

Diabetic Foot Ulcers:

A Quick Guide to Prevention,
Assessment, and Management



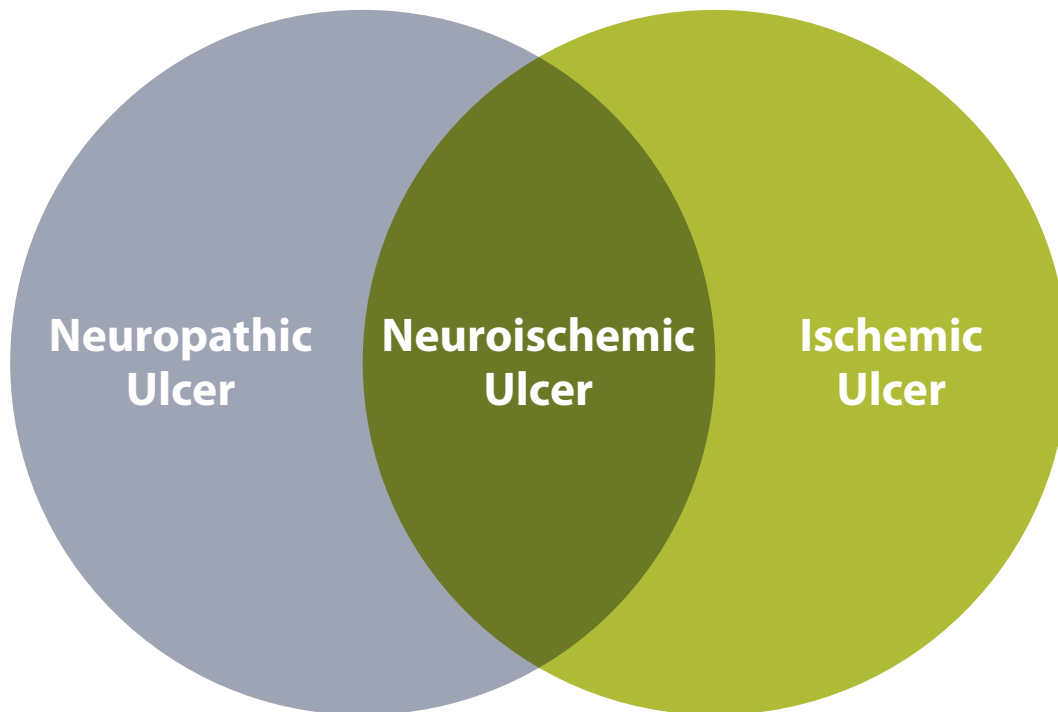
Diabetic Foot Ulcers:

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Diabetic foot ulcers (DFUs) are among the most challenging types of chronic ulcerations to manage given their multifactorial nature. Thorough, systematic assessment of a patient with a DFU is essential to developing a comprehensive plan of care. To implement the treatment plan successfully, clinicians and patients must work together to address each factor contributing to ulcer development and perpetuation.

Classification of Diabetic Foot Ulcers

At present, subclassification of DFUs can be divided into three categories: neuropathic, ischemic, and neuroischemic.



Neuropathic Ulcer:

Neuropathic ulcers have a prevalence rate of approximately 35%.¹ These usually occur in those patients who have sensory loss in the feet and often present with a thick callus. The wound bed is pink and granulating, surrounded by callus, and the surrounding skin is dry and fissuring. These ulcers usually occur in weight-bearing areas of the foot, including the metatarsal heads, heel, and the dorsum area of clawed toes.

Neuroischemic Ulcer:

Neuroischemic ulcers occur in those patients who have at least some degree of sensory loss and, while they are prone to necrosis, tend to have minimal callus. These ulcers have poor granulation and a high risk of infection. They tend to occur on the margins of the toes and foot, and have a prevalence of approximately 50%.¹

Ischemic Ulcer:

Ischemic ulcers have a prevalence rate of approximately 15%.¹ These ulcers are painful and commonly have some degree of necrosis. The wound bed tends to be pale with slough and poor granulation. These ulcers occur on the tips of the toes, along the nail edges, between the toes, and along the lateral borders of the foot.

The most prevalent of the three categories of DFU is the neuroischemic DFU, which comprises approximately 50% of such ulcerations.¹ Organization and reproducibility of the assessment process are crucial to success in treating these ulcers.

There are no universally accepted classification scales for DFUs. The two most widely accepted are the Wagner Diabetic Foot Ulcer Grade Classification System and the University of Texas Diabetic Foot Ulcer Classification System. The Wagner System is an older classification scale for foot ulcers and takes into account the depth, appearance, and presence of osteomyelitis or gangrene, using grades 0 through 5²:

Grade 0 – intact skin

Grade 1 – superficial ulcer of skin or subcutaneous tissue

Grade 2 – ulcer extends into tendon, bone, or joint capsule

Grade 3 – deep ulcer with osteomyelitis or abscess

Grade 4 – partial foot gangrene

Grade 5 – whole foot gangrene

A newer scale is the University of Texas Diabetic Foot Ulcer Classification System, which grades DFUs by depth and then stages, based on the presence or absence of infection and ischemia, as follows:

Grade 0 – pre-ulcerative site or post-ulcerative site that has healed

Grade 1 – superficial wound not involving tendon, joint capsule, or bone

Grade 2 – wound penetrating to tendon or joint capsule

Grade 3 – wound penetrating the bone or joint

The stages within each wound include:

Stage A – clean wounds

Stage B – non-ischemic infected wounds

Stage C – ischemic non-infected wounds

Stage D – ischemic infected wounds

Patient's History

Capturing a thorough patient history will provide the foundation for a comprehensive evaluation of the patient's condition for treatment:

History of Present Illness: Clinicians will often have varied processes for obtaining the same information, but using an assessment model that is reproducible will be most useful. OLDCHARTS (Onset, Location, Duration, Characteristics, History of same symptoms, Aggravating factors, Relieving factors, Timing, Symptoms associated) is one example. Some basic questions you should ask your patient are:

- Age
- Sex
- Ulcer onset/history
 - Any attempted home/self-treatments
 - History of infection
 - Associated symptoms, including pain (see mnemonic OLDCHARTS mentioned previously)
 - Any previous treatments, including custom footwear or other offloading attempts
 - Any exposure to external trauma
- Lower extremity ischemic symptoms (claudication)
- Ability to tolerate prescribed treatments, including offloading and other therapies (patient may not have functional reserve or strength to ambulate in offloading system)

Pertinent Medical History and Review of Systems: There is a multitude of comorbid physiologic conditions and contributing factors that negatively affect the healing of DFUs. It is imperative that the patient is managed medically by providers skilled in each specialty relating to the condition being treated (e.g., rheumatologist for autoimmune disease, endocrinologist for metabolic disorders).

- Diabetes mellitus (DM) history, including onset, duration
- Immunosuppressed state/autoimmune disorders
- Metabolic disorders (thyroid disease, adrenal disease, obesity, degree of insulin resistance in DM)
- History of foot deformities, including any previous surgical correction
- Lymphatic disorders (congenital, acquired, post-operative)
- Nutritional state, including patient's health literacy and understanding of personal nutrition needs, ability to prepare food for self, and any financial issues affecting access to food
- Cardiac history, including ischemic disease, congestive heart failure, or hypertension
- Renal disease, including chronic kidney disease or end-stage renal disease
- Collagen vascular disorders
- Anemia, pernicious or related to chronic disease

- Other conditions affecting ability to adhere to plan of care, including offloading of the affected limb, other issues affecting general medical management of chronic disease such as debility, weakness/hemiplegia from cerebrovascular accident, retinopathy/vision loss from microvascular complication of DM
-

Surgical History: Patients with DFUs who have had prior non-traumatic amputation are at greater risk of additional amputation. In addition, patients who have undergone lower extremity vascular procedures may present with atypical lower extremity edema. Moreover, if a patient has a corrective procedure that resulted in resolution of an ulceration, and the same phenomenon occurs on the contralateral limb, it is of great clinical importance to note this in the history because the patient may benefit from repeating the procedure on the affected side.

- History of surgical correction of foot deformities
 - Previous surgical debridements or amputations
 - History of vascular surgery, such as coronary artery bypass grafting requiring vein harvest from the lower extremity or ablations/thrombectomies
-

Medications: A variety of medications may affect the healing of DFUs. Patients taking insulin have higher rates of wound healing overall.³ Other medications to be cognizant of are those that delay healing, such as anti-inflammatory drugs; their use on a short-term basis can be beneficial, but in the long-term they can be a barrier to healing.

- Use of oral or injected hypoglycemic agents or insulin
 - Immunosuppressive medications (e.g., methotrexate, antirheumatics, disease-modifying antirheumatic drugs)
 - Corticosteroids
 - Non-steroidal anti-inflammatory drugs
-

Social History: This portion of the history and physical examination is sometimes overlooked as pertinent to the patient's overall condition. The patient's health literacy level should be catered to because interventions that patients do not fully comprehend are far less likely to be followed. The patient should be counseled regarding resources if any gaps in care are encountered (e.g., if the patient does not have running water, referral to case management to seek assistance programs for utilities, etc., may be warranted).

- Nicotine dependence/tobacco use, including smoking or chewing, vaping with substances containing nicotine
- Alcohol use
- Socioeconomic status, capacity to afford medications and prescribed medical treatments
- Education level and health literacy
- Occupation, including physical requirements such as standing/weight bearing
- Exercise, if any
- Preventive care

Physical Examination

A thorough physical examination will reveal an abundance of useful clinical information. The information garnered will allow for appropriate grading and classification of the DFU, by providing prognostic value and guiding treatment. Some information in the examination may even reveal undiagnosed conditions impeding the healing process (e.g., lower extremity swelling despite adequate elevation and compression may indicate the need for a cardiology referral).

Skin	General dermatologic assessment for skin quality, trophic changes including xerosis, alopecia, atrophie blanche, previous areas of scarring, condition of nails
Extremity	<p>Fissures, bullae, pre-ulcerative callus, interdigital maceration</p> <p>Wound assessment, including wound measurements (length, width, depth), sinus tracts/tunneling or undermining, wound bed description including exposed structures or probe to bone, periwound condition, wound edges/presence of callus, exudate quality, odor, local or spreading signs of infection (DFU surface area is expected to demonstrate 1% to 2% daily reduction in size, which translates to 40% to 50% or greater reduction in size at four weeks⁴). DFUs should be classified on initial assessment and reclassified as necessary throughout treatment. Appropriate classification and grading are vital to obtaining payer approval for specific therapies, including hyperbaric oxygen therapy, cellular and/or tissue-based products, and other adjunctive therapies.</p>
Cardiovascular	<p>Lower extremity edema, pitting and nonpitting</p> <p>Vascular assessment</p> <ul style="list-style-type: none"> • Palpation and grading of femoral, popliteal, dorsalis pedis (DP), and posterior tibial (PT) pulses, including auscultation for bruits (PT pulses are absent in a small number of individuals. It should also be noted that the presence of pulses does not rule out presence of peripheral arterial disease).⁵ • Evaluate for the "6 Ps": pain (acute onset), pallor, pulselessness, paresthesias, paralysis, and poikilothermia (temperature change, i.e., cold leg). If critical limb ischemia is suspected, it is a clinical emergency, and the patient should be immediately evaluated by a vascular specialist. • Other perfusion diagnostics such as ankle brachial index (ABI), toe brachial index (TCI)/toe pressure, transcutaneous oximetry (transcutaneous oxygen pressure; TcPO₂/TCOM), and skin perfusion pressures (SPP) may be performed. ABI is not generally diagnostic in long-standing DM secondary to calcification and macrovascular complications. Toe pressures are better indicative of perfusion because toe vessels are less subject to calcification. ABI with plethysmography can identify extent of disease by demonstrating triphasic, biphasic, or monophasic arterial waveforms.
Neurologic	<p>Sensory neuropathy testing using Semmes-Weinstein monofilament</p> <p>Vibratory sense, position sense, sharp/dull discrimination</p>
Musculoskeletal	<p>Gait pattern</p> <p>Assistive devices needed for ambulation</p> <p>Biomechanical abnormalities such as claw toe, hammer toe, bunion, prominent malleoli, or neuroarthropathy</p> <p>Range of motion of ankle/plantar and dorsiflexion (limited dorsiflexion can result in increased plantar pressures on the metatarsal heads)</p> <p>Overall functional status as it contributes to self-care capacity and ability to perform activities of daily living (ADLs)</p> <p>Deep tendon reflexes</p> <p>Inspection of footwear for abnormal wear and tear or any foreign objects that may precipitate foot trauma and subsequent ulceration or infection</p>
Psychological	Depression is commonly associated with a diagnosis of DFU, especially the primary episode. ⁵

Diagnostic Tests

Data from diagnostic tests, in isolation, are not always clinically useful. Combining these data with the medical history and physical examination data will further clarify the clinical picture of the patient with a DFU. At times, the data will show a positive correlation (e.g., the wound assessment reveals positive probe to bone, and erythrocyte sedimentation rate [ESR] is 85). Conversely, it may reveal a negative correlation (e.g., the patient may have normal white blood cell [WBC] count, but wound assessment reveals erythema and a purulent, malodorous exudate).

"Combining these data with the medical history and physical examination data will further clarify the clinical picture of the patient with a DFU."

Consider testing for the following serum laboratory values:

- WBC count (typically elevated with developing infection, but response blunted in some states of severely uncontrolled DM and other disorders)
- Hemoglobin and hematocrit (Hgb/Hct) (Anemia, acute or chronic, can negative affect already altered states of perfusion)
- Pre-albumin (PAB), transferrin, retinol-binding protein (RBP) (PAB is still standard for nutritional status in chronic wounds but in chronic inflammatory states is not as indicative of true nutritional/protein status. A combination of values may paint a better clinical picture)⁶
- ESR (sed rate) and C-reactive protein (CRP) (ESR over 70 unofficially diagnostic of osteomyelitis in patients with DFU)⁷
- Blood glucose, glycosylated Hgb (Hgb A1c) (relating to overall disease management. Normalization of glucose levels delays onset of microvascular and macrovascular complications secondary to DM and lessens risk factors such as sensory neuropathy or peripheral vascular disease that can contribute to DM-related foot problems.⁸)

Standard of Care for Diabetic Foot Ulcers

A comprehensive DFU management plan entails a multifactorial, multidisciplinary approach, including the involvement of the following specialists⁹:

- 1** A diabetologist/endocrinologist to help with the management of metabolic control for patients with DM
- 2** A diabetes educator and/or a qualified nurse to assist with educational needs
- 3** A podiatrist who can help the patient avoid ulceration and provide treatment as necessary
- 4** A vascular surgeon to provide assessment of the vascularity of lower limbs, as well as intervene if necessary
- 5** An orthotist to help with the selection or creation of proper footwear that will allow for pressure redistribution and aid in wound healing and prevention
- 6** An infectious disease specialist to help determine appropriate antibiotics as needed, based on culture results
- 7** A nutritionist to help manage patient glucose levels, aid in weight loss, and encourage wound healing

Management of DFUs should focus on the following: ulcer offloading; treating any underlying infection or bioburden; debridement once vascular status has been confirmed; and revascularization procedures for patients with DM who have poor vascularization.

"Consider advanced modalities to help the ulcer close at an accelerated rate..."

Topical management:

- Select wound dressings based on ulcer characteristics (e.g., dry, exudative, infected).
- Reassess dressing choice as needed to encourage wound healing.
- Consider advanced modalities to help the ulcer close at an accelerated rate, depending on local coverage determination and indications for use.

Offloading:

- Offloading is applicable to non-ischemic, non-infected DFUs.
- The gold standard for offloading interventions includes use of non-removal devices such as total contact casts.

Infections:

- The Infectious Diseases Society of America (IDSA) cautions against treating patients who have clinically uninfected wounds with antibiotics.¹⁰
- If there is suspected clinical infection based on thorough assessment, prescribe antibiotics based on quantitative tissue culture and sensitivity.
- If empiric antibiotics must be initiated, consider factors such as:
 - Current histology data.
 - History of previous similar infection.
 - Severity of infection.
- For osteomyelitis
 - In the absence of ischemia or fulminant necrotizing infections, clinicians may elect to treat surgically versus medically (surgical excision with shorter course of antibiotics if surgical margin is clear of infection versus longer course of antibiotics).¹⁰

"(IDSA) cautions against treating patients who have clinically uninfected wounds with antibiotics."

Adjunctive therapies:

- Adjunctive therapies should be used for DFUs that fail to demonstrate greater than 50% reduction in surface area after four weeks of standard therapy.^{1,10}
 - The recommendation is made according to the IDSA 2012 practice guidelines and the 2016 joint guidelines of the Society for Vascular Medicine (SVM) and the American Podiatric Medical Association (APMA) for management of the diabetic foot.
 - This recommendation is reflected in most insurance payer structures for approval of such therapies.
- Current evidence does not support use of advanced therapies earlier in the course of treatment for DFUs.
 - These therapies have the potential to increase cost of care if they are utilized inappropriately, and they should not be used before attempting lower-cost, evidence-based modalities.¹

Patient Education

No comprehensive DFU management plan would be complete without encouraging the patient to be invested in their own care. Below are some key measures at-risk patients should take to help prevent diabetic foot complications from occurring and to address issues as they arise. The mnemonic DIABETIC LIMB will serve as a useful tool in supporting patients with delivering good self-care (M. Kelso, unpublished data, July 2019):

- ✓ **D**aily visualization of the foot and leg (use mirror if needed)
- ✓ **I**nvestigate unusual or new feelings (i.e., burning, tingling, numbness, pain)
- ✓ **A**nnual measurements for diabetic shoe wear
- ✓ **B**e diligent wearing hard-sole shoes (i.e., never walk around barefoot)
- ✓ **E**at a balanced diet with balanced carbohydrates
- ✓ **T**reat any break in the skin urgently (i.e., do not wait to get to the doctor if the area doesn't heal timely)
- ✓ **I**nvolve podiatry or other trained professional to trim toenails
- ✓ **C**onsistent blood glucose levels (i.e., not too high, not too low)
- ✓ **L**ook for changes in circulation or coloration
- ✓ **I**nvolve primary care physician for monitoring changes in circulation or coloration
- ✓ **M**ove! Ambulatory exercise is important
- ✓ **B**e screened for neuropathy on an ongoing basis so areas of neuropathy can be identified and protected

Adapted with permission from Martha Kelso, unpublished data, July 2019.

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64%

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Dermagraft has not been studied in children under the age of 18 years, in pregnant women, in patients with ulcers over a Charcot deformity of the mid-foot, or in patients receiving corticosteroids or immunosuppressive or cytotoxic agents. To ensure the delivery of metabolically active, living cells to the patient's wound, do not hold Dermagraft at room temperature for more than 30 minutes. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation for Use instructions. The persistence of Dermagraft in the wound and the safety of this device in diabetic foot ulcer patients beyond six months has not been evaluated. Testing has not revealed a tumorigenic potential for cells contained in the device. However, the long-term response to these cells is unknown. Always thaw and rinse product according to the Preparation for Use instructions to ensure the delivery of metabolically active, living cells to the patient's wound. Do not use Dermagraft after the expiration date indicated on the labeled unit carton. (5) **Adverse Events:** In clinical studies conducted to date, the overall incidence of reported adverse events was approximately the same for patients who received Dermagraft compared to those who received the Control treatment. (6) **Maintaining Device Effectiveness:** Dermagraft must be stored continuously at $-75^{\circ}\text{C} \pm 10^{\circ}\text{C}$. Dermagraft must be thawed and rinsed according to the Preparation for Use instructions. After the initial application of Dermagraft, subsequent sharp debridement of the ulcer should continue as necessary. Additional wound preparation should minimize disruption or removal of previously implanted Dermagraft. (13) **Patient Counseling Information:** After implantation of Dermagraft, patients should be instructed not to disturb the ulcer site for approximately 72 hours (three days). After this time period, the patient, or caregiver, should perform the first dressing change. The frequency of additional dressing changes should be determined by the treating physician. Patients should be given detailed instructions on proper wound care so they can manage dressing changes between visits. Compliance with non weight-bearing instructions should be emphasized. Patients should be advised that they are expected to return for follow-up treatments on a routine basis, until the ulcer heals or until they are discharged from treatment. Patients should be instructed to contact their physician, if at any time they experience pain or discomfort at the ulcer site or if they notice redness, swelling, or discharge around/from the ulcer. (8) **How Supplied:** Dermagraft is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single-use application. 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(9) **Caution:** Federal (U.S.) law restricts this device to sale by, or on the order of, a physician (or properly licensed practitioner). **US Patent Numbers:** 4,963,489; 5,266,480; 5,443,950. **Manufactured and Distributed by:** Organogenesis La Jolla, CA 92037

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