

# **Optimal Management of Diabetic Foot Ulcers**

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## OPTIMAL MANAGEMENT OF DIABETIC ULCERS OF THE LOWER EXTREMITY



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NO FINANCIAL CONFLICT  
OF INTEREST TO DISCLOSE

## 2021 CDC NATIONAL DIABETES STATISTICS REPORT

- 38.1 Million adults 18 years or older in U.S. have diabetes
- 14.7% of adults 18 years or older in U.S. population have diabetes
- 8<sup>th</sup> Leading cause of death in U.S.

## 2021 CDC NATIONAL DIABETES STATISTICS REPORT

- 60%-70% diabetics have nervous system damage
- Severe nervous system damage increases chance of ulceration
- > 60% non-traumatic lower limb amputations occur in people with diabetes

## INTERNATIONAL DIABETES FEDERATION GLOBAL POSITION STATEMENT

- Global prevalence 589 million adults in 2024
- Predicted to reach 853 million by 2050
- \$966 billion USD spent yearly globally to treat diabetes
- 1 in every 6 people with diabetes will develop foot ulcer
- 85% diabetes related amputations are preceded by foot ulcers
- 49% - 85% of amputations are preventable
- Requires well-organized diabetic multidisciplinary team

So, just how do you evaluate  
and treat a diabetic ulcer of  
the lower extremity?

Just like you do any other lower extremity ulcer!

- ### SYSTEMIC FACTORS AFFECTING WOUND HEALING
- Diabetes
  - Tobacco use
  - Malnutrition
  - Hereditary disorder
  - Alcohol use
  - Malignancy
  - Renal failure
  - Autoimmune
  - Chemotherapy
  - Steroids
  - Extremes of age
  - Systemic infection

- ### LOCAL FACTORS AFFECTING WOUND HEALING
- Ischemia
  - Edema
  - Infection
  - Scarring
  - Radiation injury
  - Topical steroids
  - Local toxins
  - Trauma/Pressure
  - Foreign bodies
  - Local malignancy

- ### Why Diabetics Don't Heal
- High levels of matrixmetalloproteinases (MMP-9)
  - Low levels of growth factors (Cullen et. al: Wound Rep Reg 10: 2002)
  - If hypoxic:
    1. Poor collagen production
    2. Impaired resistance & response to local infection
    3. Limited angiogenesis
    4. Decreased fibroblast replication

- ### CHRONIC WOUNDS HAVE:
- Inhibitors or blockers of growth factor action
  - Inadequate quantities of growth factors
  - Primary inadequate response to available growth factors
  - Have 30 X more MMP activity than acute wounds



## DIAGNOSIS OF DELAYED WOUND HEALING

Evaluation of:

1. Vascular status
2. Infection (local or systemic)
3. Immune system
4. Nutritional status
5. Mechanical factors
6. Malignancy (exclude)

## VASCULAR EVALUATION

### History

- Diabetes
- DVT
- Tobacco use
- Radiation
- Local toxins (Spider bite)
- Collagen vascular disease
- Scarring
- Claudication
- Rest Pain

## VASCULAR EVALUATION

### Examination

- Pulses (palpable/audible)
- Skin color (dependent rubor/hyperpigmentation)
- Rate of capillary refill (< 3 sec)
- Edema (even trace amounts)
- Hair (minor finding)

## VASCULAR EVALUATION

### Diagnostic Testing

- CBC (anemia)
- TCOM
- Arterial doppler
- Venous doppler
- Tissue biopsy
- Collagen vascular Screening
- Arteriogram
- MRA
- MRV
- CTA
- CTV

## NUTRITIONAL EVALUATION

- Physical examination
- Total protein
- Albumin
- PreAlbumin
- CBC (anemia)
- Glucose (blood sugar, HgbA1C 6.5% or <)

## EVALUATION OF MECHANICAL FACTORS

- Pressure
- Foreign body
- Edema

## EVALUATION OF MECHANICAL FACTORS

### Pressure Due To Immobilization

- CVA
- Paralysis (spinal)
- Closed head injury
- Trauma with loss of consciousness
- Surgery
- Traction

## EVALUATION OF MECHANICAL FACTORS

### Pressure Due To Orthotics

- Shoes
- Stockings
- Braces
- Prosthesis

## EVALUATION OF MECHANICAL FACTORS

### Pressure Due To Dressings

- Cast
- Splint
- Circumferential dressings
- Dressing packing

## EVALUATION OF MECHANICAL FACTORS

### Foreign Body

- | <u>Intentional</u> | <u>Incidental</u>                         |
|--------------------|---|
| ● ORIF             | ● Retained suture                         |
| ● Joint implant    | ● Bone (sequestrum)                       |
| ● IV Access        | ● Needle                                  |
| ● Mesh             | ● Retained dressing Material              |
| ● Synthetic grafts | ● Retained fingernail or toenail fragment |

## EVALUATION OF MECHANICAL FACTORS

### Edema

- Trauma
- CHF
- Renal failure
- Lymphedema (congenital acquired)
- Tumor
- Surgery

## IMMUNE SYSTEM EVALUATION

- Collagen vascular disease
- Drugs
  - Steroids
  - Chemotherapy
- HIV
- Systemic malignancy

## EVALUATION FOR MALIGNANCY

- “Think of It”
  - Primary malignancy
  - Secondary malignancy
- Biopsy
  - Incisional
  - Excisional
- Location
  - Especially lower leg or arm
  - History of “almost healing”

## EVALUATION FOR INFECTION

- Soft Tissue “bioburden”
  - Swab culture
  - Wound biopsy (gold standard)
  - (> 100,000 Organisms per gram of tissue)
- Bone infection
  - Clinical inspection
  - Bone biopsy
  - Plain X-Ray
  - CT scan
  - MRI scan
  - Labeled WBC scan

## TREATMENT OF DELAYED WOUND HEALING

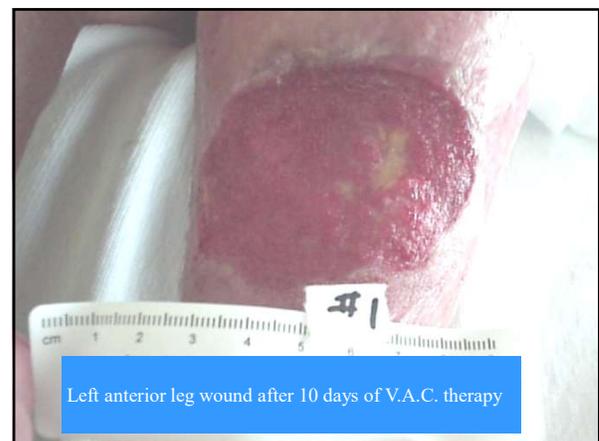
● Surgery	● Pressure relief
- Debridement	● Nutritional supplements
- Revascularization	● Removal of foreign bodies
- Skin graft	● Resolution of infection
- Flap	● Excise malignancy
- Amputation	● Medical adjunctive care
● Edema reduction	● Local care of wound
● Hyperbaric oxygen therapy	- Topical care
	- Dressing care

## (SURGERY) SKIN GRAFTS AND FLAPS

- Split thickness skin graft
  - Requires a uniform, granulating, infection Free bed
- Skin and Skin/Muscle flaps
  - To cover non-vascularized wounds (bare bone)
  - To cover pressure areas (sacral, ischial, trochanteric pressure ulcers)
  - To cover exposed, non-infected, foreign body (prosthesis)

## (SURGERY) SKIN GRAFTS AND FLAPS

- Skin stretching device
- Epidermal autograft (CelluTome®)
  - Donor site less painful than STSG
  - Donor site heals in 3-4 days and care be reharvested
  - Good for patients with large wounds
  - Requires no anesthesia
  - Epidermal grafts take on characteristics of recipient site
  - Can be used on patients with scleroderma or pyoderma gangrenosum





### EFFECTS OF EDEMA

- CIRCULATION
  - Arterial and venous
- MECHANICAL
  - Distracts wound edges
- NUTRITION
  - Protein loss in excessive swelling/  
drainage

## EDEMA REDUCTION

- Compression
  - Multi-layer compression wraps
  - Unna's boot
  - Compression stockings
  - Sequential pressure devices
  - Ace wrap/short stretch ace
- Elevation (as tolerated)
- Negative pressure wound therapy
- Diuretics

## COMPRESSION

- Must be appropriate to arterial circulatory status
- ABI of  $<0.7$  or TCOM of lower extremity  $<40$  mmHg calls for modification of compression strength

## COMPRESSION

All patients/caregivers must be instructed on the signs/symptoms of vascular (arterial) compression/compromise and its immediate treatment



***Hyperbaric oxygen is not a primary treatment for chronic diabetic ulcers of the lower extremity:***

***IT IS ADJUNCTIVE THERAPY***

## CMS CRITERIA

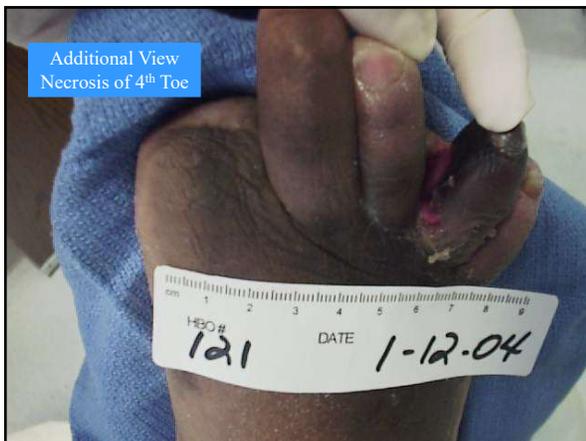
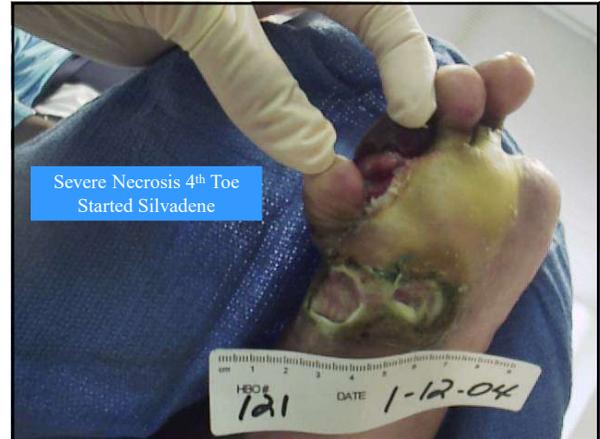
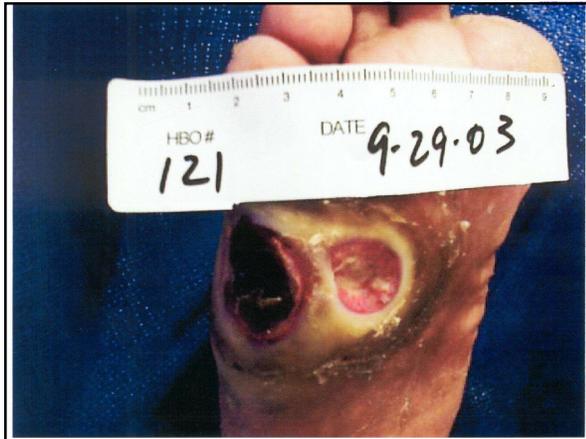
- Diabetic Ulcer
  - Type I or II diabetes
  - Lower extremity ulcer as a result of diabetes
  - Wagner grade 3 or greater
  - 30 days of failed standard wound care

### EVALUATION AND TREATMENT MUST ALSO INCLUDE:

1. Appropriate debridement
2. Offloading/pressure relief
3. Optimizing nutritional status
4. Optimizing vascular status
5. Appropriate antibiotics
6. Wound dressings to maintain a moist granulating bed

### Patient #121

- 45 year old black male
- Adult onset diabetes mellitus
- History of left BKA
- 10/4/99 Right femoral-distal peroneal bypass with insitu saphenous vein
- 9/23/03 presented to wound center with two diabetic, neuropathic Wagner III ulcers to right foot
- No osteomyelitis
- Previous bypass left no revascularization options
- Began HBO for a total of 40 treatments





### PRESSURE RELIEF

- Beds
  - Water beds
  - Egg crate topper
  - Reactive surface beds (low air loss)
  - Clinitron
- Cushions (Foam, Felt)
- Crutches
- Rolling walker
- Turning/Repositioning
- Orthotics
  - Shoes
  - Total contact cast (Gold standard)
  - Active offloading walker
  - Specialty splints

### NUTRITION

Probably the most neglected parameter in wound healing, especially in nursing home patients.

### NUTRITION TREATMENT

- Maximize glucose control in diabetics:
  - Medication
  - Diet
- Vitamins/Minerals
- Anabolic steroids
- Maximize protein in diet (especially L-Arginine)

## L-ARGININE

- Main substrate nitric oxide pathway
- Precursor to endothelial-derived nitric oxide
- Nitric Oxide:
  - Vasodilator (helps pain from PVD)
  - Non-specific immunity
  - Supports collagen production
  - Enhance wound tensile strength

## ARGINADE – 30 Calories

**\$1.80/Pkg    4.5 g L-ARGININE**  
**5.0 g Total Carbs**

## JUVEN – 90 Calories

**\$3.36/Pkg    7.0 g L-ARGININE**  
**2.5 g Protein (collagen)**  
**8.4 g Carbohydrates**  
**2.0 g Sugars**  
**7.0 g Glutamine**

**Nestlé HealthScience**  
**arginaid**  
Arginine Powder  
Orange  
Natural & Artificial Flavor

**NUTRITION INFORMATION PER 1 packet (9.2g)**

NUTRIENT COMPOSITION	AMOUNT
CALORIES	30 kcal
SODIUM	30 mg
TOTAL CARBOHYDRATE	5 g
VITAMIN C	150 mg
VITAMIN E	40.9 mg
L-ARGININE	4.5 g
TOTAL NITROGEN	1.4 g

**INGREDIENTS:** L-ARGININE, CITRIC ACID, MALIC ACID, SODIUM ASCORBATE, MALTODEXTRIN, AND LESS THAN 2% OF MODIFIED FOOD STARCH, D,L-ALPHA-TOCOPHERYL ACETATE, ASPARTAME, ACESULFAME POTASSIUM, NATURAL AND ARTIFICIAL FLAVOR, COLOR (BEET JUICE, TURMERIC, AND ANNATTO EXTRACTS), PHENYLETHANOLINE HYDROCHLORIDE, SODIUM BENZOATE, SODIUM CITRATE, SODIUM PHOSPHATE, SODIUM SACCHARIN, SODIUM SORBATE, SODIUM SULFATE, SODIUM TARTRATE, SODIUM BENZOATE, SODIUM CITRATE, SODIUM PHOSPHATE, SODIUM SACCHARIN, SODIUM SORBATE, SODIUM TARTRATE.

**Product of USA**

**Nestlé HealthScience**  
**arginaid**  
Orange Burst  
8 oz (227 mL)

**NUTRITION INFORMATION PER 237 mL**

NUTRIENT COMPOSITION	amount	kcal
CALORIES	230	
TOTAL FAT	0	g
MCT		g
SODIUM	50	mg
POTASSIUM	10	mg
TOTAL CARBOHYDRATE	52	g
DIETARY FIBER		g
PROTEIN	10.5	g
VITAMIN A		mcg
RETINOL	300	mcg
B-CAROTENE		mcg
VITAMIN C	250	mg
CALCIUM	0	mg
IRON	3.6	mg
VITAMIN D	2	mcg
VITAMIN E	60	mg
VITAMIN K	16	mcg
THIAMIN	0.3	mg
RIBOFLAVIN	0.34	mg
NIACIN	4	mg
VITAMIN B6	0.4	mg
FOLIC ACID	60	mcg
VITAMIN B12	1.2	mcg
BIOTIN	6.0	mcg
PANTOTHENIC ACID	2	mg
PHOSPHORUS	850	mg
IODINE	30	mcg
MAGNESIUM	15	mg
ZINC		mg

**L-ARGININE PRO**  
CARDIO HEALTH FORMULA\*  
VIRILITY\*  
STRENGTH\*  
ANTI-AGING\*

**Delicious Citrus Orange**  
DIETARY SUPPLEMENT

**Supplement Facts**  
Serving size: 1 packet (13.6g)  
Servings per packet: 1

	Amount per serving	% DV
Calories	45	
Vitamin C (as ascorbic acid)	60 mg	67%
Vitamin D (as cholecalciferol)	82.5 mcg	165%
Vitamin K (as phytylquinone)	20 mcg	17%
Vitamin B6 (as pyridoxine HCl)	2 mg	118%
Folate	657 mcg DFE (400 mcg folate)	163%
Vitamin B12 (as cyanocobalamin)	6 mcg	250%
Cobalamin	300 mcg	250%
Magnesium (as magnesium citrate)	20 mg	5%
L-Arginine	8.5 g	
L-Citrulline	1.1 g	
Stem leaf extract	125 mg	
Aquamin™ (from mineralized seaweed extract (Lithothamnion sp.))	100 mg	

**Other Ingredients:** Citric acid, xylitol, natural orange flavor, beta carotene (for color) and silica.

**CAUTION:** Keep out of reach of children. Protect from heat, light, and moisture. Store at 15-30°C (59-86°F). Do not purchase if seal is broken. Consult your health care provider prior to using this product if you are pregnant, nursing, or have a serious medical condition.

**Juven**  
From the makers of Ensure®

**Therapeutic Nutrition Powder FOR WOUND HEALING**

**Supplement Facts**  
Serving size: 1 packet (13.6g)  
Servings per packet: 1

	Amount per serving	% DV
Calories	90	
AMINO ACID Arginine	7.0 g	
AMINO ACID Glutamine	2.5 g	
AMINO ACID HMB	2.0 g	
PROTEIN	11.5 g	
Collagen	2.5 g	
Glutamine	2.5 g	
HMB	2.0 g	
Carbohydrate	8.4 g	
Sugars	2.0 g	
Vitamin C	150 mg	
Vitamin E	40.9 mg	
Vitamin B6	2 mg	
Vitamin B12	6 mcg	
Calcium	200 mg	
Zinc	15 mg	

**Other Ingredients:** Citric acid, xylitol, natural orange flavor, beta carotene (for color) and silica.

**CAUTION:** Keep out of reach of children. Protect from heat, light, and moisture. Store at 15-30°C (59-86°F). Do not purchase if seal is broken. Consult your health care provider prior to using this product if you are pregnant, nursing, or have a serious medical condition.

## REMOVAL OF FOREIGN BODY ASSOCIATED WITH WOUNDS

### Unintentional Foreign Bodies

- Sewing needles
- Pebbles
- Bullets
- Thorns
- Retained dressings (packing, foam sponges)
- Gouty tophi

## REMOVAL OF FOREIGN BODY ASSOCIATED WITH WOUNDS

### Intentional Foreign Bodies

- ORIF orthopedic devices (exposed)
- Prosthetic devices
- Retained, non-absorbable suture (infected)

## TREATMENT OF INFECTION

- Debride non-viable tissue
  - Soft tissue/Bone
  - Excisional
  - Enzymatic
  - Curettage
  - Amputation
- Antibiotics (culture guided)
  - (6 weeks for osteomyelitis)
- Topical antibiotics

## TREATMENT OF MALIGNANCY

- Surgical excision (with skin margins clear)
- Moh's chemosurgery
- Radiation therapy
- Topical chemotherapy (5-FU)

## MEDICAL ADJUNCTIVE CARE

- Anticoagulation
- RBC wall deformation
- Control gout (foreign body)
- Maximize control Of CHF & HTN
  - Circulation
- Maximize control of diabetes
- Maximize control of autoimmune and/or collagen vascular diseases

## GUIDING PRINCIPLES FOR LOCAL WOUND CARE

- Many wounds will improve if anything is done regularly
- Choice of topicals (and treatment) must be driven by diagnosis and not by what product is on the shelf

## GUIDING PRINCIPLES, CONTINUED

- Topical agents will **NOT** defeat:
  1. Failure to relieve pressure
  2. Inadequate Circulation
  3. Malnutrition
  4. Unrelieved edema
- Cost **IS** a factor

## LOCAL WOUND CARE

- Topical Antibiotics/Antibacterials
- Debriding agents
- Stimulating agents
- Enzyme (MMP) inactivators  
(Protease modulating dressings)

## (LOCAL CARE) TOPICAL ANTIBIOTICS/ANTIMICROBIALS

- Antibiotic ointments/Gels (Mupirocin, Bacitracin, Neomycin)
- Sodium hypochlorite (Anasept, Vashe)
- Silver compounds
- Iodine compounds

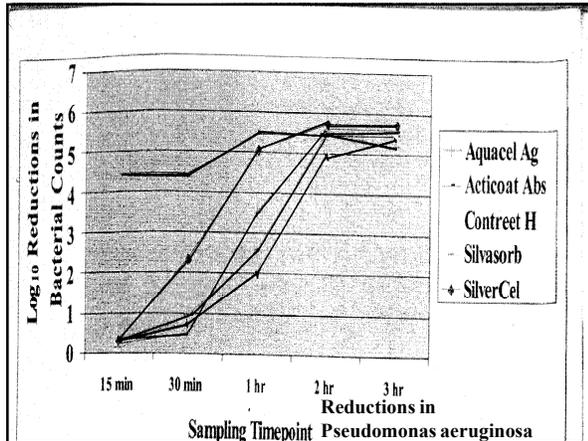
## SILVER

- EXISTS IN TWO FORMS:
  1. Elemental or metallic Ag(0)
  2. Ionic silver/Silver cation  
Ag(I) or Ag<sup>+</sup>

## SILVER

- The biologically active form of silver is the ionic (silver cation)
- **ALL** silver products have to produce the **same** biologically active ingredient to be effective: Ag<sup>+</sup>

If there is any difference in the various silver products it has to be in the dressing, **not** the active agent

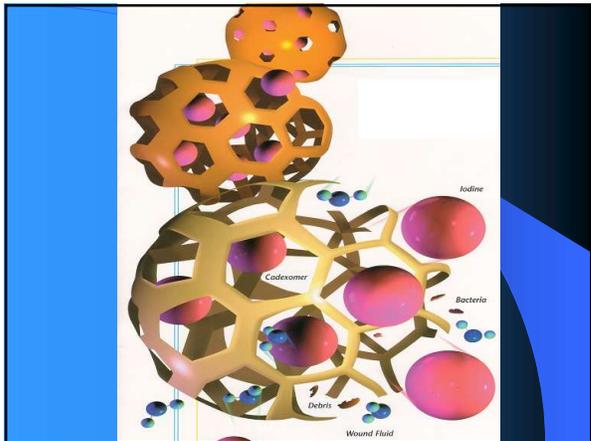


**TOPICAL IODINE IS AVAILABLE IN TWO FORMS:**

- Povidone iodine (10%)
- Cadexomer iodine

**CADEXOMER IODINE**

- 3 dimensional starch lattice formed into spherical microbeads (0.9% Iodine in starch lattice)



**THE LATTICE:**

- Has a high absorption capacity
- Absorption increases the size of the lattice, releasing the iodine at 1 part per million, until the reservoir is exhausted

**(LOCAL CARE) DEBRIDING AGENTS**

- Collagenase/Santyl
- Maggots
- Medical grade honey ?
- Sharp debridement (remains the quickest & most effective means)



**(LOCAL CARE)**  
**STIMULATORY AGENTS**

- Balsam Of Peru (Vasolex)
- Growth factors
  - Platelet derived (Regranex, black box warning >3 tubes, *bought out by Lynch Regenerative, New NDC causing supply shortage until March/April 2026*)
  - Cultured human neonatal skin (Apligraf & Dermagraft)
  - Allograft (Theraskin, Graft Jacket, Epifix)
  - Porcine xenograft (Oasis Matrix)
  - Bovine xenograft (Primatrix)



**(LOCAL CARE)**  
**ENZYME INACTIVATORS**  
**(PROTEASE MODULATING DRESSING)**

MMPs:

- Play a key role in wound healing
- Protein degrading enzymes that require calcium for conformation and zinc to be active
- Degrade growth factors, matrix protein, & protease inhibitors
- 24 Identified

**INDICATIONS FOR PROTEASE MODULATING DRESSING**

- To protect endogenous GF
- To prepare wound bed for application of exogenous GF
- To protect previously applied GF (Apligraf, Dermagraft, Regranex)

**PROMOGRAN**

- Protease Modulating Matrix
- Bovine Collagen
- Oxidized Regenerated Cellulose
- Can bind growth factors but they remain biologically active as the Promogran is resorbed



**QUESTIONS?**

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