness of Mechanically and Electrically Powered Negative Pressure Wound Devices: A Multicenter Randomized Controlled Trial

## Clinical Data: Study 2

- In a multicenter RCT, 132 patients with lower extremity diabetic and venous wounds were enrolled in the study
- 118 patients were treated either with MP-NPWT (n=59) or EP-NPWT (n=56), with 115 patients completing the study
- Patients were treated for up to 16 weeks or complete wound closure
- Primary end point analysis of wound size reduction found that MP-NPWT treated participants demonstrated non-inferiority to EP-NPWT participants at 4, 8, 12, and 16 weeks (*P*=.0030, .0130, .0051, and .0044, respectively)

**RCT = randomized controlled trial.**
**Armstrong DG, et al. *Wound Repair Regen.* 2012;20(3):332-341.**

## Clinical Data: Study 2 (cont'd)

- The study indicated that the effect of the MP-NPWT was not significantly different than that of the EP-NPWT in promoting complete wound closure in the population studied (*P*=.9620)
- MP-NPWT patients reported less interruption of activities on daily living compared to EP-NPWT patients. However, pain associated with treatment was not significantly different between treatment groups
- Other benefits noted by the authors were shorter time to dressing application and ease of use
- However, despite randomization, the initial wound size was significantly greater in the EP-NPWT patients than in the MP-NPWT patients (mean of 9.95 $cm^2$ vs 5.37 $cm^2$; *P*=.0093)

**Armstrong DG, et al. *Wound Repair Regen.* 2012;20(3):332-341.**

# MP-NPWT vs EP-NPWT Venous Leg Ulcers

A Multicenter Randomized Controlled Trial Comparing Treatment of Venous Leg Ulcers Using Mechanically Versus Electrically Powered Negative Pressure Wound Therapy

# Clinical Data: Study 3

- In a multicenter RCT, 40 patients with venous leg ulcers were treated either with MP-NPWT (n=19) or EP-NPWT (n=21)
- Patients were evaluated for 16 weeks or complete wound closure
- Primary end point analysis of wound size reduction found that MP-NPWT treated participants significantly greater wound size reduction than in EP-NPWT participants at 4, 8, 12, and 16 weeks (*P*=.0039, .0086, .0002, and .0005, respectively)
- 53% of MP-NPWT patients achieved 50% wound closure at 30 days compared to 24% of EP-NPWT patients
- However, despite randomization, the initial wound size was significantly greater in the EP-NPWT patients than in the MP-NPWT patients (mean of 11.6 $cm^2$ vs 4.49 $cm^2$)

**Marston WA, et al. *Adv Wound Care.* 2015;4(2):75-82.**

# Case Studies

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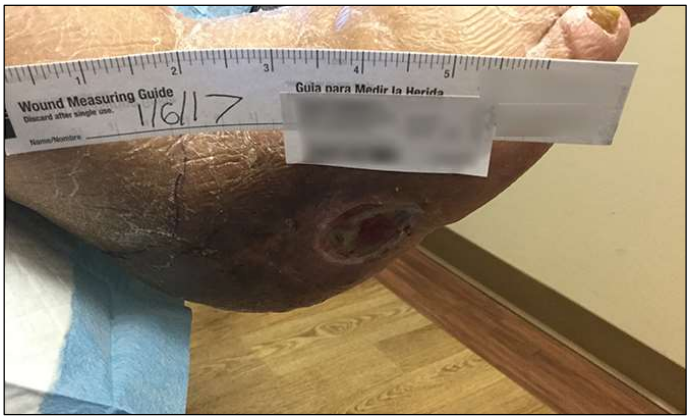
# Case 1: Charcot Deformity with Ulceration and Osteomyelitis

- 74-year-old male with diabetes and a history of right foot Charcot Deformity with ulceration and osteomyelitis
- Underwent surgical bone debridement and osseous rebalancing/ reconstruction
- Initial empiric post-operation care, including serial debridement and parenteral antibiotic therapy
- MP-NPWT initiated

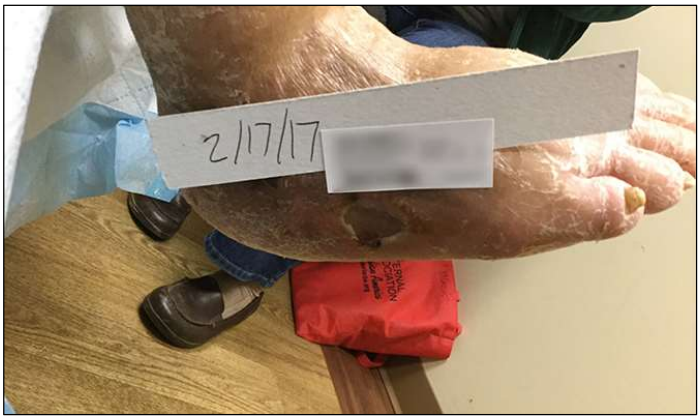
# Case 1: Initial Presentation

# Case 1: 4 Weeks




# Case 1: 7 Weeks

# Case 1: 11 Weeks




# Case 2: Surgical Dehiscence

- 71-year-old healthy, active male. Sustained right ankle fracture requiring ORIF
- Reduction was without complication; however, developed post-operation swelling and dehiscence
- Standard empiric care followed by initial MP-NPWT. Needed to convert to traditional NPWT because MP-NPWT trial period ended
- Suction blister epidermal grafting carried out when depth improved and wound bed disposition was appropriate

**ORIF = open reduction and internal fixation.**

## Case 2: 9 Days

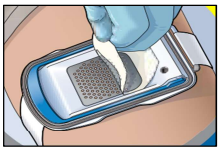
## Case 2: 18 Days

1/27/17

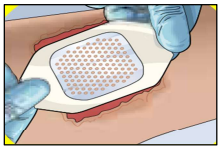
# Epidermal Harvesting System

# Epidermal Harvesting System Technology

Autologous epidermal microdomes raised



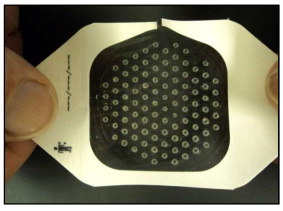
Epidermal micrografts harvested in minimally-invasive manner



Micrograft spacing and orientation maintained via dressing, yielding significant expansion ratio

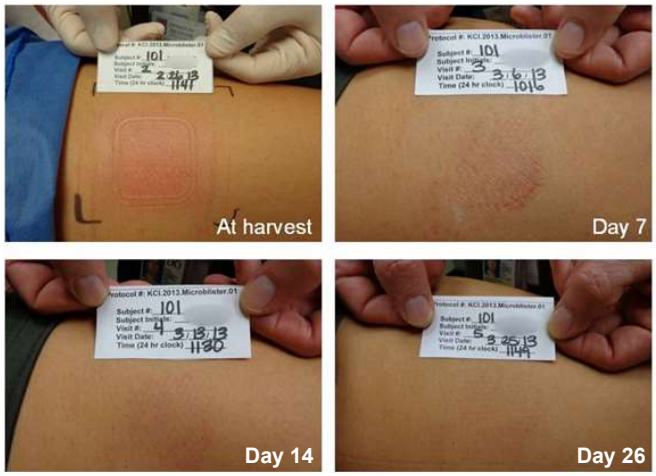
**Solution**

A ready-to-apply array of autologous epidermal micrografts that virtually eliminates donor site issues



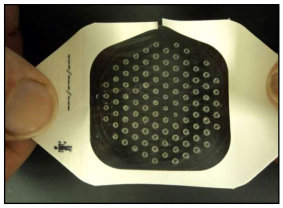
# Donor Site Experience

- Minimal donor-site trauma, without need for general anesthesia
- Donor site typically healed within 2 to 4 weeks




Osborne SN, et al. *Adv Skin Wound Care.* 2016;29(2):57-64.

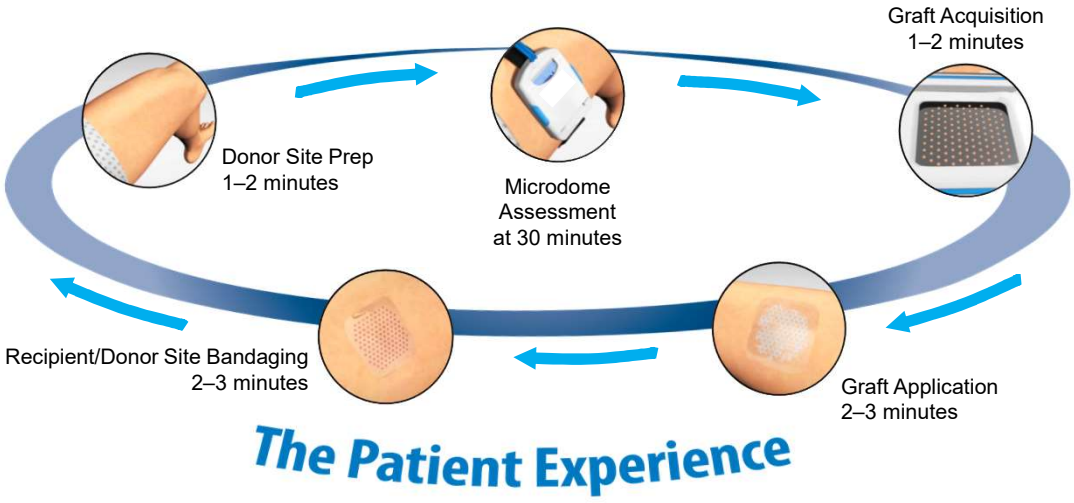
# Epidermal Harvesting System Technology



?...or

*Non-Adhering Silicone Dressing

# Epidermal Harvesting System Procedure




# Epidermal Harvesting System Summary

- Donor site-sparing epidermal harvesting system
- Automated harvesting process
- No need for anesthesia at donor site
- Pre-existing CPT coding or patient pay
- Office/outpatient clinic procedure <60 minutes
  - The Epidermal Harvesting System is the first market-enabling technology for suction blister epidermal graft harvesting

# Case 2: 3.5 Months


# Case 3: Surgical Dehiscence

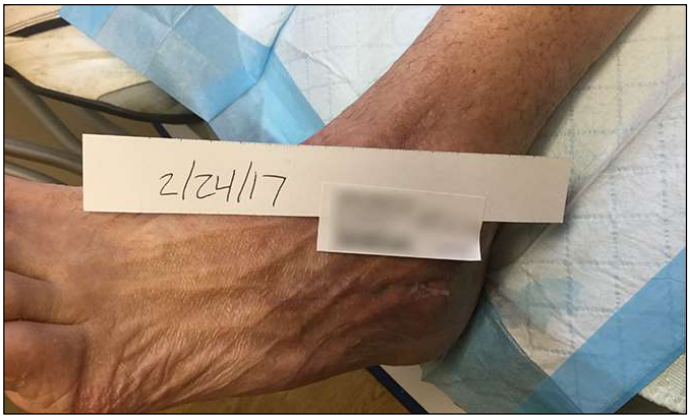
- 49-year-old male with diabetes. Had right foot reconstruction several years ago at the hands of another surgeon because of arthritis and deformity
- Eventually developed a valgus deformity several years later and sought the opinion of a different surgeon
- Underwent major revision surgery by the second surgeon
- Osseous procedure successful; however, did develop dorsal lateral dehiscence
- Initial empiric care included MP-NPWT

## Case 3: Initial Presentation


## Case 3: 5 Weeks

# Case 3: 7 Weeks

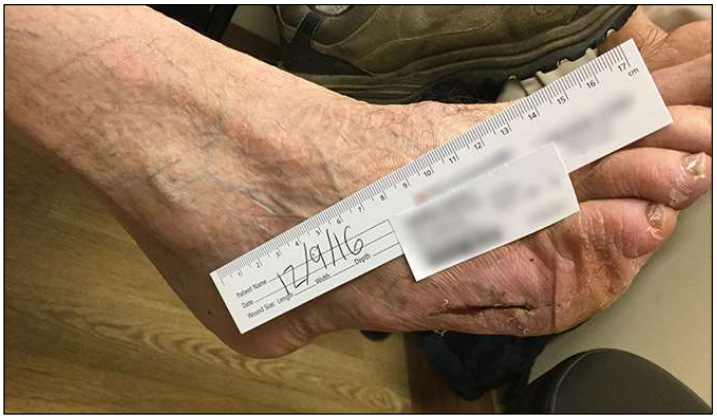

# Case 3: Closure 9 Weeks



# Case 4: Surgical Dehiscence

- 65-year-old male with idiopathic neuropathy
- Underwent right 5th ray offloading surgery
- Developed some incisional healing issues and dehiscence
- Wound bed was felt to be optimized at initial presentation with the exception of depth
- MP-NPWT initiated immediately
- Had full course of therapy

# Case 4: Initial Presentation



# Case 4: Closure 4 Weeks


# Case 5: Diabetic Foot Ulcer with Osteomyelitis

- 44-year-old male with diabetes with a long history of high sugars and neuropathy
- Developed a lateral right foot 5th metatarsal head ulceration with contiguous osteomyelitis
- Was treated by another surgeon prior
- Upon initial presentation was found to have a large amount of exuberant granulation tissue and more osteomyelitis
- Required additional surgical wound debridement and bone resection
- Surgical technique involved distal 5th metatarsal resection, implantation of vancomycin impregnated restorable bone substitute pellets and the MP-NPWT application

## Case 5: Initial Presentation


## Case 5: 1 Week

# Case 5: 3 Weeks


**First post-operation, MP-NPWT initiated**

# Case 5: 4 Weeks

## Case 5: 5 Weeks

## Case 5: 5.5 Weeks

# Case 5: Closure 6 Weeks

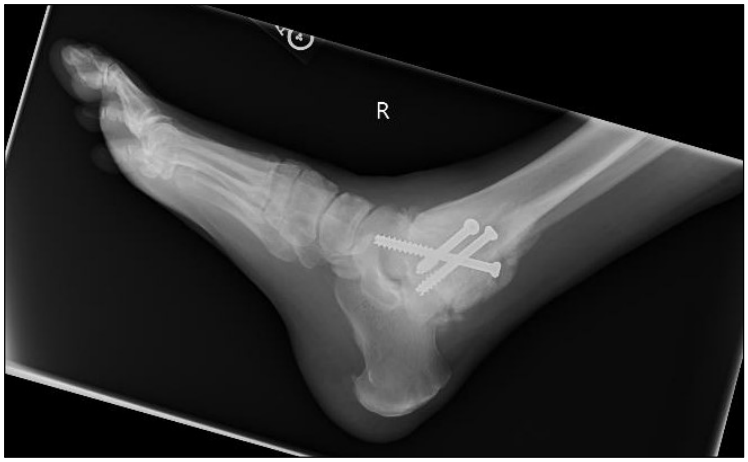
# Case 6: Ankle Fusion Salvage

- 59-year-old male
- Long withstanding history of ankle arthritis and ankle fusion in the past. Was treated by 2 other surgeons prior to presenting to our group
- Developed gradual ankle instability and breakdown of the fusion site resulting in a valgus deformity, gait compromise, and significant pain
- Revision reconstruction was proposed requiring fusion site take down and hardware removal. Tandem surgery with Dr. Nicholas Cheney, OrthoNeuro foot and ankle orthopedic surgeon

# Case 6: Ankle Fusion Salvage

- Percutaneous hardware removal was attempted under fluoroscopy through small medial and lateral exposures. Medial removal was successful but lateral removal was not
- Required lateral and medial incisions for exposure
- Lateral and central hardware was found to be deeply embedded in the osseous structures of the ankle. Distal tibial osteotomy was necessary for exposure and removal

# Case 6



## Case 6


## Case 6

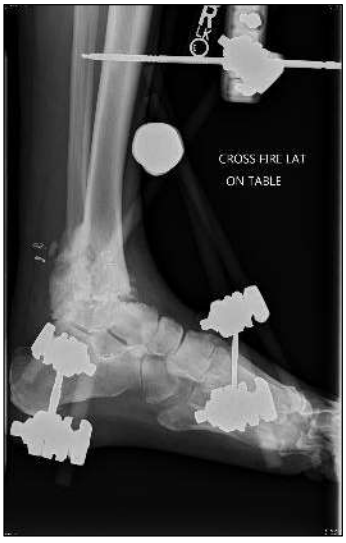
# Case 6


# Case 6

- Surgical technique included tibial osteotomy and soft tissue releases to reduce the valgus deformity
- Medial closure was obtained but due to significant soft tissue and scar contractures, lateral incision closure was not possible
- Spanning external fixator necessary to maintain reduction. Antibiotic impregnated resorbable bone substitute pellets placed in the ankle joint to aid in maintaining correction and fill void
- Traditional NPWT placed intra-op and maintained/changed for short hospital course. Transition to the MP-NPWT when discharged to skilled nursing facility
- Goal is to heal the lateral wound so revision ankle fusion can be done

## Case 6: Post-operation X-ray


## Case 6: Post-operation X-ray



## Case 6: Post-operation Day 1

## Case 6: Post-operation Day 1

## Case 6: Post-operation Day 1

## Case 6: Post-operation Day 1

# Case 6: Initiate MP-NPWT

**Once ready for transfer to skilled nursing facility, began MP-NPWT.**

# Case 6: First MP-NPWT Change

**After 3 days of MP-NPWT**

# Case 6: First MP-NPWT Change

**After 3 days of MP-NPWT**

# Case 6: After 1 Week of MP-NPWT (QOD Changes)

QOD = quality outcomes database.

# Case 6

- Continued wound improved demonstrated with MP-NPWT
- During planning period for second surgery, **PATIENT REMOVED HIS OWN EXTERNAL FIXATOR!**
- No choice but to proceed with second surgery. Fortunately, lateral wound had progressed enough such that complication risk was low. Second surgery involved ORIF, tibiotalocalcaneal nail technique

# Case 6: Final X-rays

# Case 6: Final X-rays


# Case 6

- Post-operation course, second surgery: No significant alignment regression or bone healing complications (so far). All incisions from second surgery (most small or percutaneous) healed uneventfully with the exception of the plantar calcaneal incision
- Although lateral wound from first surgery had improved significantly (ie, depth), significant defect still remained
- Both wounds (original lateral and new plantar calcaneal) were felt to be suitable for Suction Blister Epidermal Grafting
- Epidermal Harvesting System utilized

## Case 6

## Case 6: X-rays

# Case 6: Hardware Removal

# CPT® Code Description

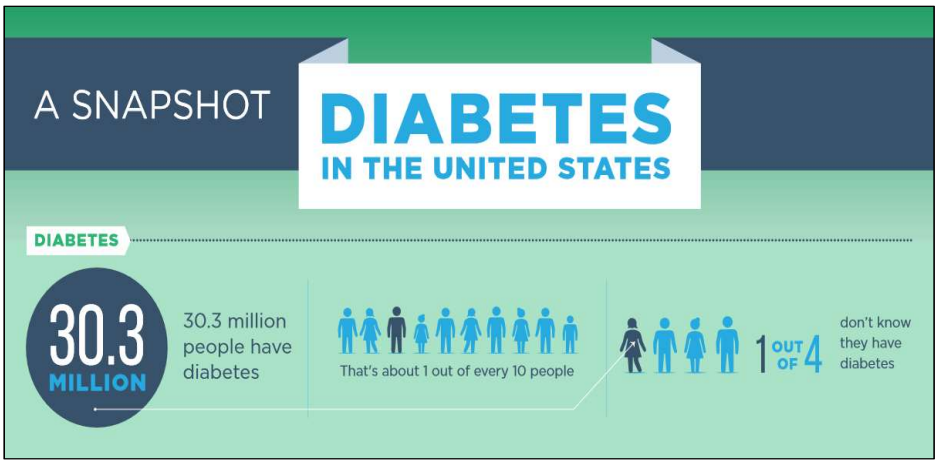
- 97607 & 97608
- Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area ≤50 $cm^2$ or >50 $cm^2$

## Benefits to Clinicians and Patients

- **Indicated** for the same wound types as NPWT
- **Off the Shelf** – Immediately available for clinicians, no waiting time for approval, paperwork, or unit to be delivered
- **Continuous** – Consistent and constant therapy over a 24-hour period; works even during power outages
- **Single Use, Disposable**
- **Discreet** and **Non-invasive** – May enhance patient adherence
- **Silent** – May improve sleep and general patient quality of life
- **Mechanically Powered** and **Ultra-Portable** – May assist in patient mobility

## Case Studies

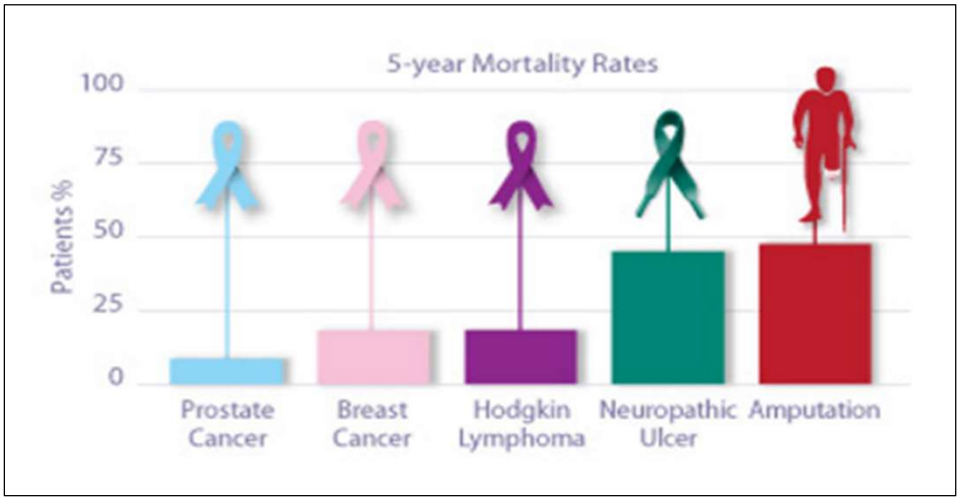
**Christopher Barrett, DPM, CWS**
Program Director
The Center for Wound Healing
Crozer Chester Medical Center
Chester, Pennsylvania




Centers for Disease Control and Prevention. www.cdc.gov/diabetes/library/socialmedia/infographics.html. Accessed April 6, 2018.

# Deaths from DFU or DFU-Related Amputation

equal or exceed deaths from prostate cancer, breast cancer, and Hodgkin lymphoma combined




**Every 30 seconds a leg is lost to diabetes somewhere in the world**

DFU = diabetic foot ulcer.

Armstrong DG, et al. *Int Wound J*. 2007;7(7):286-287.

# The Cost of Chronic Wounds

- Retrospective analysis: 2014 Medicare 5% Data Set
- Looked at prevalence and treatment cost for ≥1:
  - *arterial ulcers, chronic ulcers, DFUs, diabetic infections, pressure ulcers, skin disorders, skin infections, surgical wounds, surgical infections, traumatic wounds, venous ulcers, or venous infections*
- **Result**
  - Nearly 15% of Medicare beneficiaries (8.2 million) had at least 1 type of wound or infection
  - Surgical and diabetic infections most prevalent
  - Surgical and diabetic wounds most costly
  - Total Medicare spending estimates for all wound types: $28.1 to $96.8 billion
- Site of service with highest cost: **Outpatient**

**Nussbaum SR, et al. *Value Health*. 2018;21(1):27-32.**

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ELSEVIER

An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds

Samuel R. Nussbaum, MD[1], Marissa J. Carter, PhD, MA[2], Caroline E. Fife, MD[3,4,5], Joan DaVanzo, PhD, MSW[6], Randall Haught[7], Marcia Nusgart, RPh[1,*], Donna Cartwright, MPA[8]

ABSTRACT

Objective: The aim of this study was to determine the cost of chronic wound care for Medicare beneficiaries in aggregate, by wound type and by setting. Methods: This retrospective analysis of the Medicare 5% Limited Data Set for calendar year 2014 included beneficiaries who experienced episodes of care for one or more of the following arterial ulcers, chronic ulcers, diabetic foot ulcers, diabetic infections, pressure ulcers, skin disorders, skin infections, surgical wounds, surgical infections, traumatic wounds, venous ulcers, or venous infections. The main outcomes were the prevalence of each wound type, Medicare expenditure for each wound type and aggregate, and expenditure by type of service. Results: Nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound or infection (not pneumonia). Surgical infections were the largest prevalence category (4.0%), followed by diabetic infections (3.4%). Total Medicare spending estimates for all wound types ranged from $28.1 to $96.8 billion. Including infection costs, the most expensive estimates were for surgical wounds ($11.7, $13.1, and $38.3 billion), followed by diabetic foot ulcers ($6.2, $6.9, and $18.7 billion). The highest cost estimates in regard to site of service were for hospital outpatients ($9.5–$35.8 billion), followed by hospital inpatients ($3.0–$14.3 billion). Conclusions: Medicare expenditures related to wound care are far greater than previously recognized, with care occurring largely in outpatient settings. The data could be used to develop more appropriate quality measures and reimbursement models, which are needed for better health outcomes and smarter spending for this growing population.

Keywords: Medicare 5% Limited Data Set, Medicare spending, prevalence of wounds, wound care.

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The true cost of wound care, including chronic wounds, such as venous leg ulcers, diabetic foot ulcers, and pressure ulcers, remains unknown for the national population of the United States [1]. This is also true for subgroups, such as Medicare beneficiaries.

A rough prevalence rate for chronic nonhealing wounds in developed countries is 1% to 2% of the general population [2,3], similar to the prevalence rate for heart failure [4]. Unlike heart failure, the morbidity and associated costs of chronic wounds, including amputation and death, have been largely ignored from a public policy standpoint in the United States, perhaps because no specific medical specialty is clearly responsible. Nonhealing wounds are not so much a disease as a symptom. Patients with nonhealing wounds are likely to be older adults, nonambulatory or paralyzed, unable to provide self-care, and/or suffering from dementia. Their ulcers may occur as a result of unique medical conditions (e.g., sickle cell anemia, vasculitis) [5,6], in association with immunosuppression (e.g., steroid use) [7,8], renal impairment (e.g., calciphylaxis) [9], autoimmune diseases (e.g., systemic lupus erythematosus), dermatologic diseases (e.g., epidermolysis bullosa), and age-related debility or paralysis (which can lead to pressure ulcers) [10,11], result from peripheral neuropathy (e.g., diabetic), and occur in patients with peripheral arterial and venous disease (e.g., arterial and venous ulcers). From an International Classification of Diseases 9 (ICD-9) coding perspective, these cutaneous lesions are divided into "ulcers"—related to an underlying chronic disease—and "wounds" resulting from physical trauma or surgical intervention. We use the term "wound" to encompass both meanings.

Traditionally, wound care procedures were done in the hospital setting, but like many chronic, complex conditions, nonhealing wounds have been usually treated in the outpatient setting since 2000, when the Centers for Medicare and Medicaid Services (CMS) created the hospital-based outpatient payment system with the goal of providing care in complex cases where patients did not require hospitalization. Approximately 1500 specialized hospital-based outpatient "wound centers" across the United States provide standard wound care treatment, as

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# The Cost of Chronic Wounds

- **Conclusion:**

  *"The cost of wound care for Medicare beneficiaries is conservatively estimated at nearly $32 billion, with the majority of costs accruing in various outpatient settings. The results of this study have* ***important implications for CMS payment policies*** *…"*

  *"The data could also be used to develop* ***more appropriate quality measures and reimbursement models****, which are needed for better health outcomes and smarter spending for this growing population."*

Nussbaum SR, et al. *Value Health*. 2018;21(1):27-32.

# Biochemical Differences

| Healing Wounds | Chronic Ulcers |
|---|---|
| • ↑ Cell mitosis | • ↓ Mitogenic activity |
| • ↓ Pro-inflammatory cytokines | • ↑ Pro-inflammatory cytokines |
| • ↓ MMPs | • ↑ MMPs |
| • ↑ Growth factors | • Varied levels of growth factors |
| • Cells capable of rapid response | • Senescent cells |

MMP = matrix metalloproteinase.
Schultz GS, et al. *Wounds*. 1998;10(Suppl F):1F-9F.

# Wound Bed Preparation

- Developed by plastic surgeons
- A systematic approach to wound management
- Removes local barriers to wound healing
- Goal is a clean, healthy, well perfused wound bed
- Enables interventions to be more effective


# TIME
## Principles of Wound Bed Preparation

| **T**issue non-viable or deficient | **I**nfection or inflammation | **M**oisture imbalance | **E**dge of wound non-advancing or undermined |
|---|---|---|---|
| Defective matrix and cell debris | High bacterial counts or prolonged inflammation | Desiccation or excess fluid | Non-migrating keratinocytes Non-responsive wound cells |
| ⬇ | ⬇ | ⬇ | ⬇ |
| **Debridement** | A **Debridement** Antimicrobials | Dressings Compression | **Debridement** Biological agents Skin Grafts |
| ⬇ | ⬇ | ⬇ | ⬇ |
| Restore wound base and ECM proteins | Lower bacteria, protease levels; remove biofilm, reduce inflammation | Restore cell migration, maceration avoided | Stimulate keratinocyte migration Closure |

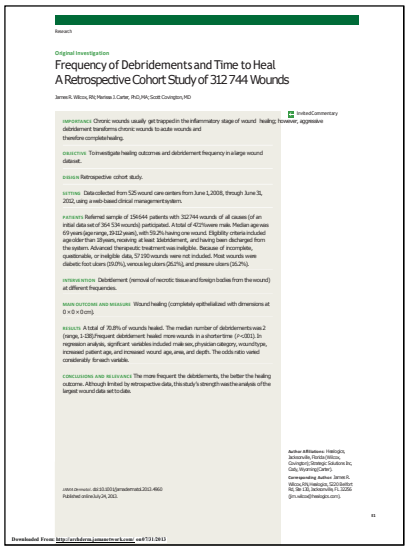
**ECM = extracellular matrix.**

**Schultz GS, et al. *Wound Repair Regen.* 2003;11 Suppl 1:S1-28.**

# The Importance of Debridement

## Frequency of Debridement and Time to Heal

- Retrospective data from 525 WCC from 2008–2012
- 154,664 patients, 312,744 wounds
- Outcome measure = complete epithelialization
- Result: Higher frequency of debridement = shorter healing rates
- DFU
  - 21 days weekly
  - 64 days every other week
  - 76 days every 3 weeks +



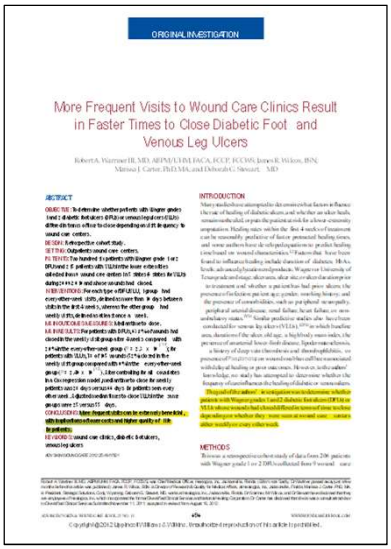
Frequency of Debridements and Time to Heal
A Retrospective Cohort Study of 312 744 Wounds

**WCC = wound care centers.**
**Wilcox JR, et al. *JAMA Dermatol.* 2013;149(9):1050-1058.**

# The Importance of Visit Frequency

## More Frequent Visits to Wound Care Clinics Results in Faster Time to Heal Diabetic Foot and Venous Leg Ulcers

- Retrospective data from 9 clinics in 5 states 2010–2011
- 206 DFUs, 215 VLUs
- Outcome measure = median time to heal
- Result:
  - DFU healing of **63.8%** after 4 weeks (weekly visit) vs **2%** (every other week)
  - VLU healing of **52%** after 4 weeks (weekly visit) vs **0%** (every other week)
- Conclusion: More frequent visits = lower costs and improved patient QOL



ORIGINAL INVESTIGATION

More Frequent Visits to Wound Care Clinics Result in Faster Times to Close Diabetic Foot and Venous Leg Ulcers

**VLU = venous leg ulcer.**
**Warriner RA 3rd, et al. *Adv Skin Wound Care.* 2012;25(11):494-501.**

# The Importance of 4 Weeks

### Percent Change in DFU Area at Week 4 Key Predictor of Complete Healing at Week 12

- Prospective multicenter trial conducted in 11 US sites
- 276 patients enrolled; 138 patients in each treatment arm
- Midpoint between PAR at 4 weeks in patients healed vs unhealed at 12 weeks = **53%**

### Significance?

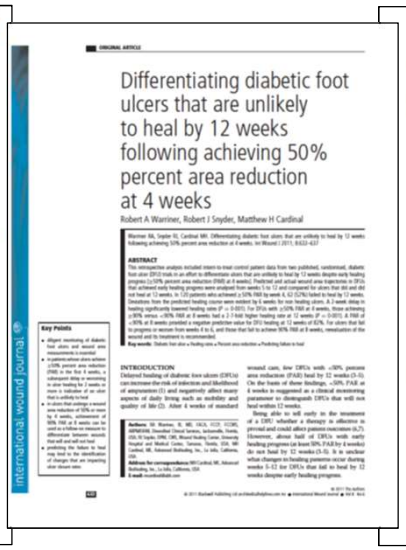
- Patients with ulcer area reduction > median (53%) at week 4 = **58%** healing at week 12
- Patients with ulcer area reduction < median (53%) at week 4 = **9%** healing at week 12
- Healers – 82% change in wound area at week 4
- Non-Healers – 25% change in wound area at week 4

**Sheehan P, et al. *Diabetes Care.* 2003;26(6):1879-1882.**

# The Importance of 4 Weeks

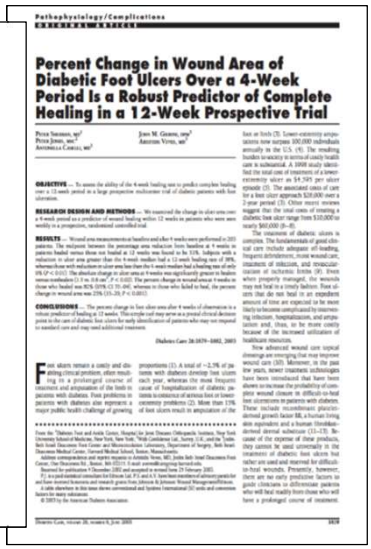
A Post-hoc Analysis of Reduction in Diabetic Foot Ulcer Size at 4 Weeks as a Predictor of Healing by 12 Weeks

Robert J. Snyder, DPM, CWS; Matthew Cardinal, ME; Damian M. Dauphinée, DPM, FACFAS, CWS; and James Slavosky, DPM



Differentiating diabetic foot ulcers that are unlikely to heal by 12 weeks following achieving 50% percent area reduction at 4 weeks

Robert A Warriner, Robert J Snyder, Matthew H Cardinal



Pathophysiology/Complications

Percent Change in Wound Area of Diabetic Foot Ulcers Over a 4-Week Period Is a Robust Predictor of Complete Healing in a 12-Week Prospective Trial

**Sheehan P, et al. *Diabetes Care.* 2003;26(6):1879-1882.**

# The Evolution of TIME

**"Four developments stand out:"**

- Recognizing the importance of biofilms
- Use of NPWT
- Evolution of topical antiseptics as dressings and wound lavage
- The molecular biology of wounds

Leaper DJ, et al. *Int Wound J*. 2012;9 Suppl 2:1-19.

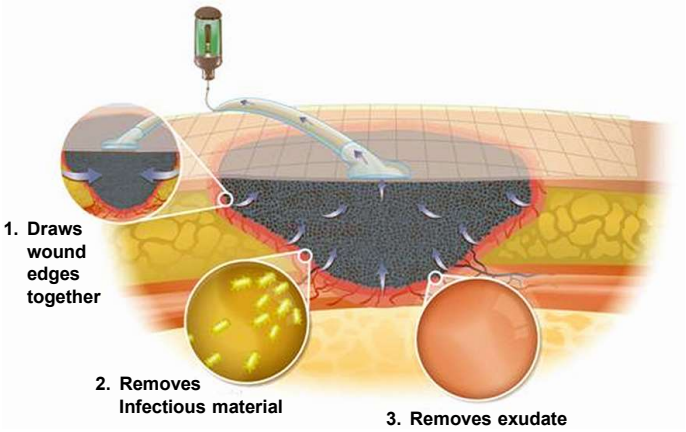
# The Evolution of TIME

*"Negative pressure, when applied to the wound via a sealed foam or gauze dressing, facilitates wound drainage, and reduces edema and the bioburden of microorganisms, while increasing wound perfusion. Recent developments have revealed that NPWT may loosen slough and necrosis, and facilitate sharp debridement …"*

*"The combination of NPWT with several other debridement methods has been demonstrated to support TIME principles, as it expedites removal of exudate and infective material and promotes granulation tissue formation, contraction and epithelialization."*

Leaper DJ, et al. *Int Wound J*. 2012;9 Suppl 2:1-19.

# Mechanisms of Action




**MP-NPWT helps to promote wound healing by drawing wound edges together and removing small amounts of infectious material and exudate.**

# TIME
## Principles of Wound Bed Preparation

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|---|---|---|---|
| Defective matrix and cell debris | High bacterial counts or prolonged inflammation | Desiccation or excess fluid | Non-migrating keratinocytes Non-responsive wound cells |
| ⬇ | ⬇ | ⬇ | ⬇ |
| **Debridement** | Antimicrobials **Debridement** | Dressings Compression | Biological agents Skin Grafts **Debridement** |
| NPWT ⬇ | NPWT ⬇ | NPWT ⬇ | NPWT ⬇ |
| Restore wound base and ECM proteins | Lower bacteria, protease levels; remove biofilm, reduce inflammation | Restore cell migration, maceration avoided | Stimulate keratinocyte migration Closure |

Schultz GS, et al. *Wound Repair Regen.* 2003;11 Suppl 1:S1-28.

## NPWT = Real-Life Challenges

- Patients still need to work
- Mobility can be a concern
  - Weight of powered devices
  - Fall risk
- Privacy
- Sleep disturbance

## Case Studies

**Christopher Barrett, DPM, CWS**
Program Director
The Center for Wound Healing
Crozer Chester Medical Center
Chester, Pennsylvania

# Radiation Wound of the Axilla

- 65-year-old female with diabetes, s/p right breast cancer treated with lumpectomy, radiation, and chemotherapy in 1992
- 21 years later noted serous drainage from “pinhole” wound in her right axilla
- Biopsy was (-) but surgical wound failed to heal

# Radiation Wound of the Axilla

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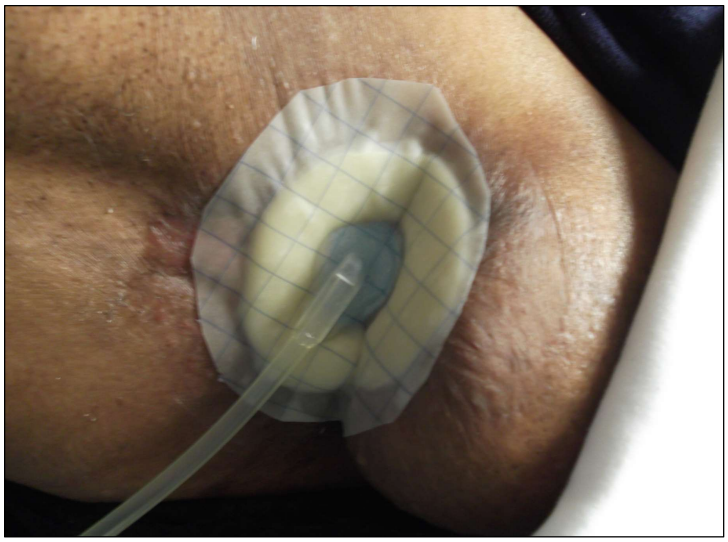


## Radiation Wound of the Axilla

## Radiation Wound of the Axilla

## Radiation Wound of the Axilla

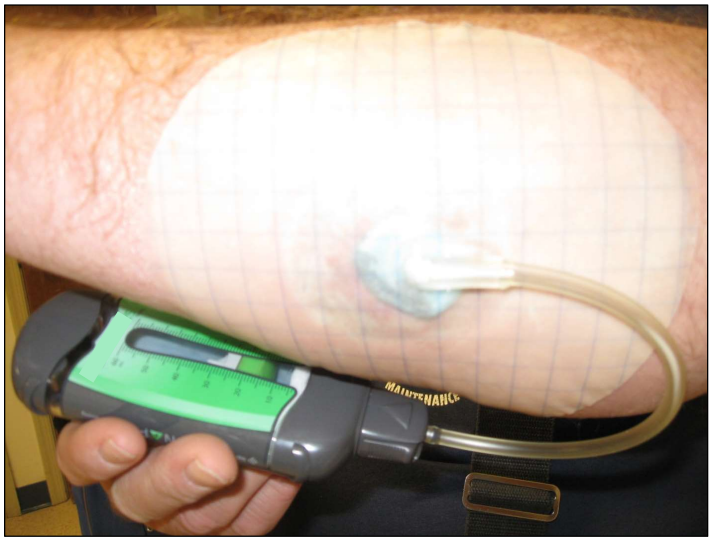
## Radiation Wound of the Axilla

## Venomous Insect Bite

- 58-year-old male with suspected insect bite to left forearm
- Developed significant pain, swelling, and inflammation × 72 hours

## Venomous Insect Bite

## Venomous Insect Bite



## Venomous Insect Bite

## Venomous Insect Bite

## Venomous Insect Bite

## Venomous Insect Bite

# Venous Leg Ulcer

- 73-year-old male with long-standing VLU
- Failing multi-layer and pneumatic compression
- Non-adherent with activity and home care
- Poor exudate management dressing selection following biologic graft

# Venous Leg Ulcer

## Venous Leg Ulcer

## Venous Leg Ulcer

## Venous Leg Ulcer

## Venous Leg Ulcer

## Venous Leg Ulcer

## Venous Leg Ulcer

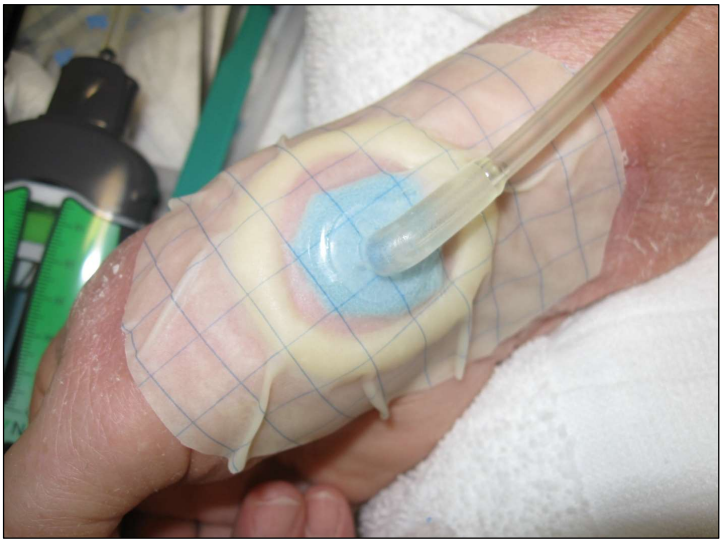
## Venous Leg Ulcer

## Post-Surgical Hand Wound

- 67-year-old female s/p right thumb tenosuspension with post-operative wound infection and dehiscence
- Required multiple operative debridements with residual wound extending to the tendon

## Post-Surgical Hand Wound

## Post-Surgical Hand Wound



## Post-Surgical Hand Wound

## Post-Surgical Hand Wound

# Traumatic Leg Wound

- Healthy 83-year-old female slipped off ladder, resulting in hematoma, cavity wound, and necrotic flap of the right anterior leg
- Measured 7 x 5 x 3 with >10-cm tunnel and extension to fascia/muscle

# Traumatic Leg Wound

# Traumatic Leg Wound


# Traumatic Leg Wound


# 3 Days Later


# SIS Matrix, MP-NPWT



**SIS = porcine small intestine submucosa.**

## 10 Days of MP-NPWT


6 x 2.5 x 1.5


4 x 2.2 x 0.3

## Epidermal Harvesting

# DFU with TCC

- 55-year-old obese diabetic with peripheral neuropathy, Charcot arthropathy, equinus and plantar midfoot ulcer of weeks duration and unknown etiology

TCC = total contact cast.

# 10/17/16: Initial Presentation

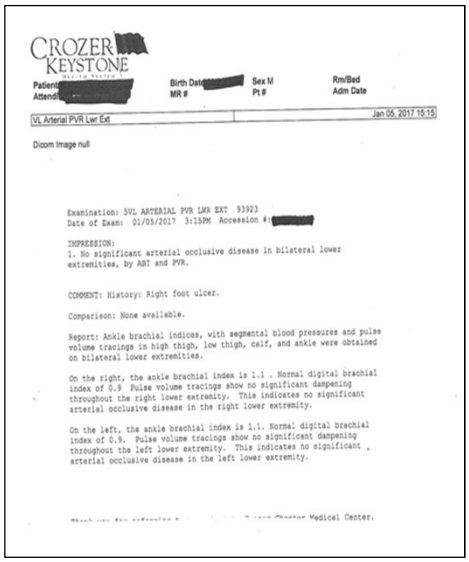
## 10/31/16: Refused TCC

## 11/28/16: TCC #1

# After TCC #6: ???

# Arterial Study

ABI = 1.1
TBI = 0.9



CROZER KEYSTONE

Patient [redacted]
Attend [redacted]
Birth Date [redacted] Sex M
MR # Pt #
Rm/Bed
Adm Date

VL Arterial PVR Lwr Ext — Jan 06, 2017 15:15

Dicom Image null

Examination: 5VL ARTERIAL PVR LWR EXT 93923
Date of Exam: 01/05/2017 3:15PM Accession #: [redacted]

IMPRESSION:
1. No significant arterial occlusive disease in bilateral lower extremities, by ABI and PVR.

COMMENT: History: Right foot ulcer.

Comparison: None available.

Report: Ankle brachial indices, with segmental blood pressures and pulse volume tracings in high thigh, low thigh, calf, and ankle were obtained on bilateral lower extremities.

On the right, the ankle brachial index is 1.1 . Normal digital brachial index of 0.9 Pulse volume tracings show no significant dampening throughout the right lower extremity. This indicates no significant arterial occlusive disease in the right lower extremity.

On the left, the ankle brachial index is 1.1. Normal digital brachial index of 0.9. Pulse volume tracings show no significant dampening throughout the left lower extremity. This indicates no significant , arterial occlusive disease in the left lower extremity.

Medical Center.

**ABI = ankle-brachial index; TBI = toe-brachial index.**

# Radiograph


# Biofilm?

**1/5/17**
Debridement, collagen/ORC, TCC, and …


**ORC = oxidized regenerated cellulose.**

# MP-NPWT


# MP-NPWT

# 1/23/17: Cast #4 Healed

# MP-NPWT Wound Care System Value Proposition

## High QOL Scores

- Patient QOL Exit Survey findings:
- MP-NPWT Wound Care System vs NPWT
  - Less noticed in social situations
  - Less noise
  - Less interference with daily activities
  - Less interference with sleep

Armstrong DG, et al. *Wound Repair Regen.* 2012;20(3):332-341.

# Summary

- This is NPWT evolution, not revolution!
- Meant to augment, not replace, powered systems
- Easier to use for short periods/special populations
  - Wound bed preparation
  - Skin grafts
  - Small, deep wounds
  - Elderly with mobility issues
  - Power source impaired (workers)
  - **Home care patients**
- We will all find our way with it in practice
  - Important to be coached at first
  - Do not use for your worst “train wreck”
    - Avoid “one and done”

# Thank you