Harnessing a Clean, Cover, and Close Approach to Chronic Wounds

Supported by an educational grant from Smith & Nephew

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Learning Objectives

- Investigate the potential of collagenase in enhancing the pro-ECM response in chronic wounds through macrophage conversion to a fibroblast-like state
- Evaluate the impact of advanced therapies utilizing placental allografts on health outcomes for chronic wounds, supported by recent big data research findings
- Examine the mechanism of action and application of single-use NPWT across the continuum
- Explore illustrative case studies leveraging a clean, cover, and close method integrating advanced therapies for optimal healing outcomes

ECM = extracellular matrix; NPWT = negative pressure wound therapy.

Wound Chronicity Pivots with Use of Enzymatic Debridement

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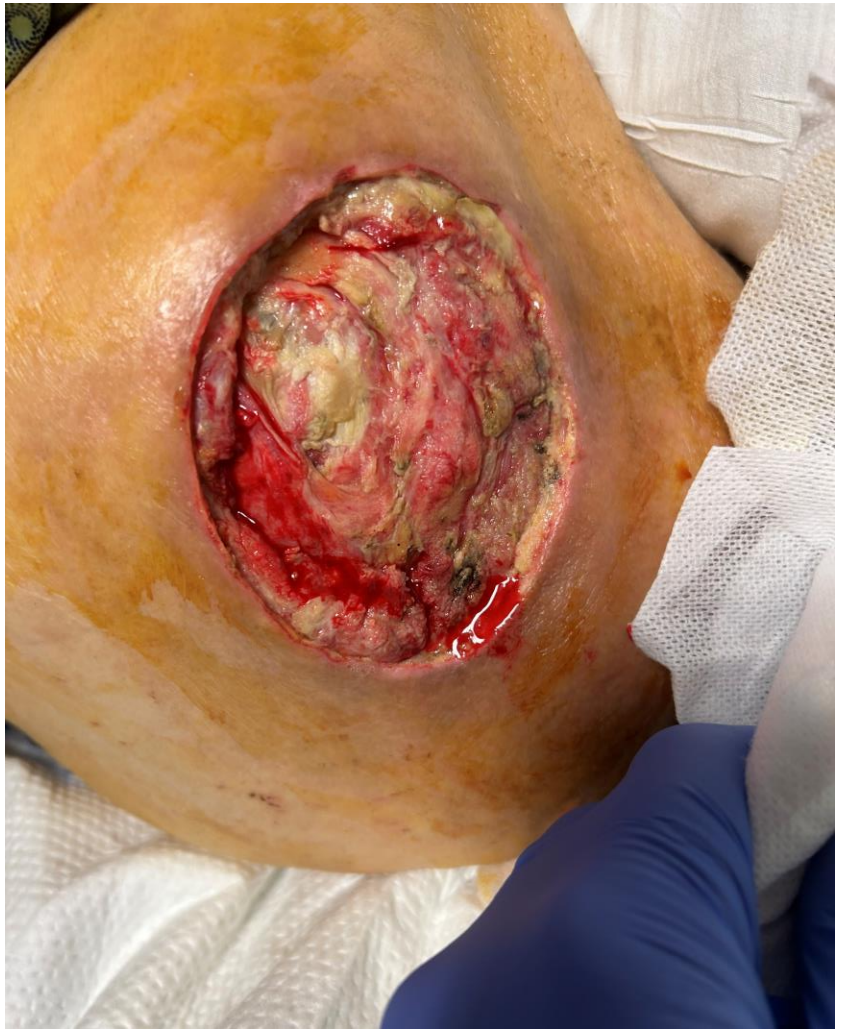
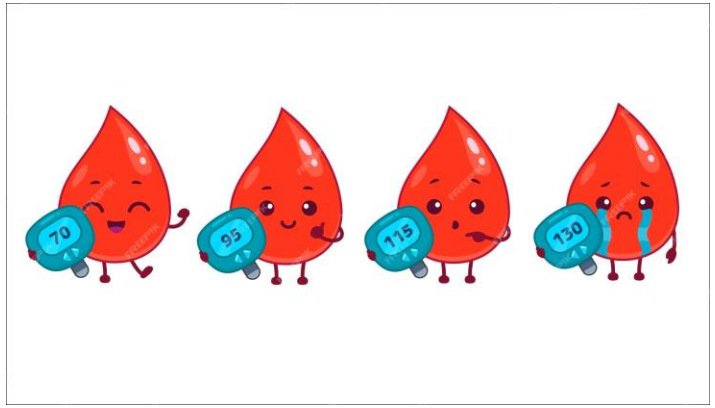
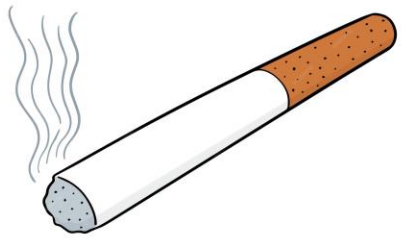
The State of Chronic Wounds



Risk Factors for Stalled/Chronic Wounds

- 10.5 million patients in the U.S. are affected by chronic wounds[1]
- Chronic wounds, often referred to as stalled, are characterized by a failure to reduce in size by 40%-50% in 30 days[5]
- Comorbidities such as diabetes, obesity, smoking, cardiovascular disease, immunodeficiency, age, and nutrition are risk factors that significantly contribute to the development of stalled, chronic, non-healing wounds[2-5]





Sen CK. *Adv Wound Care.* 2023;12(12):657-670. **2.** Guo S, Dipietro LA. *J Dental Res*. 2010;89(3):219–229. **3.** Pocock ES, et al. *Vascular Cell.* 2014;6(1):24. **4.** Strbo N, et al. *Adv Wound Care.* 2014;3(7):492–501. **5.** Atkin L, et al. *J Wound Care*, 2019;23:S1-S52.

Management of Chronic Wounds

- Comprehensive patient assessment
- Diagnostic testing
- Development of initial plan

Predictors of Healing

- Benchmark: Wounds that show a 50% or more reduction in wound size after 4 wks of treatment are more likely to be completely healed at wk 12 than wounds that show a reduction in size of less than 50% at wk 4, as demonstrated in a study of diabetic foot ulcers (DFUs)[1]

DFU = diabetic foot ulcer,
Sheehan PJ, et al. *Diabetes Care.* 2003;26(6):1879-1882.

Chronic Wounds

There is a cycle of recurring inflammation and tissue damage which prevents progression to healing.

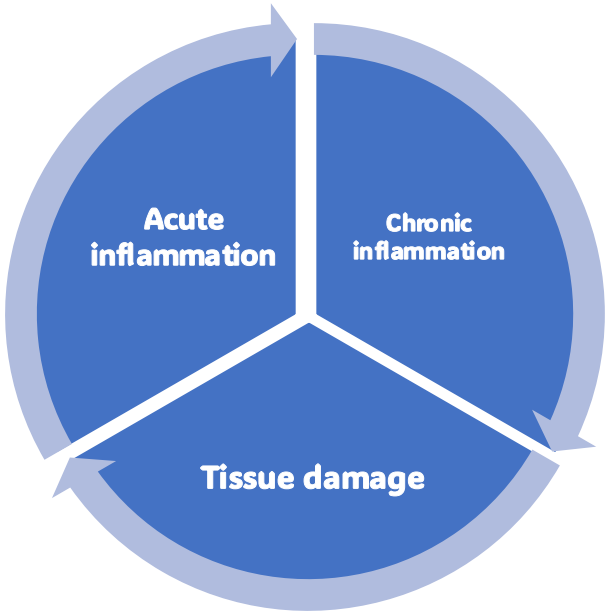
Injury

Hemostasis phase

Bacteria + Comorbidities + Environment

Inflammatory phase

Increased bacterial bioburden can inhibit wound progression toward healing due to induction of chronic inflammation

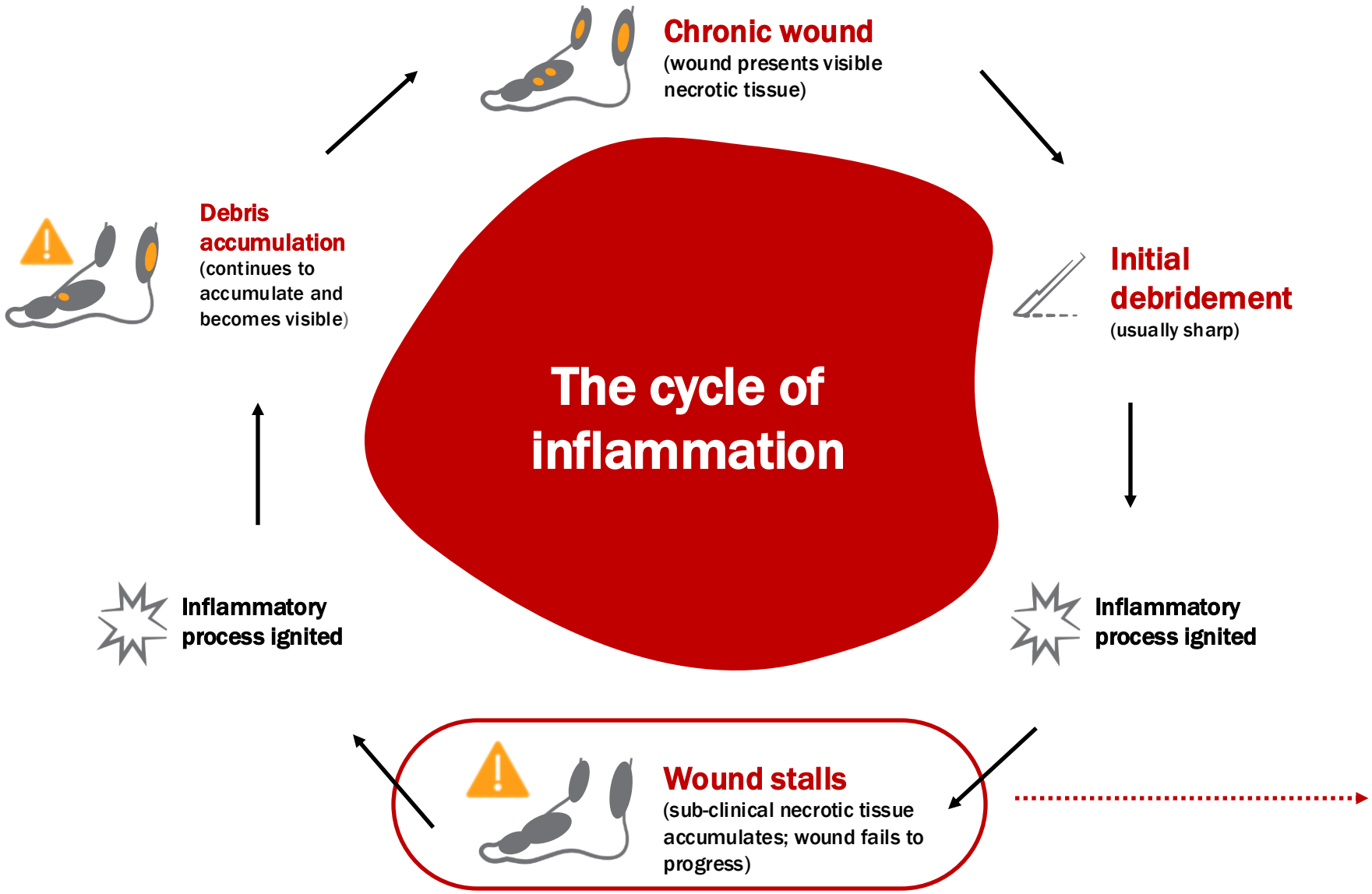


~~Proliferative phase~~

~~**Closure**~~

~~Epithelialization phase~~

Diegelmann RF, Evans MC. *Front Biosci,* 2004;1:283–289. **2.** Menke NB, et al. *Clin Dermatol.* 2007;25:19-25.



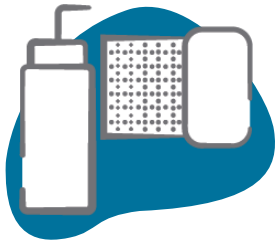
Breaking the cycle of inflammation[1]

Remove necrotic tissue; preserve granulating tissue; progress through the normal phases of wound healing[1]

1. Velnar T, et al. *J Int Med Res.* 2009;37:1528-1542. **2.** Enoch S, et al. *Wounds.* 2003;15:213-229. **3.** Sen CK, et al. *Wound Repair Regen.* 2009;17:763-771.

Common Wound Debridement Methods[1,2]

Sharp



Autolytic support

Mechanical

Biosurgical
(maggot therapy)

Hydrosurgical

Enzymatic

1. Enoch S, et al. *Wounds*. 2003;15:213-229. **2.** Vowden K, et al. *Wounds UK* [serial online]. 2011;7:1-4. Available at: http://www.wounds-uk.com/pdf/content_10133.pdf.

Collagenase Ointment Selectively Digests Collagen

- **Incomplete debridement** may stall wounds in the inflammatory phase of healing
- Wounds stalled in the **inflammatory phase** continue to generate debris that is anchored to the wound bed by collagen strands

Clostridial Collagenase Cleaves Denatured Collagen At 7 Sites vs 1[1,2]

Works faster than passive autolytic support as shown in multiple clinical studies

Cleaves necrotic tissue at **7 specific sites** along the triple-helix collagen strand

Breaks and unwinds denatured collagen while preserving healthy granulation tissue

Through its specific enzymatic debridement process, unique collagen fragments are created that **recruit cells that contribute to the formation of granulation tissue and microvasculature**[3-4]

Exogenous debridement with collagenase ointment

VS

Endogenous debridement with honey, hydrogels, hydrocolloids, and transparent films

1. French M, et al. *J Protein Chem*. 1992;11:83-95. **2.** Kim M, et al. *Biochim Biophys Acta*. 2007;1770:1627-1635. **3.** Shi L, et al. *Int Wound J*. 2010;7:87–95. **4.** Sheets AR, et al. *PLoS ONE*. 2016;11(7):e0159598.

Products Utilized on the Market

Endogenous debridement methods	Exogenous debridement methods
Hydrogels	Collagenase Ointment
Honey	
Hydrofibers	
Topical antibiotics	

Collagen Breakdown

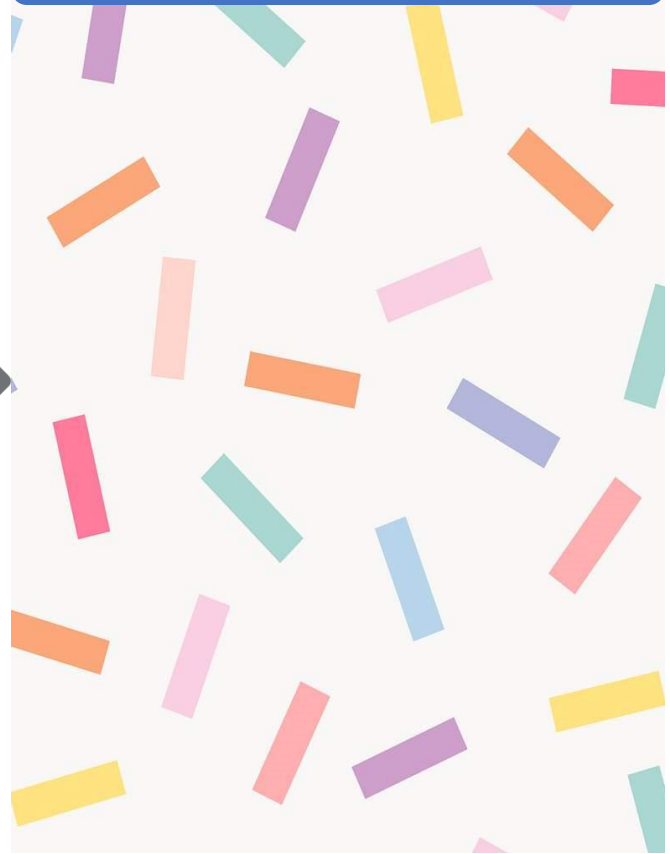
native collagen
(intact)

denaturation

denatured collagen
(unwound)

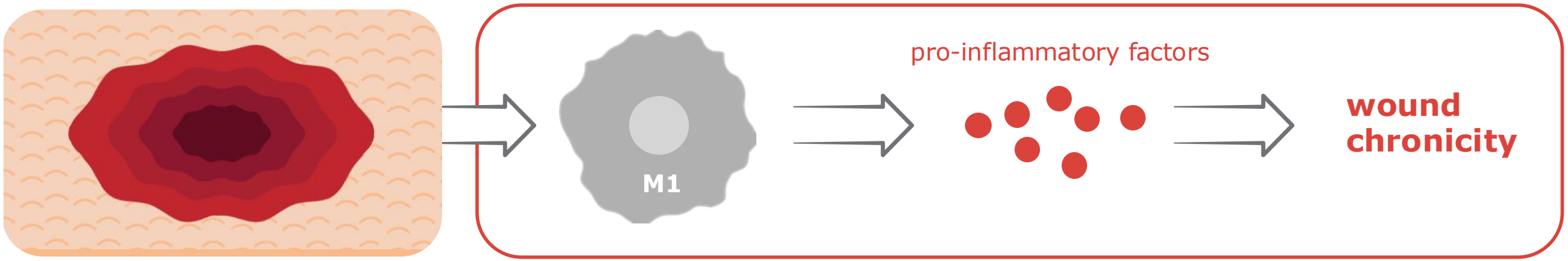
Enzymatic cleavage

What happens to the collagen fragments?



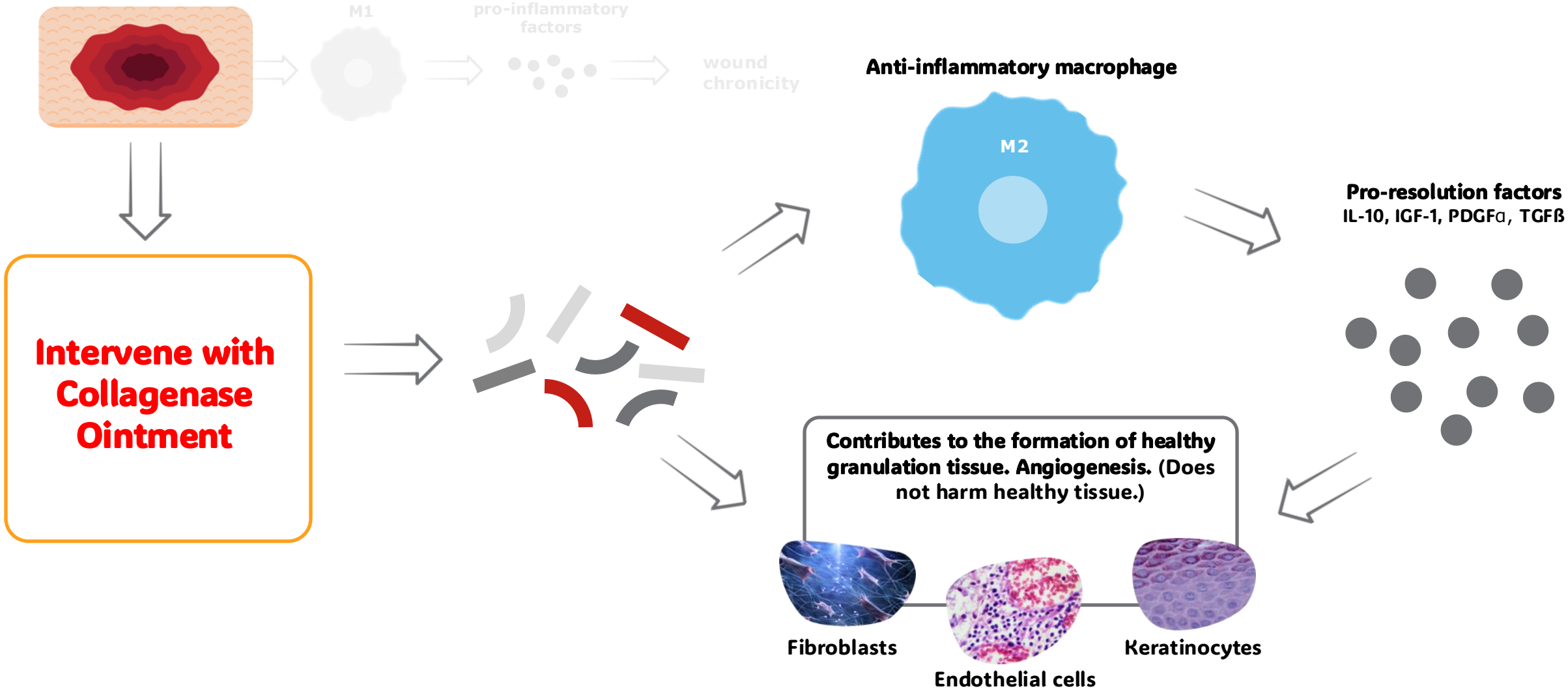
digested collagen
(broken down)

The Cellular Cascade



1. Das A, et al. *Am J Pathol*. 2015;185:2596-2606.

The Cellular Cascade



1. Das A, et al. *Am J Pathol.* 2015;185:2596-2606.

Enzymatic Debridement

Oct. 5 and Oct. 12

Enzymatic Debridement

Oct. 26 and Nov. 27

Clinical Pearls

Enzymatic Debridement

Collagenase Ointment 250 units/gram

- Indicated for debriding both chronic dermal ulcers and severely burned areas[1]
- Contributes to the **formation of granulation tissue and subsequent epithelialization** of dermal ulcers and severely burned areas[1]
- Removes necrotic tissue and preserves healthy granulation tissue-selective **and active**[2-4]
- **Faster debridement** than passive autolytic support[5-7]

1. SANTYL Ointment Prescribing Information 2. Enoch S, et al. *Wounds.* 2003;15:213-229. 3. Kim M, et al. *Biochim Biophys Acta.* 2007;1770:1627-1635. 4. French M, et al. *J Protein Chem*, 1992;11:83-95. 5. Jimenez JC, et al. *Wounds*. 2017;29:133-139. 6. Gilligan AM, et al. *Adv Wound Care* (New Rochelle). 2017;6:125-134. 7. Milne CT, et al. *Wounds.* 2010;22:270-274.

Mechanism of Action and Application of sNPWT

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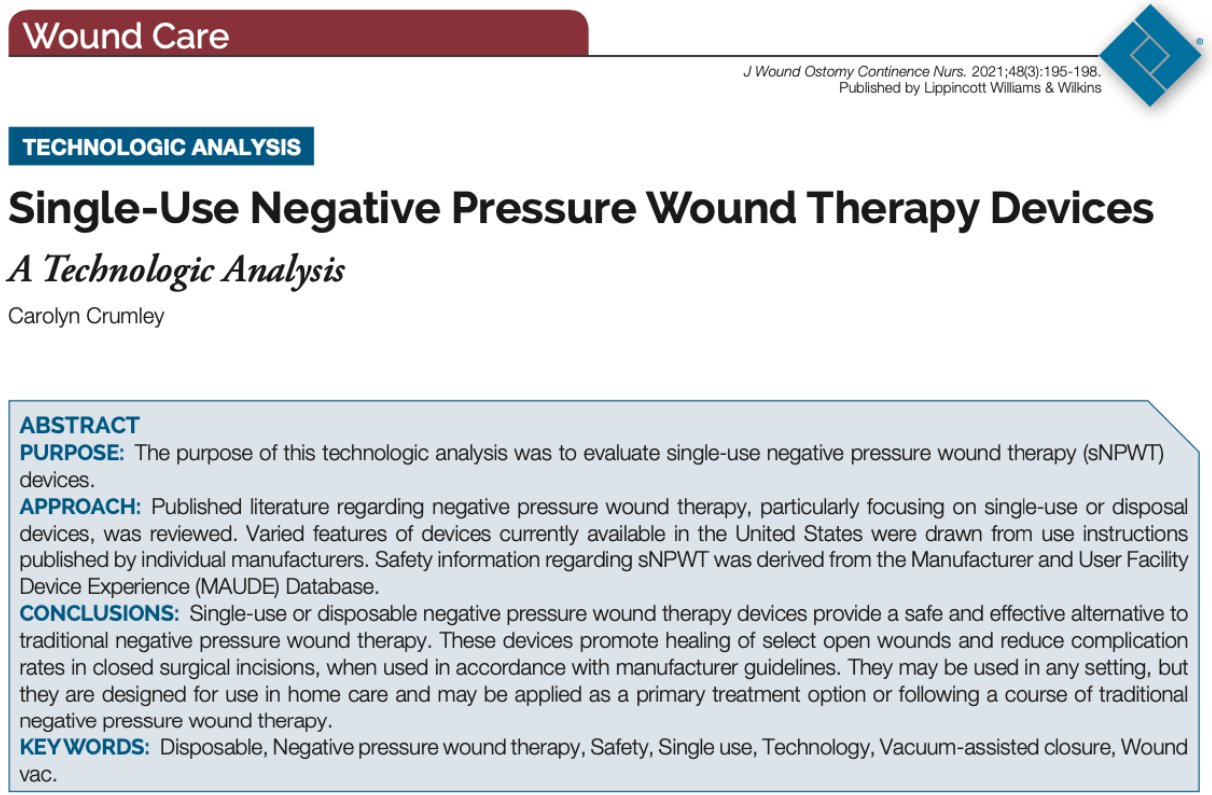
Learning Objectives

1. Examine the mechanism of action (MOA) of single-use negative pressure wound therapy (sNPWT) devices
2. Review clinical applications of sNPWT

MOA = mechanism of action; sNPWT = single-use negative pressure wound therapy.

Commercially Available Products



Wound Care

J Wound Ostomy Continence Nurs. 2021;48(3):195-198.
Published by Lippincott Williams & Wilkins

TECHNOLOGIC ANALYSIS

Single-Use Negative Pressure Wound Therapy Devices

A Technologic Analysis

Carolyn Crumley

ABSTRACT

PURPOSE: The purpose of this technologic analysis was to evaluate single-use negative pressure wound therapy (sNPWT) devices.

APPROACH: Published literature regarding negative pressure wound therapy, particularly focusing on single-use or disposal devices, was reviewed. Varied features of devices currently available in the United States were drawn from use instructions published by individual manufacturers. Safety information regarding sNPWT was derived from the Manufacturer and User Facility Device Experience (MAUDE) Database.

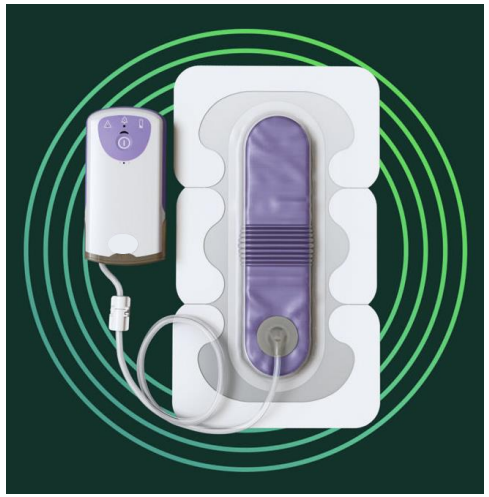
CONCLUSIONS: Single-use or disposable negative pressure wound therapy devices provide a safe and effective alternative to traditional negative pressure wound therapy. These devices promote healing of select open wounds and reduce complication rates in closed surgical incisions, when used in accordance with manufacturer guidelines. They may be used in any setting, but they are designed for use in home care and may be applied as a primary treatment option or following a course of traditional negative pressure wound therapy.

KEYWORDS: Disposable, Negative pressure wound therapy, Safety, Single use, Technology, Vacuum-assisted closure, Wound vac.

- 2021 Review lists 9 distinct devices
- Several new devices since then

1. Crumley C. *J Wound Ostomy Continence Nurs.* 2021;48(3):195-198.

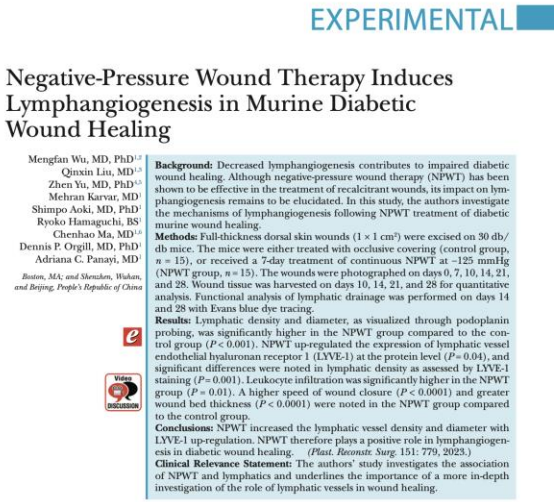
Commercially Available Products



1. Crumley C. *J Wound Ostomy Continence Nurs.* 2021;48(3):195-198.

Mechanism of Action
Single Use NPWT

- Macrodeformation
- Microdeformation
- Fluid removal
- Alteration of the wound environment
- Modulation of inflammation
- Cellular responses
  - Proliferation
  - Migration
  - Angiogenesis
- Alterations in bioburden
- Oxygen gradient
- Lymphatic clearance



EXPERIMENTAL

Negative-Pressure Wound Therapy Induces Lymphangiogenesis in Murine Diabetic Wound Healing

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Zhen Yu, MD, PhD[4,5]
Mehran Karvar, MD[1]
Shimpo Aoki, MD, PhD[1]
Ryoko Hamaguchi, BS[1]
Chenhao Ma, MD[1,2]
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Adriana C. Panayi, MD[1]

Boston, MA; and Shenzhen, Wuhan, and Beijing, People's Republic of China

Background: Decreased lymphangiogenesis contributes to impaired diabetic wound healing. Although negative-pressure wound therapy (NPWT) has been shown to be effective in the treatment of recalcitrant wounds, its impact on lymphangiogenesis remains to be elucidated. In this study, the authors investigate the mechanisms of lymphangiogenesis following NPWT treatment of diabetic murine wound healing.

Methods: Full-thickness dorsal skin wounds (1×1 cm^2) were excised on 30 db/db mice. The mice were either treated with occlusive covering (control group, $n = 15$), or received a 7-day treatment of continuous NPWT at −125 mmHg (NPWT group, $n = 15$). The wounds were photographed on days 0, 7, 10, 14, 21, and 28. Wound tissue was harvested on days 10, 14, 21, and 28 for quantitative analysis. Functional analysis of lymphatic drainage was performed on days 14 and 28 with Evans blue dye tracing.

Results: Lymphatic density and diameter, as visualized through podoplanin probing, was significantly higher in the NPWT group compared to the control group ($P < 0.001$). NPWT up-regulated the expression of lymphatic vessel endothelial hyaluronan receptor 1 (LYVE-1) at the protein level ($P = 0.04$), and significant differences were noted in lymphatic density as assessed by LYVE-1 staining ($P = 0.001$). Leukocyte infiltration was significantly higher in the NPWT group ($P = 0.01$). A higher speed of wound closure ($P < 0.0001$) and greater wound bed thickness ($P < 0.0001$) were noted in the NPWT group compared to the control group.

Conclusions: NPWT increased the lymphatic vessel density and diameter with LYVE-1 up-regulation. NPWT therefore plays a positive role in lymphangiogenesis in diabetic wound healing. (*Plast. Reconstr. Surg.* 151: 779, 2023.)

Clinical Relevance Statement: The authors' study investigates the association of NPWT and lymphatics and underlines the importance of a more in-depth investigation of the role of lymphatic vessels in wound healing.

Contents lists available at ScienceDirect

Current Problems in Surgery

journal homepage: www.elsevier.com/locate/cpsurg

Effect of negative pressure wound therapy on wound healing

Contents lists available at ScienceDirect

Journal of Tissue Viability

journal homepage: www.elsevier.com/locate/jtv

Oxygen levels during negative pressure wound therapy

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Wound Repair and Regeneration

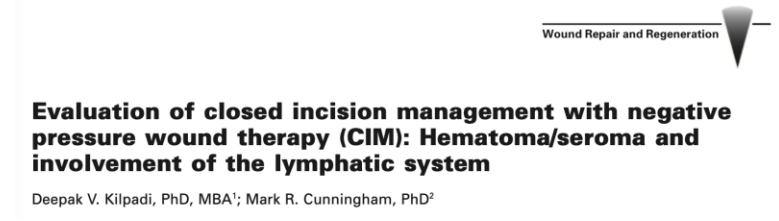
Evaluation of closed incision management with negative pressure wound therapy (CIM): Hematoma/seroma and involvement of the lymphatic system

Deepak V. Kilpadi, PhD, MBA[1]; Mark R. Cunningham, PhD[2]

1. Huang C, et al. *Curr Probl Surg.* 2014;51(7):301-331. **2.** Biermann N, et al. *J Tissue Viability*. 2020;29(1):32-36. **3**. Kilpadi DV, et al. *Wound Repair Regen*. 2011;19(5):588-596. Nov;28(4):223-226.
4. Wu M, et al. *Plast Reconstr Surg*. 2023;151(4):779-790.

Mechanism of Action
Single Use NPWT

- Macrodeformation
- Microdeformation
- Fluid removal
- Alteration of the wound environment
- Modulation of inflammation
- Cellular responses
  - Proliferation
  - Migration
  - Angiogenesis
- Alterations in bioburden
- Oxygen gradient
- Lymphatic clearance



1. Huang C, et al. *Curr Probl Surg.* 2014;51(7):301-331. **2.** Biermann N, et al. *J Tissue Viability*. 2020;29(1):32-36. **3.** Kilpadi DV, et al. *Wound Repair Regen*. 2011;19(5):588-596. Nov;28(4):223-226.
4. Wu M, et al. *Plast Reconstr Surg*. 2023;151(4):779-790.

Mechanism of Action

tNPWT vs sNPWT

Wound Repair and Regeneration

ORIGINAL RESEARCH-CLINICAL SCIENCE

A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities

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2. Advanced Foot & Ankle Center, Las Vegas, NV,
3. Associate Professor, Department of Medicine, California School of Podiatric Medicine at Samuel Merritt University, Co-Director UCSF Center for Limb Preservation, San Francisco, CA,
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ABSTRACT

Multicenter, phase-4, randomized, comparative-efficacy study in patients with VLUs or DFUs comparing for noninferiority the percentage change in target ulcer dimensions (area, depth, and volume) a single-use negative pressure wound therapy (s-NPWT) system versus traditional NPWT (t-NPWT) over a 12-week treatment period or up to confirmed healing. Baseline values were taken at the randomization visit. Randomized by wound type and size, 164 patients with non-infected DFUs and VLUs were included. The ITT population was composed of 161 patients (101 with VLUs, 60 with DFUs) and 115 patients completed follow-up (64 in the s-NPWT group and 51 in the t-NPWT group) (PP population). The average age for all patients was 61.5 years, 36.6% were women, and treatment groups were statistically similar at baseline. Primary endpoint analyses on wound area reduction demonstrated statistically significant reduction in favor of s-NPWT ($p = 0.003$) for the PP population and for the ITT population ($p < 0.001$). Changes in wound depth ($p = 0.018$) and volume ($p = 0.013$) were also better with s-NPWT. Faster wound closure was observed with s-NPWT (Cox Proportional Hazards ratio (0.493 (0.273, 0.891); $p = 0.019$) in the ITT population. Wound closure occurred in 45% of patients in the s-NPWT group vs. 22.2% of patients in the t-NPWT group ($p = 0.002$). Median estimate of the time to wound closure was 77 days for s-NPWT. No estimate could be provided for t-NPWT due to the low number of patients achieving wound closure. Device-related AEs were more frequent in the t-NPWT group (41 AEs from 29 patients) than in the s-NPWT group (16 AEs from 12 patients). The s-NPWT system met noninferiority and achieved statistical superiority vs. t-NPWT in terms of wound progression toward healing over the treatment period. When NPWT is being considered for the management of challenging VLUs and DFUs, s-NPWT should be considered a first choice over other types of NPWT.

INTRODUCTION

The most common types of chronic wounds worldwide are venous leg ulcers (VLUs), diabetic foot ulcers (DFUs), and pressure ulcers. More than 40 million new chronic wounds are reported annually.[1]

Most leg ulcers (at least 70%) are the result of chronic venous insufficiency[2] and others are due to mixed venous and arterial disease.[3] Estimated to occur in 1–2% of the population worldwide, the prevalence of leg ulcers may rise to

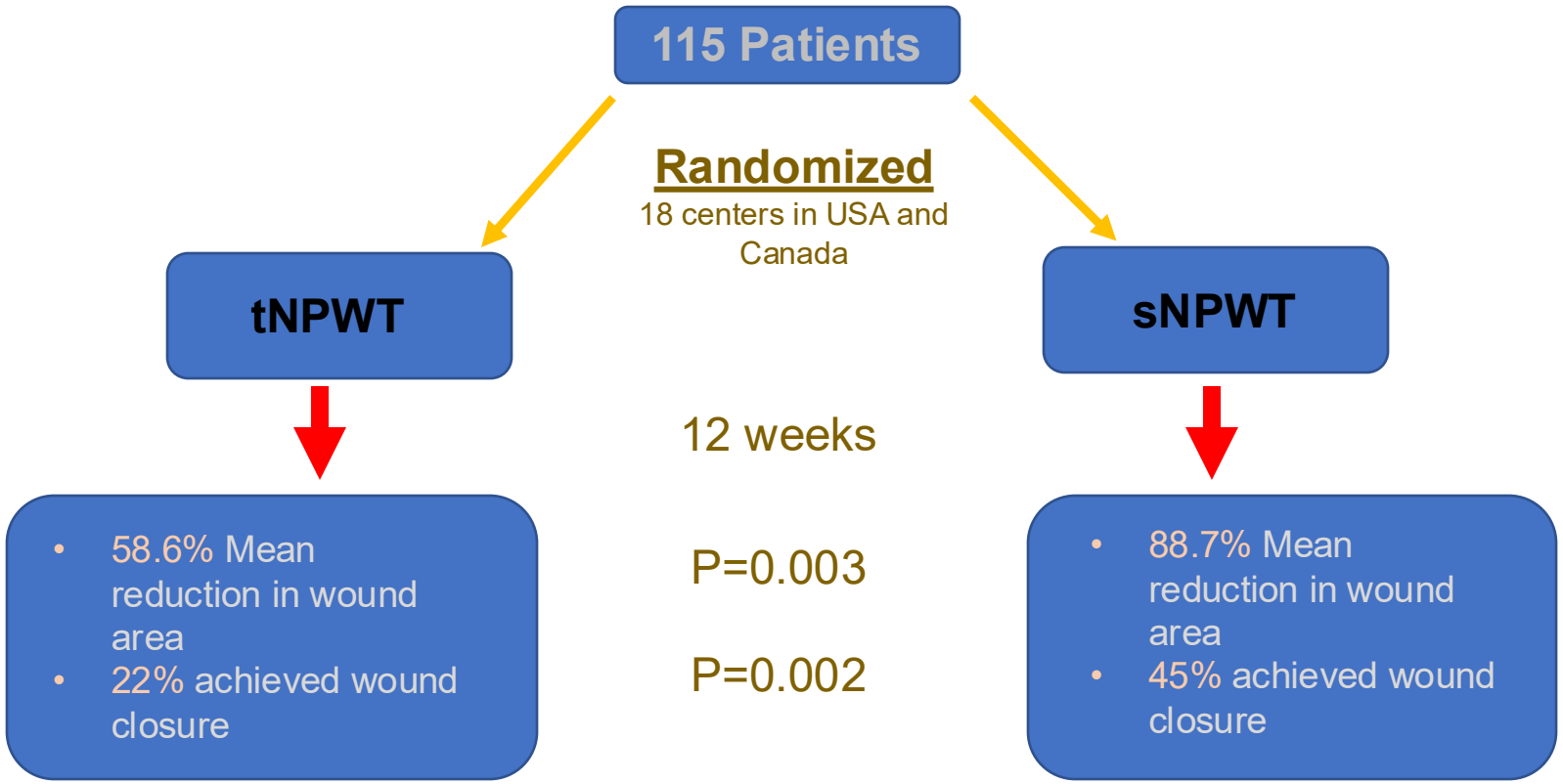
BWAT-m	modified Bates-Jensen Wound Assessment Tool
EQ-5D-5 L	EuroQoL 5 Dimensions, 5 Levels
MVTR	Moisture Vapor Transmission Rate
SSC	Surgical Site Complications
SSI	Surgical Site Infection
s-NPWT	Single-use Negative Pressure Wound Therapy
t-NPWT	Traditional Negative Pressure Wound Therapy

tNPWT = traditional negative pressure wound therapy.

1. Kirsner R, et al. *Wound Repair Regen*. 2019;27(5):519-529.

Mechanism of Action

tNPWT vs sNPWT in open wounds



Kirsner R, et al. *Wound Repair Regen*. 2019;27(5):519-529.

Mechanism of Action
sNPWT

Reduction of the force on sutures ~50%

Computer model and biomechanical studies

Closed Incision Management With Negative Pressure Wound Therapy (CIM): Biomechanics

Surgical Innovation 19(1) 67-75 © The Author(s) 2012 Reprints and permission: sagepub.com/journalsPermissions.nav DOI: 10.1177/1553350611414920 http://sri.sagepub.com SAGE

Robert Peyton Wilkes, MS[1], Deepak V. Kilpadi, PhD , MBA[1], Yabin Zhao, MS[1], Richard Kazala, BS[1], and Amy McNulty, PhD[1]

Abstract

A novel closed incision management with negative pressure wound therapy (CIM) has been developed for convenient use with closed incisions that has the potential to be beneficial for patients at risk for postoperative complications. Incisions are typically under lateral tension. This study explored the biomechanical mechanisms by which integrity of the incisional closure is enhanced by CIM. CIM was hypothesized to affect local stresses around closed incisions in a beneficial manner. Finite element analyses (FEA) indicated that application of CIM decreased the lateral stresses ~50% around the incision and changed the direction of the stresses to a distribution that is typical of intact tissue. Bench evaluations corroborated findings that CIM significantly increased the force required to disrupt the closed incision by ~50% as compared with closure alone. In conclusion, using 2 FEAs and bench modeling, CIM was shown to reduce and normalize tissue stresses and bolster appositional forces at the incision.

Keywords

biomedical engineering, hernias, orthopedic surgery, Cesarean section, dehiscence, finite element analysis, tissue mechanics, negative pressure wound therapy, CIM, modeling

Introduction

Underlying comorbidities such as obesity, diabetes, and poor vascular status as well as risk factors such as smoking, radiation therapy, chemotherapy, and use of steroids present potential challenges in maintaining incision closure after an open surgical procedure.[1-3] Closed incisions with a high risk of complications include those from hip and knee arthroplasty,[4] lower-extremity bypass,[5] abdominal laparotomies,[6,7] and cardiothoracic procedures.[8] These incisions have been traditionally closed by primary intention using sutures, staples, adhesive strips, or a combination thereof. In addition to the higher risk for surgical site complications in these procedure groups, the use of sutures and staples induce stress concentrations where they engage the tissue, and elevated stress concentrations can cause ischemia, fibrosis, or other tissue injury.

Negative pressure wound therapy (NPWT), as delivered by VAC Therapy (KCI USA, Inc, San Antonio, TX),[9-11] involves the controlled application of intermittent or continuous subatmospheric pressure to the wound bed typically via a pressure-manifolding dressing (eg, a reticulated, open-cell foam dressing). NPWT has been shown to have significant clinical success in the treatment of wounds that have a tissue deficit.[9-11] This success with open wounds has led some clinicians to use NPWT on closed surgical incisions using modifications of dressings that were designed for open wounds. In a randomized prospective clinical trial comparing NPWT to standard postoperative dressings used over closed incisions following high-energy trauma, Stannard et al[9,12] reported the incidence of dehiscence and infections to be lower in the NPWT-treated group. The authors recommend that NPWT be considered for high-risk wounds following severe skeletal trauma. A retrospective study by Atkins

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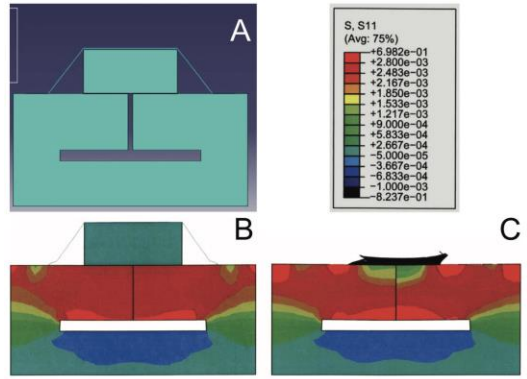

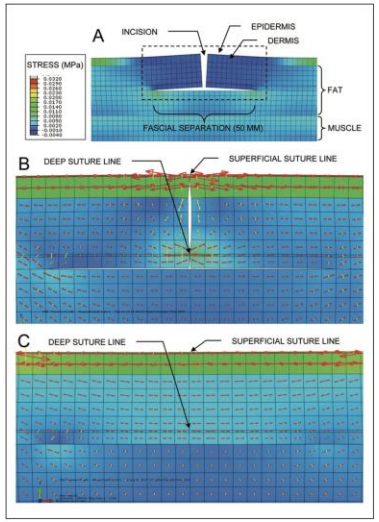

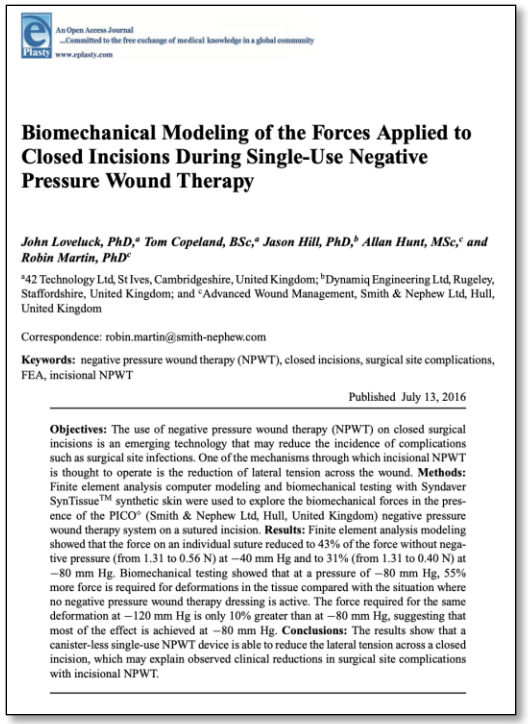

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Biomechanical Modeling of the Forces Applied to Closed Incisions During Single-Use Negative Pressure Wound Therapy

John Loveluck, PhD,[a] Tom Copeland, BSc,[a] Jason Hill, PhD,[b] Allan Hunt, MSc,[c] and Robin Martin, PhD[c]

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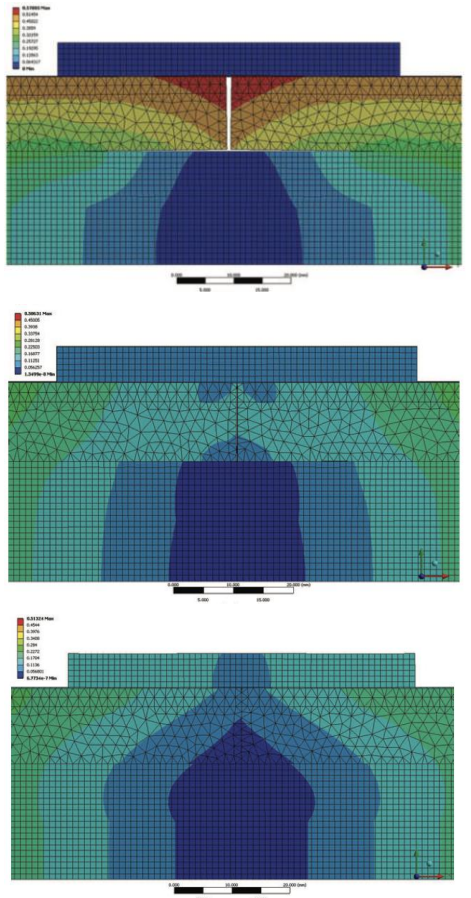
Correspondence: robin.martin@smith-nephew.com

Keywords: negative pressure wound therapy (NPWT), closed incisions, surgical site complications, FEA, incisional NPWT

Published July 13, 2016

Objectives: The use of negative pressure wound therapy (NPWT) on closed surgical incisions is an emerging technology that may reduce the incidence of complications such as surgical site infections. One of the mechanisms through which incisional NPWT is thought to operate is the reduction of lateral tension across the wound. **Methods:** Finite element analysis computer modeling and biomechanical testing with Syndaver SynTissue™ synthetic skin were used to explore the biomechanical forces in the presence of the PICO® (Smith & Nephew Ltd, Hull, United Kingdom) negative pressure wound therapy system on a sutured incision. **Results:** Finite element analysis modeling showed that the force on an individual suture reduced to 43% of the force without negative pressure (from 1.31 to 0.56 N) at −40 mm Hg and to 31% (from 1.31 to 0.40 N) at −80 mm Hg. Biomechanical testing showed that at a pressure of −80 mm Hg, 55% more force is required for deformations in the tissue compared with the situation where no negative pressure wound therapy dressing is active. The force required for the same deformation at −120 mm Hg is only 10% greater than at −80 mm Hg, suggesting that most of the effect is achieved at −80 mm Hg. **Conclusions:** The results show that a canister-less single-use NPWT device is able to reduce the lateral tension across a closed incision, which may explain observed clinical reductions in surgical site complications with incisional NPWT.



1. Wilkes RP, et al. *Surg Innov*. 2012;19(1):67-75. 2. Loveluck J, et al. *Eplasty*. 2016;16:e20.

Mechanism of Action
sNPWT

Computer model and biomechanical studies

Closed Incision Management With Negative Pressure Wound Therapy (CIM): Biomechanics

Surgical Innovation
19(1) 67-75
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DOI: 10.1177/1553350611414920
http://sri.sagepub.com
SAGE

Robert Peyton Wilkes, MS[1], Deepak V. Kilpadi, PhD , MBA[1], Yabin Zhao, MS[1], Richard Kazala, BS[1], and Amy McNulty, PhD[1]

Abstract

A novel closed incision management with negative pressure wound therapy (CIM) has been developed for convenient use with closed incisions that has the potential to be beneficial for patients at risk for postoperative complications. Incisions are typically under lateral tension. This study explored the biomechanical mechanisms by which integrity of the incisional closure is enhanced by CIM. CIM was hypothesized to affect local stresses around closed incisions in a beneficial manner. Finite element analyses (FEA) indicated that application of CIM decreased the lateral stresses ~50% around the incision and changed the direction of the stresses to a distribution that is typical of intact tissue. Bench evaluations corroborated findings that CIM significantly increased the force required to disrupt the closed incision by ~50% as compared with closure alone. In conclusion, using 2 FEAs and bench modeling, CIM was shown to reduce and normalize tissue stresses and bolster appositional forces at the incision.

Keywords

biomedical engineering, hernias, orthopedic surgery, Cesarean section, dehiscence, finite element analysis, tissue mechanics, negative pressure wound therapy, CIM, modeling

Introduction

Underlying comorbidities such as obesity, diabetes, and poor vascular status as well as risk factors such as smoking, radiation therapy, chemotherapy, and use of steroids present potential challenges in maintaining incision closure after an open surgical procedure.[1-3] Closed incisions with a high risk of complications include those from hip and knee arthroplasty,[4] lower-extremity bypass,[5] abdominal laparotomies,[6,7] and cardiothoracic procedures.[8] These incisions have been traditionally closed by primary intention using sutures, staples, adhesive strips, or a combination thereof. In addition to the higher risk for surgical site complications in these procedure groups, the use of sutures and staples induce stress concentrations where they engage the tissue, and elevated stress concentrations can cause ischemia, fibrosis, or other tissue injury.

Negative pressure wound therapy (NPWT), as delivered by VAC Therapy (KCI USA, Inc, San Antonio, TX),[9-11] involves the controlled application of intermittent or continuous subatmospheric pressure to the wound bed typically via a pressure-manifolding dressing (eg, a reticulated, open-cell foam dressing). NPWT has been shown to have significant clinical success in the treatment of wounds that have a tissue deficit.[9-11] This success with open wounds has led some clinicians to use NPWT on closed surgical incisions using modifications of dressings that were designed for open wounds. In a randomized prospective clinical trial comparing NPWT to standard postoperative dressings used over closed incisions following high-energy trauma, Stannard et al[9,12] reported the incidence of dehiscence and infections to be lower in the NPWT-treated group. The authors recommend that NPWT be considered for high-risk wounds following severe skeletal trauma. A retrospective study by Atkins

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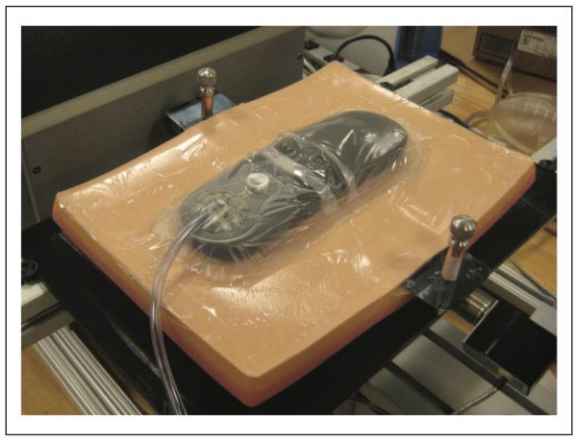
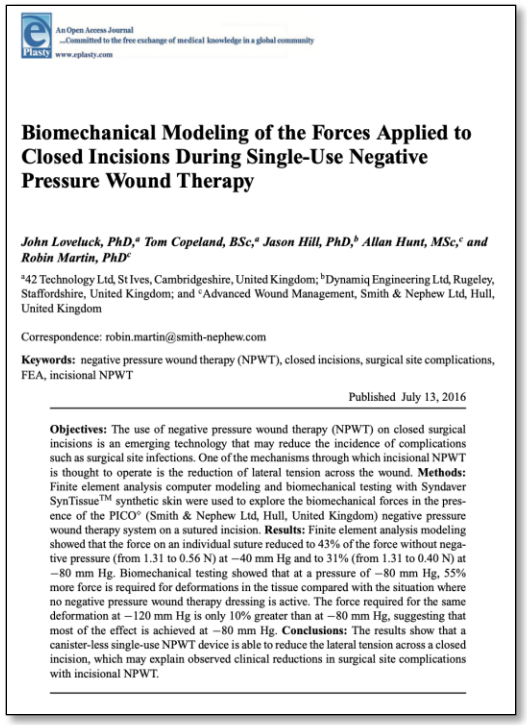
Email: robert.wilkes@kci1.com



Force required for 10mm distraction increased 43% with sNPWT



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Biomechanical Modeling of the Forces Applied to Closed Incisions During Single-Use Negative Pressure Wound Therapy

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[a]42 Technology Ltd, St Ives, Cambridgeshire, United Kingdom; [b]Dynamiq Engineering Ltd, Rugeley, Staffordshire, United Kingdom; and [c]Advanced Wound Management, Smith & Nephew Ltd, Hull, United Kingdom

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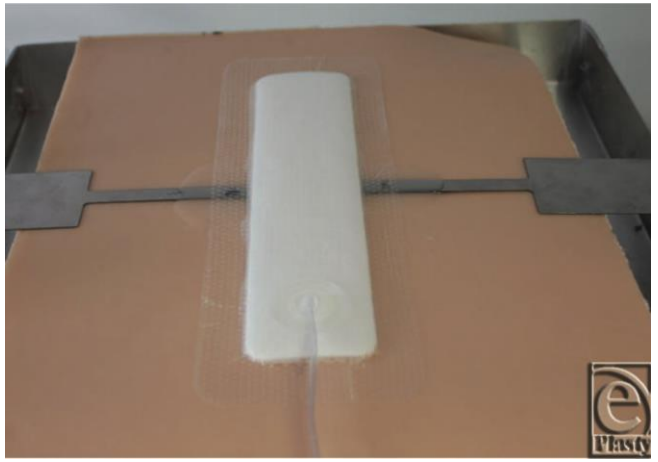

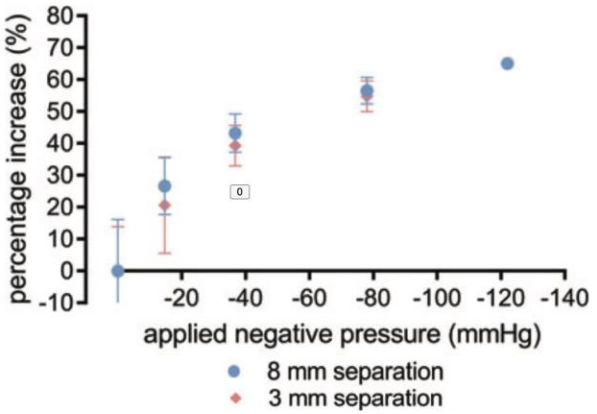

Mechanism of Action sNPWT

Pre-Clinical Assessment of Single-Use Negative Pressure Wound Therapy During *In Vivo* Porcine Wound Healing

Varuni R. Brownhill,[1] Elizabeth Huddleston,[1] Andrea Bell,[2] Jeffrey Hart,[2] Iain Webster,[1] Matthew J. Hardman,[3,*] and Holly N. Wilkinson[3]

12-day study in porcine model with standardized wounds comparing tNPWT vs sNPWT

Evaluated at day 0, day 6, and day 12

- Faster wound closure (18.56% vs 33.36% area remaining)
  - Greater re-epithelialization
  - Faster wound contraction
- Reduced inflammation
- Granulation tissue maturation
- Higher total collagen deposition
- Reduced surrounding skin disruption and periwound inflammation

1. Brownhill VR, et al. *Adv Wound Care* (New Rochelle). 2021;10(7):345-356.

Mechanism of Action
sNPWT

1. Tissue perfusion effects
2. Lateral tension and wound strength
3. Effects on edema
4. Reduction in hematoma and seroma

Karlakki S, et al. *Bone Joint Res* 2013;2:276–284.

Mechanism of Action
sNPWT

"...incisional NPWT has developed so that there are now reasonable grounds for confidence that this approach is widely applicable to a range of indications...

...but we have little idea of precise mechanisms. "

Karlakki S, et al. *Bone Joint Res.* 2013;2:276–284.

Mechanism of Action sNPWT

Mounting Evidence:

- Orthopedic Surgery
- Plastic & Reconstructive Surgery
- Cardiothoracic Surgery
- Vascular Surgery
- Colon & Rectal Surgery
- OB/Gyn
- Breast Surgery
- General Surgery

Mechanism of Action
sNPWT

A randomized clinical trial evaluating negative pressure

Jeontaik
Mariano
Philadelp

Closed incision negative pressure wound t

Negative pressure wound therap

Heepe
Todd L.

RESEARCH ARTICLE

S.U.
N. T

Cost-effec
negative p
(sNPWT)

Original Article

Effectiveness of Specific Single-Use Incisional Negative Pressure Wound Therapy (PICO System) After Major Lower Extremity Amputation

The International Journal of Lower Extremity Wounds
2025, Vol. 24(1) 130–134

DOI: 10.1177/15347346231221116
journals.sagepub.com/home/ijl
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ORIGINAL CONTRIBUTIONS: OUTCOMES

Cost-Effectiveness Analysis of Negative Pressure Wound Therapy to Prevent Surgical Site Infection After Elective Colorectal Surgery

Cheung, Douglas C. M.D., M.B.A.[1]; Muaddi, Hala M.D., M.Sc.[1]; de Almeida, John R. M.D., M.Sc.[1,2,4]; Finelli, Antonio M.D., F.R.C.S.C.[1,3]; Karanicolas, Paul M.D., Ph.D.[1,4,5]

D, PhD[1],
, MD[1,4],
itsuya, MD[4],

Incisional Negative Pre

Postoperative Cardiothoracic Wound Infection

ainst ound therapy *versus*
d surgical incisions:
l meta-analysis

Kaitlin A. Nguyen, BS,[a] George A. Taylor, MD, MS,[a] Theresa K. Webster, BS,[a] Rachel A. Jenkins, BS,[a] Nicklaus S. Houston, BS,[a] Dylan L. Kahler, MD,[a] Andrew A. Gassman, MD,[b] and Christine M. Jones, MD[a]

Kelly James[*], A

[a] *General Surgery, United St*
[b] *Global Clinical and Medic*

Correspondence to: Global Clinical Affairs, Smith+Nephew, 101 Hessle Road, Hull HU3 2BN, UK (e-mail: Christopher.Saunders@smith-nephew.com)

Presented to the 29th Conference of the European Wound Management Association, Gothenburg, Sweden, June 2019

Clinical Application of sNPWT
Closed Incision

Single-use negative pressure wound therapy versus conventional dressings for the reduction of surgical site infections in closed surgical incisions: Systematic literature review and meta-analysis

Kelly James [a], Amy Glasswell [b], Ben Costa [b,*]

[a] *General Surgery, United Surgical Associates of Kansas City, Missouri, USA*
[b] *Global Clinical and Medical Affairs, Smith and Nephew, Hull, UK*

Single-use negative-pressure wound therapy *versus* conventional dressings for closed surgical incisions: systematic literature review and meta-analysis

C. Saunders [1,*], L. M. Nherera[2], A. Horner[1] and P. Trueman[2]

[1]Global Clinical Affairs, Smith+Nephew, Hull, UK
[2]Health Economics and Market Access, Smith+Nephew, Hull, UK

*Correspondence to: Global Clinical Affairs, Smith+Nephew, 101 Hessle Road, Hull HU3 2BN, UK (e-mail: Christopher.Saunders@smith-nephew.com)

Presented to the 29th Conference of the European Wound Management Association, Gothenburg, Sweden, June 2019

1. Saunders C, et al. *BJS Open.* 2021;5(1):zraa003. 2. James K, et al. *Am J Surg*. 2024;228:70-77.

Clinical Application of sNPWT
Closed Incision

Initial Presentation

1 Wk Post-Op

Clinical Application of sNPWT
Closed Incision

Initial Presentation

2 Wk Post-Op

Application of sNPWT
Skin Graft Bolster

Safeguarding Skin Grafts

An Evidence-Based Summary of Fixation Techniques

Benjamin J. Patel, MRCS, Christian M. Asher, MRCS,
Nicola Bystrzonowski, FRCS (Plast), and Ciaran Healy, FRCS (Plast)

SKIN GRAFT FIXATION IN SEVERE BURNS: USE OF TOPICAL NEGATIVE PRESSURE

Kamolz L.P.,[1]* Lumenta D.B.,[1] Parvizi D.,[1] Wiedner M.,[1] Justich I.,[1] Keck M.,[2] Pfurtscheller K.,[3] Schintler M.[1]

BURN SURGERY AND RESEARCH

Application of Topical Negative Pressure (Vacuum-Assisted Closure) to Split-Thickness Skin Grafts

A Structured Evidence-Based Review

Ernest Anthony Azzopardi, MRCSEd, MSc Surg, MD,† Dean E. Boyce, MD, FRCS, FRCSEd, FRCS(Plast),† William A. Dickson, MBE, FRCS(Glas) FRCS,† Elayne Azzopardi, BSc, Hons, MSc,‡ James Hamish Ellsworth Laing, BSc, MBBS, FRCS(Plast),† Iain S. Whitaker, MA(Cantab), PhD, FRCS(Plast),† and Kayvan Shokrollahi, BSc, MB ChB, MSc, MSc LLM MRCS(Eng), FRCS(Plast)†§*

NPWT is associated with enhanced graft take compared with traditional techniques.

An efficient method in major burns

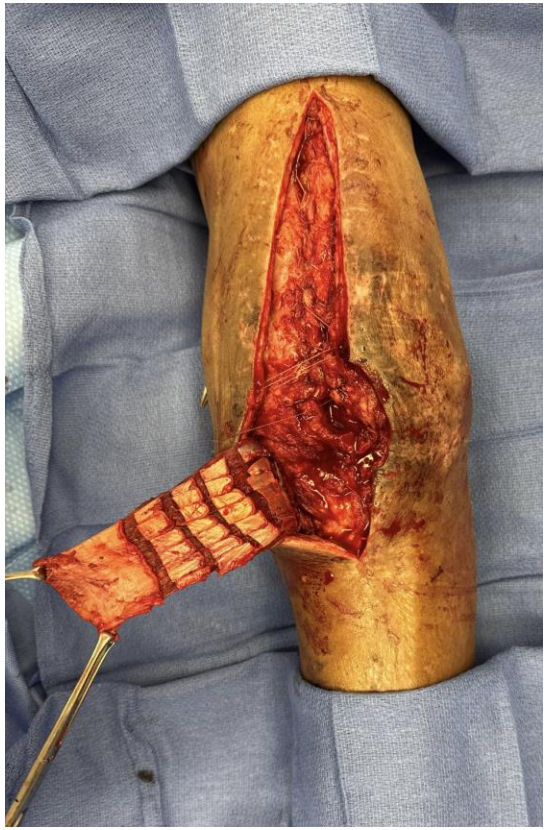
This systematic review suggests that it may impart a considerable advantage to split skin grafting over traditional dressings in quality and quantity of take.

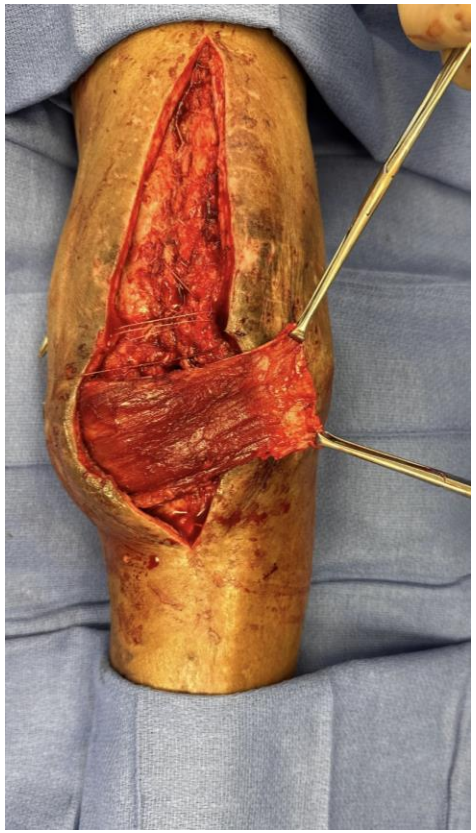
1. Azzopardi EA, et al. *Ann Plast Surg*. 2013;70(1):23-29. 2. Patel BJ, et al. *Ann Plast Surg*. 2021;87(6):e180-e188. 3. Kamolz LP, et al. *Ann Burns Fire Disasters*. 2014;27(3):141-145.

Application of sNPWT
Skin Graft Bolster

Initial Presentation

Intraoperative





POD 12

6 Wks Post-Op

Application of sNPWT
Open Wounds

WOUNDS

ORIGINAL RESEARCH

From Traditional to Single Use: The Evolution of Negative Pressure Wound Therapy as a Mechanism for Optimal Wound Management

"68% of wounds treated with tNPWT are amenable to and could be treated with sNPWT."

Lindsay R, et al. *Wounds*. 2025;37(3):125-133.

Application of sNPWT
Open Wounds

Start of Therapy

1 Wk

2 Wks

3 Wks

Clinical Pearls

Mechanism of action

All NPWT

- Macrodeformation
- Microdeformation
- Fluid removal
- Alteration of wound environment
- Modulation of inflammation
- Cellular responses
- Oxygen gradient
- Lymphatic clearance

sNPWT

- Control of periwound edema
- Reduction in lateral tension
- Faster wound contraction and re-epithelialization
- Reduced injury to periwound skin

Applications

- Open wounds
- Closed incisions
- Skin grafts

Case Studies

Allen Raphael, DPM, FACFAS
Village Podiatry Centers/Upperline Health
Smyrna, GA

Partial Calcanectomy

Rotational Flap with Cryopreserved Umbilical Tissue

Partial Calcanectomy

Patient and diagnosis

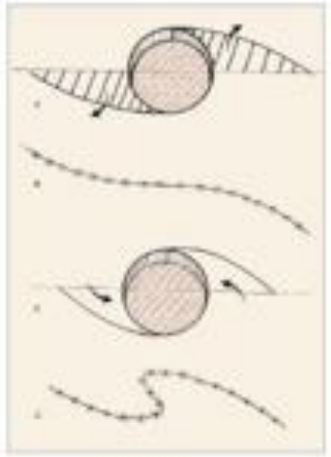
- 54 yr old Male
- Pressure ulcer due to calcaneus gait
- 3-yr duration
- DM, CAD, HTN, prior ankle fusion
- Wound probes to bone with cellulitis present
- Debridement, custom CROW boot

Wound treatment and outcome

- Partial calcanectomy, O-Z flap, implantation of cryopreserved umbilical tissue
- Proper wound closure can help flap incorporation
- Single stage procedure with concomitant IV antibiotic therapy
- Wound closure without breakdown of flap

Partial Calcanectomy

- Close Apex first
- Leave top of flap open
- Slide cryopreserved umbilical tissue below the hurricane flap



Partial Calcanectomy

ANKLE FUSED AT 10 OF DORSIFLEXION

CALCANEAL RESECTION AT 10 DEGREE ANGLE

Partial Calcanectomy

"O" to "Z" = closing a circle

Charcot Foot Ulcer

Lyopreserved placental membrane + cryopreserved umbilical tissue

Charcot Foot Ulcer

Patient and diagnosis

- 57 yr old Male
- Charcot induced pressure ulcer
- Ulcer present for 6 months, treated while abroad in Saudi Arabia
- DM, HTN, PVD, Charcot
- Plantar cuboid region with exostosis in a stable midfoot rocker-bottom foot
- Treated previously with collagen dressing

Wound treatment and outcome

- Debridement/graft/TAL/TCC for wound size reduction, followed by cuboid exostectomy and implantation/onlay grafting with cryopreserved umbilical tissue
  - Atrophied fat pad with localized ischemic tissue island at the midfoot
- Goal was offloading/antibiosis/grafting first followed by osseous correction and tissue augmentation
  - 2 graft applications in differing techniques used

Charcot Foot Ulcer

- Anchoring cryopreserved umbilical tissue with absorbable suture percutaneous to “parachute”
- Offload with total contact cast once exudate levels are manageable

Charcot Foot Ulcer

- 2 pieces of cryopreserved umbilical tissue used to address osseous deformity with consideration for adjacent soft tissue deficit
- Percutaneous anchoring reduces displacement of tissue implantation

Intraoperative

Charcot Foot Ulcer

Patient and diagnosis

- 52 yr old Male with Charcot induced pressure ulcer left plantar foot
- Relevant past medical history includes DM, HTN, Charcot

Wound treatment and outcome

- There was 100% surface area reduction in wound size demonstrated after 2 implantation/applications of cryopreserved umbilical tissue and midfoot exostectomy
- In addition to standard of care and multilayer compression, patient achieved complete closure at wk 12

Application #1
Length: 5.5 cm Width: 5.5 cm Depth: 0.6 cm

Application #2
Length: 1.5 cm Width: 1.5 cm Depth: 0.2 cm

Complete Closure
Length: 0 cm Width: 0 cm Depth: 0 cm

Pyoderma Gangrenosum

Cryopreserved umbilical tissue

Pyoderma Gangrenosum

Patient and Diagnosis

- 35 yr old Female
- Pyoderma Gangrenosum (PG)
- PG flare due to stopping oral prednisone therapy
- Chron's disease, IBS, family history of PD (mother)
- Spontaneous tissue slough to left medial ankle

Wound Treatment and Outcome

- Surgical debridement of wound with hydrosurgery
- Application of cryopreserved umbilical tissue
- Biopsy of culture taken of wound to confirm PH and diagnose presence of microorganisms
- Prescribed cyclosporine and prednisone for PG suppression

Applied cryopreserved umbilical tissue twice at 5-wk interval

- Collagen matrix and hydrophobic bacteria binding contact layer used in between graft applications with 4 x 4, ABD pad, and gauze wrap
- Periwound tissue addressed with protective barrier cream at each dressing change
- Multi-layer compression applies

Pyoderma Gangrenosum

Baseline assessment

Post debridement
Wound: 10 cm x 8 cm x 1 cm
Tunnel: 3 cm at 5 o'clock

Placement of 1st cryopreserved umbilical tissue

Pyoderma Gangrenosum

4 days post-op

7 days post-op

10 days post-op

Pyoderma Gangrenosum

Granulation tissue formation

21 days post-op

25 days post-op

31 days post-op
5.8 cm x 4.0 cm x 0.2 cm

Pyoderma Gangrenosum

Cryopreserved umbilical tissue fully incorporated with evidence of epithelial migration. Second cryopreserved umbilical tissue application at 50 days.

37 days post-op

39 days post-op
4.9 cm x 4.2 cm x 0.1 cm

2nd cryopreserved umbilical tissue application

Pyoderma Gangrenosum

Second cryopreserved umbilical tissue progression

1 wk

5 wks
2.8 cm x 2.0 cm

9 wks
2.2 cm x 1.5 cm

12 wks
1.5 cm x 0.6 cm

Pyoderma Gangrenosum

Full closure achieved at 20 wks

Wound with Failed Primary Closure

Cryopreserved umbilical tissue + lyopreserved umbilical tissue

Wound with Failed Primary Closure

Patient and diagnosis

- 43 yr old Male
- DM, HTN, obesity, Charcot neuroarthropathy
- Abscess over dorsal midfoot requiring I&D
- Measures 8 cm x 3 cm x 1 cm
- Dorsal midfoot with exposed extensor hallucis tendon
- Surgeon attempted primary closure after I&D

Wound treatment/procedure

- Surgical debridement with hydrosurgery and cold steel, NPWT, application with cryopreserved umbilical tissue
- Second procedure 3 wks later to wrap tendon in lyopreserved umbilical tissue secured with monocryl suture
- Cryopreserved umbilical tissue used as overlay for overall wound coverage
- Third cryopreserved umbilical tissue 6 wks later to finalize healing
- Immobilized in pneumatic aircast boot

Pre- I&D

Attempted primary closure

Wound retraction

Wound with Failed Primary Closure

POD#5 Attempted primary closure

Pre-op – Increased depth and tissue loss

POD#3 Cryopreserved umbilical tissue application with NPWT

Wound with Failed Primary Closure

Paratenon loss with tendon desiccation

Warp EHL tendon with lyopreserved umbilical tissue

5-0 Monocryl to secure graft

Wound with Failed Primary Closure

Cryopreserved umbilical tissue 2nd layer to cover entirety of wound

POD#17 – Robust granulation with graft persistence

Wound with Failed Primary Closure

Tendon covered with granular tissue

Wound contracture

Epithelialized with functional preservation

Wound with Failed Primary Closure

Outcome

- Initial I&D on with attempted wound closure
- Wound evaluation with cryopreserved umbilical tissue and NPWT applied after failed closure 2 wks after initial I&D
- Lyopreserved umbilical tissue tendon wrap cryopreserved umbilical tissue wound onlay 3 wks post wound evaluation
- Final cryopreserved umbilical tissue graft application at 6 wks
- Wound closed at 9 wks

Final photograph taken 11 wks later

Gas Gangrene with Abscess

Cryopreserved placental membrane + cryopreserved umbilical tissue

Gas Gangrene with Abscess

Patient and diagnosis

- 48 yr old Male
- Type 2 DM, HTN, renal Dx
- Shoe irritation to 5th metatarsal base
- Gas gangrene with tissue loss right foot
- Patient hospitalized for emergent surgical intervention
- Hyperbaric oxygen therapy consult
- Previous treatment with betadine and surgical shoe by referring physician

Wound treatment/procedure

- Incision and drainage right foot with BID Dakin's dressing changes to reduce bioburden
- Second procedure 48 hrs later to apply NPWT
- Cryopreserved umbilical tissue graft application at wk #3
- 10 wkly cryopreserved placental membrane applications in office

Gas gangrene with abscess – surgical intervention

Gas Gangrene with Abscess

Post op day (POD) #2
Application of NPWT

Post op day #14
Progression of infection with tissue loss

Post op day #21 – Granular bed with bioburden reduced

Gas Gangrene with Abscess

POD # 24
Application of cryopreserved umbilical tissue

POD # 35
Cryopreserved umbilical tissue absorbed

POD # 42
cryopreserved placental membrane application #1 in office

Gas Gangrene with Abscess

POD # 70 cryopreserved placental membrane application #4

POD # 7 cryopreserved placental membrane application #5

POD # 84 cryopreserved placental membrane application #6

Gas Gangrene with Abscess

POD # 98 cryopreserved placental membrane application #8

POD # 112 cryopreserved placental membrane application #10

POD # 126 cryopreserved placental membrane collagen to finish up!

Gas Gangrene with Abscess

Outcome

- Slow progression of wound healing due to difficult infection control challenges – MRSA, VRE, *Pseudomonas*
- Patient admitted to LTAC facility to receive hyperbaric oxygen therapy, IV antibiotics, and PT for 1 month
- Time to closure approximately 5 mos
- Patient returned to work at correctional facility
- Orthotist fabricated custom diabetic inserts with fillers and stiff shank to assist with propulsion
- Patient unfortunately now being treated for similar issue with contralateral limb
- Re-emphasized need with patient for “surveillance visits” after healing wounds

Patient still healed 2 yrs later

Gangrene with PVD

Cryopreserved umbilical meshed tissue

Gangrene with PVD

Patient and diagnosis

- 80 yr old Male
- ESRD on HD, A-Fib, PVD, CHF, dementia
- Blister lances in referring physician outpatient clinic, subsequent onset of dry gangrene
- 2 wk history of wounds upon presentation
- Dx: Dry gangrene with severe PVD
- Extensive tissue loss with osteomyelitis

Wound treatment/procedure

- Endovascular procedures attempted, developed sternal pain during procedure that was aborted. Patient stabilized; revascularization was completed
- Surgical debridement with forefoot amputation, implantation of cryopreserved umbilical meshed tissue beneath flap, cryopreserved umbilical meshed tissue applied beneath NPWT for dorsal wound
- Single application thus far, further grafting pending tissue viability

Initial presentation prior to vascular intervention

Gangrene with PVD

Dorsal wound extends to 1st metatarsal burr used to remove necrotic bone

Healthy wound base

TMA with medical lateral flap

Gangrene with PVD

- Cryopreserved umbilical meshed tissue placed directly on NPWT foam and then placed on the open surface
- No contact layer required
- Set at 125 mm Hg continuous therapy
- NPWT left in place for 4 days
- Additional cryopreserved umbilical tissue placed between TMA flap to promote flap healing

Two cryopreserved umbilical meshed tissue 6” x 3”

Gangrene with PVD

Outcome

- NPWT removed at POD #4
- Held for 2 days with anti-microbial foam to reduce periwound maceration
- TMA flaps are viable with good capillary refill time
- Bone and tendon now partially covered in wound base with excellent granular ingrowth

Post op day #4 – rapid granulation

Gangrene with PVD

Outcome

- First outpatient NPWT change 10 days post-op
- Wound case is highly granular with rapid integration of cryopreserved umbilical meshed tissue into wound bed
- Bone and tendon is completely granulated
- Cryopreserved umbilical meshed tissue is well adhered with wound bed
- May opt to hold NPWT periodically to preserve periwound tissue (NPWT holiday)
- Use non-cytotoxic dressing such as hydrophobic bacteria binding contact layer or polyurethane foam dressing during NPWT
- Patient receiving vancomycin during hemodialysis for MRSA osteomyelitis

10 days post-op cryopreserved umbilical meshed tissue embedded in wound

Gangrene with PVD

- Wound continues to progress
- Will receive STSG to close wound

2 wks post op

3 wks post op

Gangrene with PVD

Outcome

- Wound continues to progress
- STSG applied to close wound

10 wks post op

Gangrene with PVD

Final Closure

Mohs Surgery, Mohs Complications

Cryopreserved umbilical tissue, Cryopreserved placental membrane

Mohs Wide Excision of Melanoma

- 68 yr old Male presents with large lateral calf ulcer
- History of recent Mohs wide excision of melanoma by surgical oncology
- Wound healing delayed due to size, depth and location of excision
- Failed STSG placed over site
- Wound measures 8 x 9 x 1cm and probes to myofascial layer near peroneal tendons

Mohs Wide Excision of Melanoma

Surgical Plan

- Excisional debridement with hydrosurgery
- Biopsy and cultures of wound
- Application of cryopreserved umbilical meshed tissue 6 x 3 cm, dual layer
- Application of NWPT at 125 mm Hg continuous
- Immobilize extremity with tall leg aircast boot

Mohs Wide Excision of Melanoma

- 1st dressing change 4 days post-op
- Rapid granulation tissue formation below graft site
- Cultures indicate presence of heavy growth of MRSA, treated with oral doxycycline for 10 days

Mohs Wide Excision of Melanoma

- 1 wk post-op
- Sutures removed, as graft is well embedded in granular base
- Continue NWPT, dressing changes 2x/wk in office

Mohs Wide Excision of Melanoma

- 2 wks post-op
- Wound is flush to surface
- Muscle completely covered
- Residual graft strands noted in wound bed
- NPWT reapplied for 1 more wk of therapy

Mohs Wide Excision of Melanoma

- Post-op wk 5
- Wound highly granular and rapidly contracting collagen and polyurethane foam dressings with compression from toes to knee 2x/wk
- Continue immobilization in cam walker boot

Mohs Wide Excision of Melanoma

- Post-op wk 8
- Wound contracture with healthy periwound skin
- Ulcer now measures 2.0 x 1.7 x 0. cm

Mohs Wide Excision of Melanoma

- Post-op wk 12
- Wound is fully epithelialized
- Tissues are soft and supple, minimal wound contracture
- No tethering of peroneal tendons to subcutaneous tissue

Mohs Wide Excision of Melanoma

1 year later…

- Pigmentation and sensation regeneration at previous wound site
- No motor deficits due to tissue tethering

Surgical Wound Dehiscence

Cryopreserved umbilical tissue, Cryopreserved umbilical meshed tissue,
Cryopreserved placental membrane

Patient History

Medical history

- Surgical hx: Hysterectomy in 2011, CABG in Sept 2023
- Comorbidities: HBP, HTN, anemia, high cholesterol, CAD, hx of ovarian cancer and chemotherapy
- Medications: clopidogrel, empagliflozin, sacubitril/valsartan, pironolactone
- Allergies: adhesive, latex, amoxicillin, shellfish

Surgical Wound Dehiscence

Initial patient presentation

- April 2023: she had an excision of basal cell carcinoma on anterior aspect of her lower limb by a dermatologist
- June 2023: s/p surgical excision presentation of wound

June 4

July 18

Surgical Wound Dehiscence

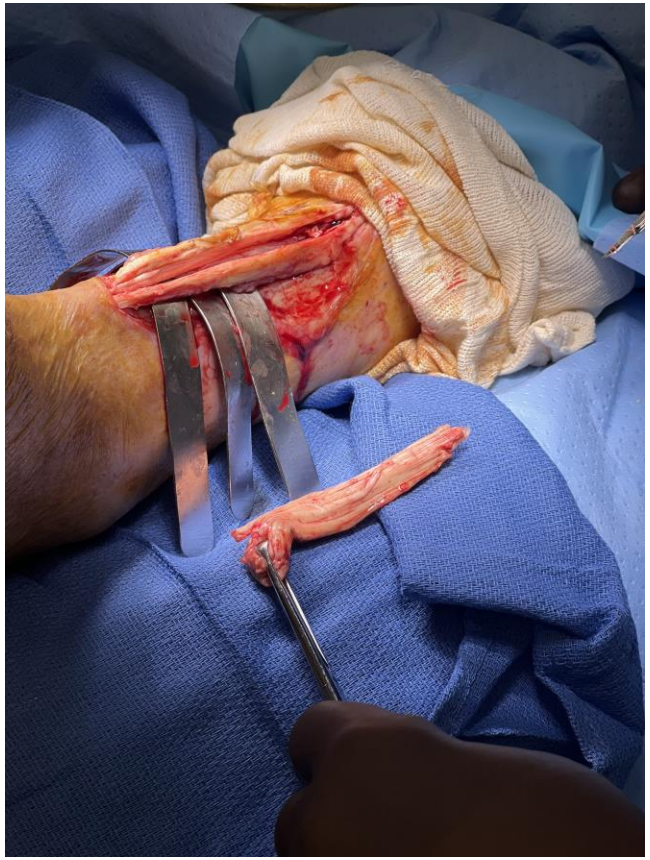
Patient and diagnosis

- 80-year-old Female
- Wound dehisced and she presented to a WCC then referred to podiatry
- First surgery was 10/10/23: debridement, application of cryopreserved umbilical tissue, cryopreserved umbilical meshed tissue, cryopreserved placental membrane
- application
- Second surgery 11/3/23: debridement and application of cryopreserved umbilical tissue

October 10: wound presentation in clinic

Surgical Wound Dehiscence

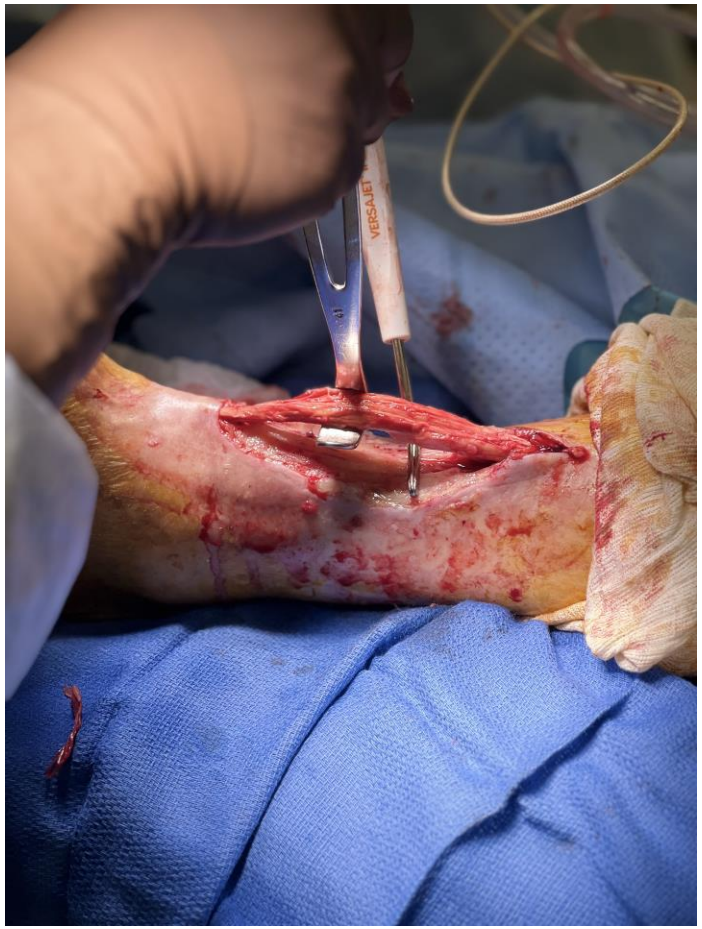
Debridement and excision of tibialis anterior



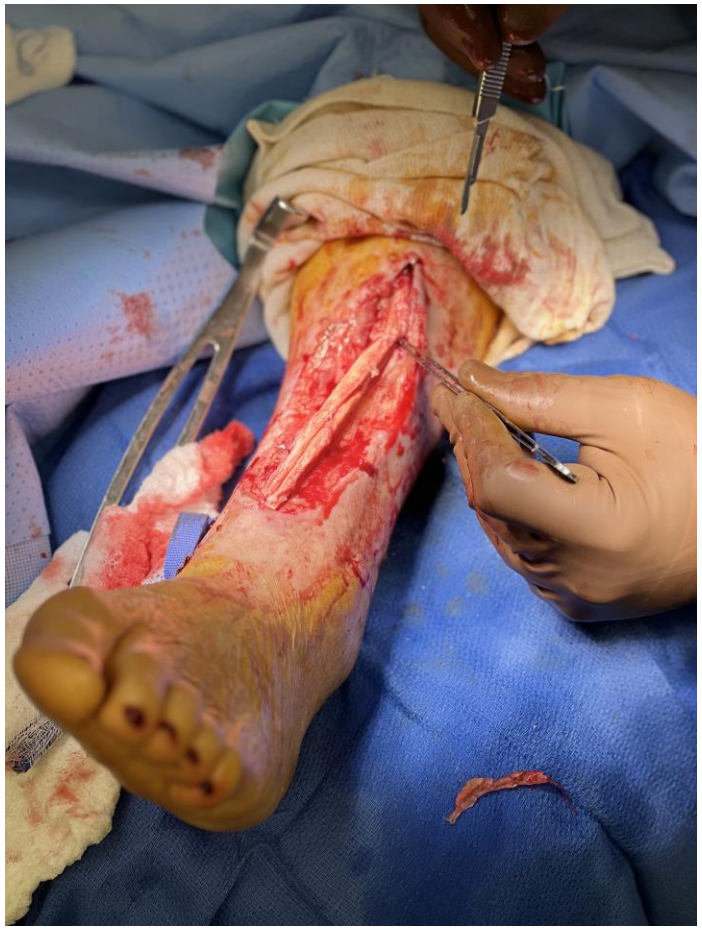
Excision of tibialis anterior

Surgical Wound Dehiscence

Tibialis anterior tendon debridement



Debridement with hydrosurgery



Tibialis anterior tendon debridement

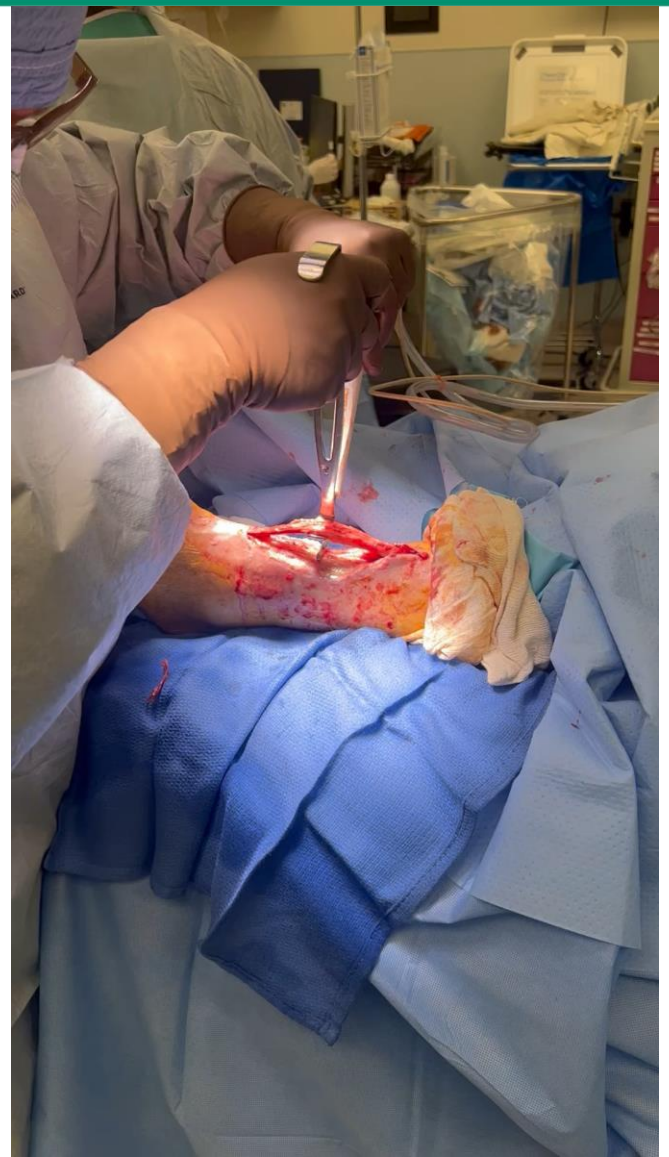
Surgical Wound Dehiscence

Wrapping tendon with cryopreserved umbilical tissue with cryopreserved placental membrane application on the wound bed inferior to tendon

Cryopreserved umbilical tissue application with cryopreserved placental membrane placed inferior to tendon

Covering wound with cryopreserved umbilical meshed tissue

Surgical Wound Dehiscence



Surgical Wound Dehiscence

Application of cryopreserved umbilical meshed tissue, superior to tendon

Wound vac application

Surgical Wound Dehiscence

Oct. 13

Oct. 19

Oct. 23

Surgical Wound Dehiscence

Oct. 26

Oct. 30

Surgical Wound Dehiscence

Second wound debridement and cryopreserved umbilical tissue application on 11/3/23

Pre op

Post op 3 days

Surgical Wound Dehiscence

Nov. 6

Nov. 9

Nov. 16

Surgical Wound Dehiscence

Nov. 22

Nov. 27

Nov. 30

Surgical Wound Dehiscence

Oct. 13

Oct. 30

Nov. 9

Nov. 16

Surgical Wound Dehiscence

Outcome

- Post- op results: Cryopreserved umbilical tissue, cryopreserved umbilical meshed tissue, cryopreserved placental membrane application

Nov. 30

Dec. 7

Complex Wound: HIV Case

Cryopreserved placental membrane

Complex Wound: HIV Case

Patient wound presentation

12/29/2022

2/2/2023

Complex Wound: HIV Case

Patient and diagnosis

- 24-year-old Black Male
- Untreated HIV/ AIDS
- Seen by burn team on 12/29/2022 for wound management
- Denies autoimmune history
- I&D of wound on 1/4/2023 with biopsy and cultures
- Biopsy was negative for Kaposi sarcoma
- Second surgery was 2/21 and last surgery was 3/17
- Labs 2/7: hepatitis A, HIV, HSV I and HSV II, syphilis
- Viral load was 202,000 in Feb 2023
- CD-4 was 5 in Feb 2023

Complex Wound: HIV Case

Feb 21, 2023: surgical debridement and cryopreserved placental membrane application

Complex Wound: HIV Case

March 20,2023
3 days post-op, 2nd wound debridement

March 27, 2023

April 3, 2023

Complex Wound: HIV Case

April 19, 2023

May 3, 2023

Complex Wound- HIV Case

Outcome

- Labs 2/7: hepatitis A, HIV, HSV I and HSV II, syphilis
- Viral load was 202,000 in Feb. 2023
- CD-4 was 5 in Feb. 2023 and now is above 232
- Current medications: bictegravir, emtricitabine & tenofovir alafenamide and sulfamethoxazole/ trimethoprim
- Following up with infectious disease

10/13/2023

Dogs: Woman's Best Friend?

Cryopreserved umbilical tissue, Cryopreserved umbilical meshed tissue,
Cryopreserved placental membrane

Patient History

Medical history

- Comorbidities: Systemic lupus erythematosus, rheumatoid arthritis, scleroderma, HTN, peripheral neuropathy, IBS, Raynaud's
- Surgical Hx: Multiple toe amputations, STSG to right lower extremity wounds
- Medications: Citaprolam, gabapentin, meloxicam, methocarbamol, prednisone
- Allergies: Adhesive, latex, doxycycline, sulfa
- Social Hx: No ETOH or tobacco use

Dog Bite

Initial patient presentation

- Feb 8, 2024: Patient sustains dog bite injury while attempting to break up fight between her German Shephard and neighbor's dog
- Trauma team at sister Wellstar hospital assumed care
- Repair of laceration

Dog Bite

- Attempted grafting with CTP with NPWT device
- Patient had graft applied to wound and covered with non-adherent contact layer, petrolatum-impregnated gauze, then NPWT device
- Minimal granular tissue
- Continued biofilm formation
- Periwound skin irritation from adhesive drape

June 4

Dog Bite

- Patient decides to seek 2nd opinion due to slow progression of wound healing
- Wound was not recently cultured, now with mild malodor and persistent biofilm
- Patient presents to my office on March 13, 2024 – approximately 6 wks after initial injury
- Wound cultures obtained at this visit demonstrate MRSA, beta *Strep, Pseudomonas* – all heavy growth and MDRO

What's the Plan, Stan?

Pre-Surgical PLAN

1. Pre-operative bloodwork: CBC, CMP, sed rate, CRP, autoimmune panel
2. Rheumatology consult
3. Vascular consult
4. Nutritional consult: therapeutic nutrition for wound healing recommended
5. Appropriate DME to facilitate immobilization and offloading
6. Dog training

Dog Bite

Surgical Plan

- Hospital admission for IV antibiotics and pain control
- General anesthesia and sciatic block with bupivacaine
- Hydrosurgery debridement
- Deep placement of cryopreserved placental membrane over gastrocnemius muscle and aponeurosis
- Cryopreserved umbilical meshed tissue graft secured with polypropylene suture
- Protect periwound skin with piecrust prep
- Used silicone-based drape instead of traditional material
- Did not use wound contact layer
- NPWT applied at 125 mm Hg continuous therapy for 4 days

Dog Bite

Hydrosurgery System – A wound Jedi's saber

- Typically start at setting 3 and slowly increase power as need
- Avoid blind passes with device to minimize neurovascular injury
- Post debridement lavage with minimally cytotoxic anti-infective
- Can remove epibole precisely to create optimal "bowl" shape
- Cryopreserved placental membrane XC placed over muscle and wrapped to emulate fascial plane of medial calf compartment

Dog Bite

Cryopreserved umbilical meshed tissue graft – Rapid vertical closure when used with NWPT

March 15

March 19

March 28t

Dog Bite

April 15

May 2

May 3

Dog Bite

May 24

May 28

June 10

Dog Bite

- Silver nitrate to areas of hypergranulation
- Moisturizer applied regularly to periwound skin
- Minimal scar contracture given patient's comorbidities, such as scleroderma and lupus
- Patient celebrates her healing and adopts stray cat that scratches her right leg, now treating this wound!
- Regenerative healing of compromised host

July 22

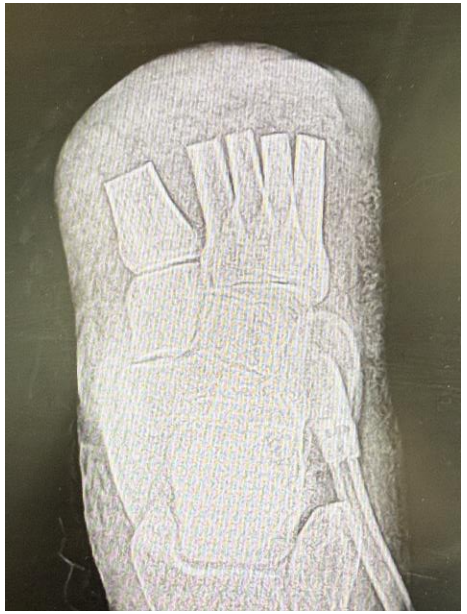
One Man Gathers What Another Man Spills

Cryopreserved umbilical tissue, cryopreserved umbilical meshed tissue, cryopreserved placental membrane, NPWT, STSG

Patient History

Medical history

- 68 y/o Hispanic Female referred by Hamilton Medical Center Wound Treatment Center
- Comorbidities: Diabetes mellitus Type 2 with HgA1C of 9.1
- Surgical Hx: I&D of gas gangrene with open TMA right foot by on-call podiatric surgeon, no follow-up arranged with physician who recommended wound care center
- Medications: Insulin aspart, metformin, lisinopril, ASA 81mg
- Allergies: PCN
- Social Hx: No ETOH or tobacco use



One Man Gathers

Initial patient presentation

- Aug 9, 2024: Patient presents for first surgery
- Guillotine TMA with violation of metatarsal parabola – Need to restore biomechanics
- Reapproximation of lax tissues
- Graft and NPWT therapy

One Man Gathers

- Resect metatarsals to restore parabola
- Remove soft tissue redundancy and use retention sutures
- Hydrosurgery 2 to entire wound
- Cryopreserved placental membrane XC applied over deep wound structures

One Man Gathers

- Resect metatarsals to restore parabola
- Remove soft tissue redundancy and use retention sutures
- Hydrosurgery 2 to entire wound
- Cryopreserved placental membrane XC applied over deep wound structures

One Man Gathers

- Cryopreserved umbilical meshed tissue grafts secured with staples
- Conformant 2 wound contact layer stapled to NPWT sponge
- Set at 125 mm Hg continuous therapy x4 days
- Immobilize extremity in posterior splint
- Right picture is 2 wks after initial graft/VAC application

One Man Gathers

- 1 application of cryopreserved placental membrane and cryopreserved umbilical meshed tissue and NPWT
- Left picture is 4 wks after first procedure
- Right picture is 7 wks after first procedure
- Are we ready for procedure #2?

One Man Gathers

- Second procedure scheduled 7 wks after first surgery
- Hydrosurgery to ulcer to prepare for autologous graft
- STSG harvested from ipsilateral thigh, meshed 1:1
- Percutaneous Achilles tendon lengthening to address ankle equinus

One Man Gathers

- Second procedure scheduled 7 wks after first surgery
- Hydrosurgery to ulcer to prepare for autologous graft
- STSG harvested from ipsilateral thigh, meshed 1:1
- Percutaneous Achilles tendon lengthening to address ankle equinus

One Man Gathers

- Left picture is 2 wks after STSG application
- Right pictures are 6 wks after STSG application
- Continue PT for gait training and proprioceptive re-education
- DME for DM shoes and TMA filler, rigid shank, and slight rocker heel