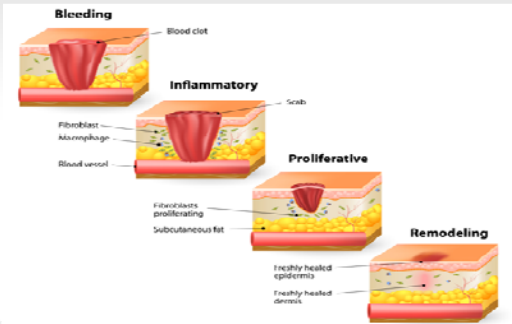


Are You Getting the Most Out of Your DME License?

Tools, Tips and Strategies for SUCCESS!

Alec O. Hochstein, DPM, DABFAS

The Basics of Healing a Wound



Collagen's Role in Medicine

Collagen is used for a variety of different medical purposes including...

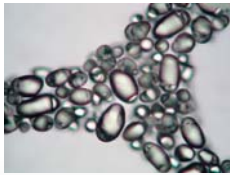
- Osteoarthritis Treatment
- Cosmetic Surgery
- Bone Grafts
- Tissue Regeneration
- Reconstructive Surgical Uses
- Wound Care
- Surgical Wounds



Collagen's Role in Wound Care

- During the process of proliferation, angiogenesis, collagen deposition, granulation tissue formation; epithelialization and wound contraction occur.
- Collagen enhances the wound contracture and cellular migration that are essential for wound healing.
- Collagen is the most abundant protein in the body.
- 90% of the dermis is composed of type 1 collagen.
- The body produces collagen via the fibroblasts when trying to heal itself, and therefore using a collagen based wound care product compliments the natural process.

Collagen Scaffolding



- Paramount for cell migration.
- Without normal scaffolding formation of the extracellular matrix (ECM), the granulation tissue will be impaired.
- Collagen based wound dressings are uniquely suited to address the issue of elevated MMP's by acting as a "sacrificial substrate" in the wound.

Characteristics of Topical Collagen

- Promotes autolytic debridement by several mechanisms
- Does not support bacterial growth
- Biocompatible
- Extremely low hypersensitivity
- Soothing to the wound
- Compatible for any wound type
- No need to remove
- Needs no preservatives
- Classified as a device not drug
- Compatible with other products applied to the wound

HELIX3 Collagen

- 100% Type 1 Bovine Collagen
- Non-Hydrolyzed Native Collagen
- Biodegradable & Biocompatible
- Maintains a Moist Wound Environment
- Effective in all Wound Phases
- No Additives, Synthetics or Fillers
- FDA Cleared for: Burns, Sores, Blisters, Ulcers and Other Wounds

** Do not use HELIX3 if patient is sensitive to materials of bovine origin. **



Podiatry Specific Uses for HELIX3

- Diabetic Ulcers
- Venous Stasis Ulcers
- Post-Debridement
- Full Thickness Wounds
- Surgical Wounds
- Verrucae Excisions
- Biopsies

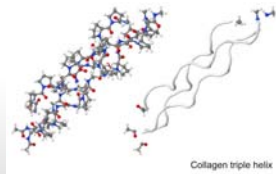


Why is Non-Hydrolyzed Important

Hydrolyzed collagen means the collagen has been broken down into its component amino acids, Glycine, Proline, & Hydroxyproline and no longer retains its native triple Helical structure.

Non-Hydrolyzed Collagen

- Retains more native triple helical protein structure
- Allows for better stability of the molecule and scaffolding in wound healing
- Lends itself to maximum exudate management



What Makes HELIX3 CP (Collagen Powder) Different?

- Each gram absorbs 40-60x its weight in fluid.
- Contributes up to 10x more non-denatured collagen protein than competing hydrolyzed collagen products.
- The retained native helical structure enhances the vital "scaffolding" process for the Extra Cellular Matrix (ECM), promoting the formation of "throughways" that allow for the re-routing of circulatory structures and the development of granulation tissue.
- Supplied in 1-gram packets for convenient application and dispensing.



HELIX3 CP Easy Application Technique

1. Prepare the wound bed – Use AMERIGEL Wound Wash to remove any necrotic or sloughy fibrotic tissue. Keep the wound bed moist to improve the powders ability to readily adhere. Applying AMERIGEL Hydrogel is one option.
2. Using a tongue depressor, gather a small amount of HELIX3 CP. Rotate the depressor to apply the powder directly to the wound surface. Gently apply pressure to allow more collagen to adhere to the wound.
 - For minimally draining wounds, apply a light layer of powder.
 - For moderate to heavily draining wounds, apply approximately 1/4" thick.
3. Apply a secondary dressing which is appropriate for the level of drainage.



Applying HELIX3 Collagen Powder



HELIX3 CM (Collagen Matrix)



- Highly absorptive porous collagen sheet
- Consists of fibrous triple-helix, collagen structure
- Can be used in combination with topical agents
- Available in 2 x 2, 3 x 4, and 4 x 5.25 sheets
- FDA Cleared for: Burns, Sores, Blisters, Ulcers and Other Wounds

** Do not use HELIX3 if patient is sensitive to materials of bovine origin. **

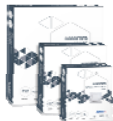
HELIX3 CM Application Technique



1. Prepare the wound bed – Use AMERIGEL Wound Wash to remove any necrotic or sloughy fibrotic tissue.
2. Apply HELIX3 Collagen Matrix to the wound. If needed, cut the dressing to fit the size of the wound. If the wound has minimal drainage, you should hydrate the dressing with sterile saline prior to applying it. HELIX3 CM may be applied dry if the wound has moderate drainage.
3. Apply a secondary dressing which is appropriate for the level of drainage.

Use With Other Products

- HELIX3 CM and CP are Biocompatible. Use with any secondary dressing or with other products (ex: antimicrobials, AMERIGEL Wound Wash, AMERIGEL Hydrogel).
- May be used on infected wounds.
- The use of collagen products in conjunction with a collagenase enzymatic debriding agent continues to be debated however, no clinical evidence has been reported to support one side or the other. However, other debriding agents may be used in conjunction with or prior to using HELIX3.



KNOW YOUR LIMITATIONS!



HELIX3 Case Study 1

Treated By: Alec Hochstein, DPM, Great Neck, NY

- Wound Presentation:
 - 55-year old diabetic male presented with neuropathic wound.
 - Patient had a previous history of MRSA.
 - Radiographs negative for signs of osteomyelitis.

Case Study 1



Initial Presentation

1.5 cm round, mild/moderate drainage
No malodor
No erythema
No deep probing

Treatment: Sharp debridement, surgical blade and tissue nipper. Removed periwound keratosis and wound base slough/fibrous tissue

Decision for application of TCC
Applied primary collagen powder dressing
Secondary dressing foam
Standard application of TCC.



2 Weeks

3 cm round, mild serous drainage
No signs of infection

Treatment: Sharp debridement, surgical blade and tissue nipper. Removed periwound keratosis. Wound base granular.
(TCC, collagen powder dressing and foam changed weekly)



5-Weeks

Ulcer completely closed.
Wound was closed at week-4, but I prefer to keep TCC therapy in place for 2 weeks post closure.

HELIX3 Case Study 2

Treated By: Alec Hochstein, DPM, Great Neck, NY

- Wound Presentation:
 - 14-year old male presented with 6-month history of two slow growing lesions on left foot/hallux.
 - Failed treatments included soaks, OTC wart remover, duct tape.

Case Study 2



Initial Presentation

Initial presentation of lesion, maceration, visible capillary heads, papular presentation. Treatment: local injection of 5% Marcaine with epinephrine. Surgical dissection of hypertrophied maceration. Hyfrecation of lesion with curettage down to basement membrane, with multiple cauterization passes to base of wound, with subsequent curetting.



10-Day Follow Up

Patient following home care instructions consisting of daily cleaning with soap and water, Amegel Wound Wash, daily application of Helix3 Collagen Powder, primary dressing, Adaptic, 2 X 2 top cover dressing.



3-Weeks Post op

Daily regimen remains the same. Products remain the same. Dressing changed to sterile cloth Bandaid at this time. Notice smaller surgical site on Hallux is healed.

Case Study 2 Continued



5-Weeks Post op

Keratic border debried at visit.



7-Weeks Post op

Notice minimal contracture and presence of normal skin lines, minimal scarring.

Practice Management Benefits

The centers for Medicare and Medicaid Services (CMS) have assigned a Medicare billing code for HELIX3 CP and HELIX3 CM.

A6010 (Powder) – Collagen based wound filler, dry form, sterile, per gram of collagen

A6021 (Dressing) – Collagen Dressing, Sterile, Size 16 square inches or less, each dressing
(Applies to 2 X 2 and 3 X 4 matrix)

A6022 (Dressing) – Collagen Dressing, Sterile, Size greater than 16 square inches but less than or equal to 48 square inches, each dressing
(Applies to 4 X 5.25 matrix)

www.dmepdac.com - Billing and Coding Resource Website

Practice Management Benefits

Dressing size must be based on and appropriate to the size of the wound. Dressing needs may change frequently (e.g., weekly/daily) in the early phases of wound treatment and/or with heavily draining wounds. Suppliers are also expected to have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly. No more than a one-month's supply of dressings may be provided at one time, unless there is documentation to support the necessity of greater quantities in the home setting in an individual case. An even smaller quantity may be appropriate.

What Does This Mean For You?

You can dispense up to 30 units of HELIX3 Collagen Powder or Collagen Matrix Per Wound Per Month.

Surgical Dressing Coverage and Payment Rules

- Medical Necessity = Following wound debridement or surgical procedure
- Full-thickness Wound = Penetrates through the dermis
 - Collagen NEW Rules: A collagen-based dressing or wound filler is covered for full thickness wounds (e.g., stage III or IV ulcers), wounds with light to moderate exudate, or wounds that have stalled or have not progressed toward a healing goal.
- Exudate = Documentation supporting dry to heavy drainage
- A1-A9 Modifiers = Denotes the number of wound(s) being treated
- Place of Service (POS) = Home (12)
- Surgical Dressings are **NOT** covered when dispensed to patients receiving home health care

HELIX3 CP Cost & Reimbursement

HELIX3 Collagen Powder

Acquisition Cost	\$12.60/Unit
HCPCS Code	A6010
Reimbursement	\$34.86/Unit
Profit/Unit	\$22.26
Allowable/Month	30 Units
Profit/Patient/Month	\$667.80



One New Patient Per Week for 52 weeks per year =
\$34,725.60 Annual Practice Profit

HELIX3 CM Cost & Reimbursement

HELIX3 Collagen Matrix (2x2, 3x4)

Acquisition Cost	\$10.30/Unit
HCPCS Code	A6021
Reimbursement	\$23.66/Unit
Profit/Unit	\$13.36
Allowable/Month	30 Units
Profit/Patient/Month	\$400.80



One New Patient Per Week for 52 weeks per year =
\$20,841.60 Annual Practice Profit

Disclaimer

This information does not guarantee reimbursement, but provides guidance for accurate documentation and appropriate usage for collagen powder and gel. Should you need further technical assistance or have specific coding questions, please contact your regional DMERC or intermediary. It is the intention of Amerx to share this information with healthcare professionals to highlight awareness of the reimbursement process.

Cost-Effectiveness of Collagen in Wound Care Outside of DMERC Model

A retrospective chart study conducted by Snyder et al reviewed patients receiving home care services, and compared wound healing using sequential therapy consisting of collagen or collagen with silver vs. saline soaked gauze.

974 patients reviewed
873 treated with collagen or collagen/silver
101 treated with saline soaked gauze

- 2 months of treatment -
 - 95% of the wounds treated with collagen closed at a total cost of \$2,145.
 - 7.2% of the wounds treated with saline soaked gauze closed at a total cost of \$7,350.
- 6 months of treatment -
 - 43% of the wounds treated with saline soaked gauze closed at a total cost of \$22,050.

Snyder RJ, Richter D, Hill ME. A retrospective study of sequential therapy with advanced wound care products versus saline gauze dressings: comparing healing and cost. *Ostomy Wound Manage.* 2010; 56 Suppl 11A:S9-S15.

Cost-Effectiveness Study 2

Lazaro-Martinez et al conducted a retrospective study to analyze cost effectiveness of treatment, using results from an earlier 6-week randomized clinical trial.

40 patients with DFU were reviewed (randomized in 2 groups)

- Group 1 (n=20) treated with collagen dressing
- Group 2 (n=20) treated with standard protocol

Effectiveness was defined as the percentage of patients whose wounds had healed at end of study. Total cost of care (including staff, ancillary supplies, dressings and patient-transport costs), the number of patients needing treatment, the mean cost, the incremental cost, and the average cost effectiveness were analyzed.

Lazaro-Martinez JL, Aragon-Sanchez FJ, Garcia-Morales E, Benoit-Montesinos JV, Gonzalez-Jurado M. A retrospective analysis of the cost-effectiveness of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers. *Ostomy Wound Management.* 2010; 56 Suppl 11A:S4-S8.

Cost-Effectiveness Study 2 Continued

Results

- Treatment effectiveness was 63% in group 1 (collagen group)
- Treatment effectiveness was 16% in group 2 (standard protocol)
- The average cost effectiveness (total cost/effectiveness in each group):
 - \$561.48 in group 1 (collagen)
 - \$2,577.65 in group 2 (standard protocol)

Lazaro-Martinez JL, Aragon-Sanchez FJ, Garcia-Morales E, Benoit-Montesinos JV, Gonzalez-Jurado M. A retrospective analysis of the cost-effectiveness of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers. *Ostomy Wound Management.* 2010; 56 Suppl 11A:S4-S8.

AMERX Wound Care Kits



TURN-KEY DME
WOUND CARE PROGRAM



✓ Increase Compliance ✓ Standardize Dressings ✓ Avoid Inventory Shortages

AMERX Wound Care Kits

- Everything needed for your patients to perform proper dressing changes at home including:
 - ✓ Primary Dressing
 - ✓ Secondary Dressing
 - ✓ Saline Wound Wash
 - ✓ Supportive Dressing
- Available in a variety of primary dressing options based on individual wound needs
- Offered in 5 DAY, 15-DAY and 30-DAY kits
- Patients appreciate the convenience and compliance rates are improving
- PDAC Approved Products



TURN-KEY DME
WOUND CARE PROGRAM

Comprehensive documentation tools to improve the flow of communication, enhance documentation and ensure compliance with the latest in PDAC requirements.

- ✓ Documentation Flow Chart
- ✓ HCPCS Coding Guidance
- ✓ Wound Documentation Templates
- ✓ Prescription Forms
- ✓ Proof of Delivery

Available Exclusively from AMERX!

Introducing Patient Direct

New to the AMERX Turn-Key DME Program

- ✓ NO Upfront Costs
- ✓ Eliminate On-Site Inventory
- ✓ Next Day Delivery to Your Patient's Doorstep
- ✓ Receive Verified Insurance with Pre-Authorization
- ✓ Ensure Accuracy with Coding/Billing Support
- ✓ Get Fast, Efficient Order Processing
- ✓ Enjoy Exceptional Support from Your Dedicated Representative

AMERX Patient Direct

1) Order

- Patient presents to practice and is a candidate for surgical (wound care supplies)
- Order is given to staff to source product for patient.
- Staff completes order form and faxes to AMERX with patient insurance information.



The image shows a detailed AMERX Patient Direct Order Form. It includes sections for Patient Information, Insurance Information, and a table for listing medical supplies. The table has columns for Item, Description, Quantity, and Unit. There are also sections for Billing Information and a signature area.

AMERX Patient Direct

2) Verification

- AMERX verifies patient enrollment, deductible, and co-pay and communicates to office
- Practice approves or declines shipping based upon insurance coverage / deductible.



The image shows an AMERX Patient Direct Insurance Verification Form. It includes sections for Patient Information, Insurance Information, and Billing Information. There are checkboxes for 'Insurance Enrollment Information' and 'Billing Information'. The form also has a table for listing medical supplies and a signature area.

AMERX Patient Direct

3) Shipping

- Upon approval, products are shipped to the patient and the practice is billed for the product.



AMERX Patient Direct

4) Documentation

- AMERX compiles delivery receipt and insurance information and electronically transfers to office.
- Practice receives documentation, completes billing paperwork, and submits claim to insurance company.



AMERX Patient Direct

5) Payment

- Insurance provider pays claim directly to the practice.
- Practice submits payment to Amerx for products and services.
- Practice keeps the PROFITS driving overall growth.



Compression 101

“You must compress ALL edema and support venous HTN to heal wounds faster and without infection or recurrence.”

~ Pamela Cole MS PT
Casting and Compression Workshop (SAWC Spring 2017)

- Practicing wound care without properly compressing edema is retarding / inhibiting wound healing.

Therapeutic Action of Compression

- When compression wraps are tightened edematous fluid reenters the veins.
- Keeping veins constricted, prevents congestion – blood pooling or flowing backward.

Differential Diagnosis

PAD vs. Vascular Insufficiency

- Vascular Insufficiency = Compress
- PAD = Do not compress
 - Diagnosing PAD
 - Determine ABI (Arterial Brachial Index) using systolic blood pressure from ankle and arm.
 - Formula:

$$\frac{\text{Ankle Systolic Pressure}}{\text{Arm Systolic Pressure}} = \begin{matrix} 1.0 \text{ to } 1.4 - \text{Healthy Person} \\ 0.9 - \text{Possible Blockage} \\ 0.5 - \text{Serious (refer to Vascular)} \end{matrix}$$

Types of Compression

- Short Stretch Compression
Low resting pressure – high active pressure
- Long Stretch Compression
High resting pressure – some increase with muscle firing

Mixed Component Bandages Proved Most Effective
(Journal of Clinical Nursing May 2017)

Difficulty in Application

- #1 Reason for Not Prescribing and/or Lack of Compliance
- JAMA Study reported when applying 30-50 mmHg:
 - Achieved by 39 of 62 nurses (63%) applying the 2-component bandage
 - 28 of 68 nurses (41%) applying the elastic bandage
 - 27 of 68 nurses (40%) applying the inelastic bandage
 - More than half the nurses applying the inelastic (38 [56%]) and elastic (36 [53%]) bandages obtained pressures less than 30 mm Hg.
 - At best, only 17 of 62 nurses (27%) using the 2-component bandage achieved sub bandage pressure within the range they aimed for.

*Delivery of compression therapy for venous leg ulcers. (JAMA Dermatology July 2014)

▶ The EXTREMIT-EASE™ Advantage



- Provides 30-50mm Hg Compression
- Easy to Apply and Adjust
- Air-Permeable Fabric, Comfortable and Light Weight
- Provides benefits of Short-stretch and Long-stretch Compression
- Reduces Pistoning

Application Video





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