The Standard of Care for Evaluation and Treatment of Diabetic Foot Ulcers

This self-study activity for physicians, podiatrists, and nurses is cosponsored by The University of Michigan Medical School, The University of Michigan Health System’s Educational Services for Nursing, and Barry University School of Podiatric Medicine.
Program Overview
Diabetic foot ulcers (DFUs), one of the most common complications of diabetes mellitus, are often recalcitrant to treatment and are associated with serious medical complications such as osteomyelitis and lower limb amputation. Diabetic foot ulcers are associated with decreased quality of life and having a history of DFU is an independent predictor of mortality in patients with diabetes. Despite the use of standard management strategies, healing rates of DFUs remain low, and rapid and complete healing of DFUs remains a challenge. Comprehensive evidence-based guidelines have defined good wound care for DFUs; however, these recommendations are not uniformly put into practice. This monograph will outline standard management strategies in the assessment and treatment of DFUs, summarize the evidence for each of these strategies, and discuss the role of adjuvant treatment modalities.

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Audiences
This monograph is intended to be a self-study activity for physicians, podiatrists, and nurses who are involved in wound healing and in the care of patients with diabetes.

Learning Objectives
After completing this self-study activity, participants should be able to:

1. Summarize examination, evaluation, and classification of diabetic foot ulcers (DFUs).
2. Identify the medical, quality-of-life, and cost implications of DFUs.
3. Analyze the treatment considerations, including debridement, off-loading, and infection control for DFUs.
4. Describe the role of adjuvant therapies in the treatment of DFUs.

Program Faculty
Robert S. Kirsner, MD, PhD
Vice Chairman & Stiefel Laboratories Professor
University of Miami, Miller School of Medicine
Department of Dermatology & Cutaneous Surgery
Chief of Dermatology, University of Miami Hospital
Miami, Florida

Guest Reviewers
William H. Herman, MD, MPH
Stefan S. Fajans/GSK Professor of Diabetes
Professor of Internal Medicine and Epidemiology
Director, Michigan Diabetes Research and Training Center
The University of Michigan Medical School
Ann Arbor, Michigan

Martha M. Funnell, MS, RN, CDE
Michigan Diabetes Research and Training Center
Juvenile Diabetes Research Foundation Center for the Study of the Complications in Diabetes
The University of Michigan Medical School
Ann Arbor, Michigan

John P. Nelson, DPM, FACFAS
Interim Dean and Professor
Barry University School of Podiatric Medicine
Miami Shores, Florida

Managing Editor
Amy M. Horton, PharmD, CMPP
Vice President, Scientific Services
The JB Ashtin Group, Inc.
Plymouth, Michigan

Oversight and Accreditation
Pierre Lavalard, MBA
Associate Director, Office of CME
The University of Michigan Medical School

Dorothy J. Nagle, MSN, RN
Educational Nurse Specialist, Educational Services for Nurses
University of Michigan Health System

Urmala Roopnarinesingh, MSHSA
Director of Continuing Medical Education
Barry University School of Podiatric Medicine
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Accreditation and Educational Credit

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The University of Michigan Medical School and The JB Ashtin Group.

The University of Michigan Medical School is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The University of Michigan Medical School designates this educational activity for a maximum of 1 AMA PRA Category 1 Credits™. Physicians should only claim credits commensurate with the extent of their participation in the activity.

Barry University School of Podiatric Medicine is approved by the Council on Podiatric Medical Education to offer recognized continuing podiatric medical education programs. This course is approved for 1 Continuing Medical Education contact hour for licensed podiatrists.

The University of Michigan Health System’s Educational Services for Nursing is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation. (2.5) contact hours for nursing will be provided.

Faculty Disclosures

Robert S. Kirsner discloses that he has received honoraria for lecturing and research grant support from Advanced BioHealing, Inc., and Organogenesis, Inc. He has also received advisor honoraria from Organogenesis, Inc., and research grant support from Healthpoint, Ltd.

William H. Herman indicates he has nothing to disclose.

Martha M. Funnell discloses that she is a consultant for Lilly, Sanofi Aventis, Novo Nordisk, and Merck.

John P. Nelson indicates he has nothing to disclose.

Disclosure of Off-Label Uses

The faculty, The University of Michigan, Barry University, and Advanced BioHealing, Inc. do not recommend the use of any pharmaceutical, diagnostic test, or device outside of the labeled indications as approved by the FDA. Please refer to the official prescribing information for each product for approved indications, contraindications, and warnings.

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Method of Instruction

Participants should read the activity overview, learning objectives, and faculty disclosure and review the monograph in its entirety. After reviewing the monograph, participants should complete the post-test and the activity evaluation.

This activity is available online at www.cme-dfu.com. You may take the post-test online. If you receive a passing score for the post-test, you will be able to download and print a certificate for physician or nursing credit. For podiatric credit, a Certificate of Completion and a copy of the Barry University CME transcript will be mailed to you within 4 weeks. A minimum score of 70% is required for certification. If you do not pass the test, you may take the test again.

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Introduction

Diabetes mellitus represents a group of chronic diseases characterized by high levels of glucose in the blood resulting from defects in insulin production, insulin action, or both. Worldwide, the number of cases of diabetes has been estimated to be 171 million, and by 2025, this number is projected to reach 366 million. As obesity represents an important risk factor for type 2 (non-insulin-dependent or adult-onset) diabetes, Behavioral Risk Factor Surveillance System data show a dramatic increase in prevalence of both obesity and diabetes in the United States. Patients with diabetes are at risk for developing serious health problems that may affect the eyes, kidneys, feet, skin, and heart. Foot ulcerations are one of the most common complications in patients with diabetes. The development of diabetic foot ulcers (DFUs) typically results from peripheral neuropathy and/or large vessel disease, but most commonly DFUs are caused by peripheral neuropathy complicated by deformity, callus, and trauma. Vascular insufficiency, infection, and failure to implement effective treatment of DFUs are linked to secondary medical complications, such as osteomyelitis and amputation. Approximately 15% of DFUs result in lower-extremity amputation. More than 85% of lower-extremity amputations in patients with diabetes occur in people who have had an antecedent foot ulcer.

DFUs have a negative impact on the quality of life (QoL) for diabetic patients. Goodridge and colleagues compared QoL parameters in 104 patients with healed and unhealed DFUs (defined as having a history of DFU ≥ 6 months) who received care in a tertiary foot care clinic using the Medical Outcomes Survey Short Form 12 questionnaire (SF-12). Significant differences in QoL scores between the healed and unhealed ulcer groups in several measures of physical health (P < .002 to .04) were noted. The patients with unhealed DFUs also completed the Cardiff Wound Impact Scale to further examine the impact of unhealed DFUs on QoL. Results showed that patients with unhealed ulcers were frustrated with healing, had anxiety about the wounds, had problems with activities of daily living and footwear, and complained of a limited social life. The economic burden of DFUs and the complications arising from them are enormous. The cost to treat a DFU over a 2-year period was $27,987 in 1995 and, based on the medical component of the US Consumer Price Index, rose to $46,841 in 2009. These high costs have been linked to associated outpatient appointments, emergency room visits, hospital stays, and secondary complications of osteomyelitis and amputation. Direct costs for a lower-extremity amputation range from $22,700 to $51,300 (2001 USD). The significant morbidity and mortality associated with diabetes is well known. A recent 10-year, prospective, population-based study found a history of DFU to be a significant independent predictor of mortality in patients with diabetes. Diabetic patients with a history of DFU had a 47% increased risk of mortality compared to those without a history of DFU. The 5-year mortality rate for patients with neuropathic and ischemic DFUs is 45% and 55%, respectively.

General healing rates for neuropathic DFUs have been reported in the literature. The meta-analysis of 10 control groups from clinical trials, using good standard wound care (including debridement and off-loading, and either saline-moistened gauze or placebo gel and gauze) demonstrated that the weighted mean rates of neuropathic ulcer healing were 24.2% (95% confidence interval [CI] 19.5–28.8%) over 12-weeks and 30.9% (95% CI 26.6–35.1%) over 20 weeks. These data provide clinicians with a realistic benchmark for the rate of healing of neuropathic ulcers over 20 weeks. Further, this emphasizes that even with good standard wound care, the healing of neuropathic ulcers in patients with diabetes continues to be a challenge.
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Assessment of Diabetic Foot Ulcer

General Medical History and Physical Examination
A complete history and physical must be performed as part of an initial evaluation. Information pertinent to the patient with a DFU includes duration of diabetes; quality of glycemic control; and presence of other complications and/or comorbidities of diabetes, such as end-stage renal disease, cardiovascular risk factors and cardiovascular disease (hypertension, hyperlipidemia, smoking, angina, myocardial infarction, transient ischemic attacks, strokes, and peripheral vascular disease). A patient’s foot-specific medical history must include information regarding footwear, chemical exposure, callus formation, foot deformity, previous foot infection or surgery, neuropathic symptoms, and claudication or at-rest pain. Factors specific to the DFU such as initial wounding event, history of recurrent wounding, previous wound healing problems, prior diagnostic testing, prior therapies and response, functional impact of the wound on the patient, and a social history sufficient to define potential adverse impact of usual activities on an optimal plan of care should also be assessed.

Laboratory screening
Because wound healing can be delayed by anemia and renal insufficiency, complete blood cell count and creatinine/blood urea nitrogen tests may be included as part of the baseline evaluation for patients with chronic wounds. Malnutrition impedes healing, so testing of protein, albumin, and prealbumin levels to assess patient nutritional status may be warranted. If deep-tissue problems or osteomyelitis are suspected, erythrocyte sedimentation rate and C-reactive protein testing may be considered as markers of inflammation.18

Hemoglobin A1C
Results from 2 randomized controlled trials, the Diabetes Control and Complication Trial and the United Kingdom Prospective Diabetes Study, have shown that rigorous regulation of blood glucose to achieve hemoglobin A1C levels of approximately 7% reduces the risk of microvascular complications in diabetic patients.19,20 However, more recent studies did not find that more intense glucose control improved macrovascular complications of diabetes.21 While there is no concrete evidence linking hemoglobin A1C to wound healing, this test should used to assess the overall degree of glycemic control as an overview of the patient’s disease state. Although optimal HbA1C levels are still in debate, the American Diabetes Association (ADA) generally recommends an A1C goal of < 7% for diabetic adults. Hemoglobin A1C testing should be ordered by the wound care specialist if one has not been performed by the patient’s generalist or endocrinologist in the previous 4 weeks.

Lipid profile
A multitude of diabetic patients with concomitant neuropathic ulcers are at high risk for, or have been diagnosed with cardiovascular disease, dyslipidemia, and/or hypertension. Thus, evaluation of the patient’s lipid profile (cholesterol, HDL and LDL) is important and wound specialists should work closely with the patient’s primary care physician or cardiologist if clinically significant changes in the patient’s panel are identified.

Prealbumin
Prealbumin is a reasonable laboratory test performed to evaluate protein deficiency and may provide information relevant to nutritional status. Prealbumin has a short half-life when compared to albumin and can be evaluated frequently to ascertain whether a particular nutritional intervention is effective.

Lifestyle
Diet
Because nutritional status is important for wound healing in patients with diabetes, a dietary history should be obtained. A nutritional risk assessment of a patient with DFU should include measurement of height and weight. In addition, patients should be questioned about unintentional changes in weight of > 10 pounds over the past 6 months; persistent or recurrent diarrhea; alcohol intake greater than 3 drinks per day; use of current dietary supplements including over the counter vitamins, etc; mouth, tooth, or swallowing problems; use of tube feeding or total parenteral nutrition; access to food (ie, limited or adequate), missing 2 meals/day
for more than 2 days out of the week; and morning fasting blood glucose levels. Answers to these questions may prompt further laboratory studies and referral to a nutritionist.

Quality of Life
Studies have shown the negative impact of DFUs on patients’ quality of life.12,23 Numerous health-related quality of life survey instruments have been used in clinical research. At the minimum, a basic line of questioning should be used at initial evaluation and subsequent visits to help guide treatment decisions. This line of questioning could include: “In general, how would you rate your overall health?” “Does your foot ulcer now limit your typical activities at work or at home?” “Are you limited a little or a lot?” “Has your wound interfered with social activities?”

Smoking, Alcohol, and Depression
Although there is little direct research on the effect of smoking on healing of DFUs, there is evidence that long-term smoking has a negative impact on endothelial and smooth muscle skin microcirculation,24 which could impair healing. This, in addition to the known macrovascular and end-organ complications associated with smoking make smoking cessation a goal in the treatment of patients with a DFU.

Additional factors that may affect healing include alcohol consumption/abuse and depression or other mental illness, as these problems may affect compliance with treatment recommendations. In fact, individuals with diabetes and coexisting major depression are more likely to experience life-threatening diabetes-related complications.25 Clinicians must be aware of comorbid depression if it exists and treat the depression along with the DFU and patient’s diabetes.

Neurologic Screening
Several techniques can be used to assess sensory function during screening for neuropathy. The current recommendation supported by the ADA22 advocates the use of the 10-g Semmes-Weinstein monofilament (Figure 1) in addition to 1 of the following tests: pinprick sensation, vibration perception with a 128-Hz tuning fork, ankle deep tendon reflexes, or vibration perception threshold testing.22

**Figure 1. Screening for neuropathy: Use of a 10-g (5.07) Semmes-Weinstein Monofilament**

1. Place patient in a supine position with his or her eyes closed
2. Ask the patient to respond “yes” when the filament is felt
3. Test 4 sites on each foot in random sequence (the sites to be tested are indicated on the diagram)
4. Apply the filament perpendicular to the surface of the skin and apply sufficient force to form a C-shape for 1 second
5. Do not allow the filament to slide across the skin or make repetitive contact at the test site
6. Randomize the order and timing of successive tests
7. Do not apply to an ulcer site, callous, or scar – apply to adjacent tissue instead
8. Mark in the patient chart areas positive or negative for sensation
Vascular Evaluation

No universal, noninvasive test can completely evaluate vascular health; however, a combination of testing, used where indicated and appropriate, can support the assessment of macrovascular disease in patients with diabetes. At screening, 1 or more measurements may be appropriate given the clinical impression, equipment requirements, and operator expertise. These measurements include palpation of pulses, ankle brachial index (ABI), and/or toe brachial index (TBI). If there is a high clinical suspicion that the wound is ischemic or for individuals at high risk for vascular disease, a referral for second-tier evaluations may be indicated. These evaluations may include segmental pressure pulse volume, skin perfusion pressure (SPP), and transcutaneous oxygen tension (TcPO_2). Tertiary approaches for more aggressive evaluation may include referrals to a cardiologist for angiography.

Palpation of pulses

Palpation of peripheral pulses, including the femoral, popliteal, and pedal vessels, should be included as part of the routine physical examination. Although pulse palpation is subjective, it can provide robust evidence for the presence of vascular disease.26 Based on clinical experience, palpation of pulses as a preliminary screening tool is likely sufficient for 60% to 80% of patients.

Ankle Brachial Index

The ADA recommends the ABI as a reproducible and quantitative test for vascular evaluation.26 Simple to perform, the ABI measures the patency of the lower-extremity arterial system using a hand-held Doppler probe and a blood pressure cuff. The ABI is calculated as a ratio of systolic blood pressure measured in the dorsalis pedis and posterior tibial arteries of the ankle divided by the systolic blood pressure in the brachial artery measured at the arm of a patient in a supine position for 5 minutes. Diagnostic interpretation indicates that low ABI ratios are associated with a high risk for vascular disease (Table 1). The ABI should be performed with an understanding of the limitations of this test in patients with diabetes. An ABI value of greater than 1.2 may be spurious secondary to medial calcinosis of the vessels and the ABI may be falsely negative in diabetic patients with aortoiliac stenoses.

<table>
<thead>
<tr>
<th>Resting ABI</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.91-1.30</td>
<td>Normal</td>
</tr>
<tr>
<td>0.70-0.90</td>
<td>Mild obstruction</td>
</tr>
<tr>
<td>0.40-0.69</td>
<td>Moderate obstruction</td>
</tr>
<tr>
<td>&lt; 0.40</td>
<td>Severe obstruction</td>
</tr>
</tbody>
</table>

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Toe Brachial Index

Because some diabetic patients may develop glycosylation or calcification in lower-limb arteries that may result in a falsely high ankle pressure, the TBI can be substituted. It should be noted that the TBI measurement requires specialized equipment not commonly found in all clinical settings and additional technical expertise.27 The TBI has been shown to be superior to the ABI in patients with neuropathy. A normal TBI can exclude the presence of arterial disease.28 This outcome may well reduce concerns of underdiagnosis in patients with diabetes and early stages of incompressible vessels, as normal ABI results do not necessarily exclude peripheral vascular disease.
Segmental pressure pulse volume
Segmental pressure pulse volume recording is considered a second-tier approach for assessing vascular health and is primarily used for patients with poorly compressible vessels or those with normal ABI results with suspicion of peripheral vascular disease. Segmental pressure pulse volume is based on the principle that obstruction is proximal to the level at which the pressure drops. To localize arterial lesions, systolic blood pressure cuffs are placed at intervals on the legs (thigh, calf, and ankle) and pressures are recorded. The shape of the observed pulse waveform is used to determine the presence, severity, and general location of vascular disease. Segmental pressure pulse volume measurements are more easily obtained than TBI in diabetic patients with foot ulcers that involve the toe.

Skin perfusion pressure
Skin perfusion pressure (SPP), a laser Doppler measurement that uses a blood pressure cuff at the ankle, indicates the presence (or lack) of perfusion in the lower limbs. In essence, SPP is a measure of cutaneous capillary circulation. Although SPP requires specialized equipment, it has been shown to be more sensitive than other techniques for detecting lower-extremity peripheral arterial disease.

Transcutaneous oxygen tension
Transcutaneous oxygen tension measures oxygen tension in areas adjacent to a wound and has been suggested as a diagnostic tool for assessing the probability of wound healing. Two evidence-based reviews support TcPO2 as a screening tool for a population at high risk for vascular disease. As TcPO2 is not affected by arterial calcifications like ABI, TcPO2 can be used to validate referral for second-tier vascular evaluation, especially in diabetic patients with critical limb ischemia. Moreover, TcPO2 measurements can aid in selecting patients with foot ulcers who may benefit from the addition of hyperbaric oxygen (HBO) therapy to heal chronic wounds. Drawbacks of TcPO2 may include variability secondary to technician experience and technique and concerns that results could be affected by changes in the ambient temperature in the room.

Angiography
Although angiograms, magnetic resonance angiography, and computed tomography angiography are not recommended as initial screening tools, such methods may be necessary to further evaluate patients once clinical suspicion of wound ischemia or high-risk vascular disease is ascertained. In some subsets of patients, advanced evaluation may be required. For example, in an observational study of 104 patients evaluated with arteriography and who had hemodynamically significant lesions in the presence of an ulcer, the majority had a normal pulse, normal ABI, or normal TcPO2. Therefore, if there is a high degree of clinical suspicion of vascular disease, angiography or arteriography should be considered in diabetic patients with nonhealing wounds to rule out arterial disease. Arterial imaging should be recommended with caution as radiocontrast dyes used for such tests may impair renal function and precipitate acute renal failure.

Endovascular vs surgical intervention
Endovascular procedures represent a treatment option for vascular disease in patients with diabetes. Many individuals with multiple underlying comorbidities who were not candidates for open interventions have benefited from endovascular techniques and, although not as robust as distal bypass surgery, these interventions have created a “window of opportunity” for ulcer healing. However, many specialists still subscribe to bypass surgery as the preferred method of treating vascular disease in the lower extremities in patients with diabetes and believe that endovascular interventions should be employed predominantly in large vessels. Therefore, if there is high clinical suspicion of critical limb ischemia, the patient should be referred to a vascular specialist with whom the referring clinician can discuss the patient’s potential for wound healing and determine which procedures would be most appropriate.
Foot and Ulcer Evaluation

The foot and ulcer examination should include the following: (1) assessment of dermatologic changes in the surrounding skin, including callus, musculoskeletal deformity and muscle wasting; (2) documentation of ulcer characteristics, including location, shape, and size of the wound (measurement of length, width, and depth); (3) determination of the condition of the wound edges, wound bed, wound base, periwound skin, and exudates; and (4) determination of the presence of necrosis and wound-associated pain. Evaluation for complications, such as cellulitis, gangrene, osteomyelitis, or Charcot deformity (neuropathic osteoarthropathy) should also be performed. Because wound depth (stage) appears to be the most important clinical measurement of delayed healing and ankle mobility is a key factor to assess in plantar ulcers, both should be evaluated by the clinician.

The Wound Ostomy & Continence Nurses Society offers further guidance for wound assessment that, although not routine, may prove helpful to the clinician. Recommendations include determination of localized inflammation by palpation and dermal thermometry; determination as to whether edema is dependent or pitting, localized or generalized, or bilateral or unilateral; evaluation of perfusion status by assessing skin temperature, capillary refill, venous refill, color changes, and paresthesias; assessment of ischemic skin changes including purpura, atrophy of subcutaneous tissue, shiny or taut skin, hair loss, or dystrophic nails; and assessment of musculoskeletal/biomechanical status for foot deformities, muscle weakness, or gait abnormalities.

Wound classification systems

Several wound classification systems are available, but there are 2 well-established systems, the Wagner and the University of Texas classifications. Although both systems provide descriptions of ulcers, each has its own set of advantages and drawbacks. The Wagner system uses 6 wound grades (scored 0 to 5) to assess ulcer depth (Table 2). However, the system is limited in its ability to identify and describe vascular disease as an independent risk factor. In addition, superficial wounds that are infected or dysvascular are not able to be classified by this system. The University of Texas system uses a matrix of stages (scored A to D) and grades (scored 0 to 3) to assess ulcer depth, the presence of wound infection, and lower-extremity ischemia (Table 3). The system allows identification of vascular disease and infection as independent factors regardless of ulcer anatomic depth. A complete wound description should be included in the assessment so that a clear picture of what the clinician is observing is available to other specialists who may read the patient's chart.

Infection evaluation

It is imperative to perform a clinical assessment of wound infection in DFUs to prevent complications, such as amputation. Heat, pain, redness, and swelling are classic symptoms of wound infection; however, patients with diabetes are typically immunocompromised and often fail to mount a physiologic response to infection. Therefore, clinicians might look for secondary signs of infection including exudates, delayed healing, friable granulation tissue, discolored granulation tissue, foul odor, pocketing at the wound base, and wound breakdown. Recent evidence indicates that erythrocyte sedimentation rate and C-reactive protein may be markers of infection. These factors, along with evidence of a positive probe-to-bone test and chronicity, may prompt an additional pathway of testing, such as culturing, to guide treatment. However, routine culturing as an evaluation method is not recommended unless an infection is apparent or sensitivities are required for appropriate antibiotic selection.
Radiography

Plain radiography represents an important initial assessment tool for evaluating infection, foreign bodies, and deformity. Radiographs of the affected foot are the gold standard; however, if clinically indicated, bilateral radiographs should be considered as a method for comparison. Radiologic changes may lag behind the clinical presentation of osteomyelitis for as long as 2 weeks. Magnetic resonance imaging (MRI) is the most specific and sensitive noninvasive test to evaluate osteomyelitis\(^4^9\) and may be clinically indicated, especially if there is a positive probe-to-bone test. Other osteomyelitis testing strategies to consider are the Ceretec\(^\text{R}\) (technetium Tc99m exametazime Injection) or indium white blood cell scans (eg, if the patient has a pacemaker). A triple-phase bone scan is often inaccurate in this patient population because it is entirely blood flow–dependent; however, this test may be useful as part of a dual peak imaging analysis to gather anatomical perspective when compared to the Ceretec or indium scans.

Table 3. University of Texas at San Antonio Diabetic Wound Care Classification System

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description of Wound</th>
</tr>
</thead>
<tbody>
<tr>
<td>A0</td>
<td>Pre- or post-ulcerative lesion completely epithelialized</td>
</tr>
<tr>
<td>A1</td>
<td>Superficial wound, not involving tendon, capsule, or bone</td>
</tr>
<tr>
<td>A2</td>
<td>Wound penetrating to tendon or capsule</td>
</tr>
<tr>
<td>A3</td>
<td>Wound penetrating to bone or joint</td>
</tr>
<tr>
<td>B0</td>
<td>Pre- or post-ulcerative lesion completely epithelialized with infection</td>
</tr>
<tr>
<td>B1</td>
<td>Superficial wound, not involving tendon, capsule, or bone with infection</td>
</tr>
<tr>
<td>B2</td>
<td>Wound penetrating to tendon or capsule with infection</td>
</tr>
<tr>
<td>B3</td>
<td>Wound penetrating to bone or joint with infection</td>
</tr>
<tr>
<td>C0</td>
<td>Pre- or post-ulcerative lesion, completely epithelialized with ischemia</td>
</tr>
<tr>
<td>C1</td>
<td>Superficial wound, not involving tendon, capsule, or bone with ischemia</td>
</tr>
<tr>
<td>C2</td>
<td>Wound penetrating to tendon or capsule with ischemia</td>
</tr>
<tr>
<td>C3</td>
<td>Wound penetrating to bone or joint with ischemia</td>
</tr>
<tr>
<td>D0</td>
<td>Pre- or post-ulcerative lesion completely epithelialized with infection and ischemia</td>
</tr>
<tr>
<td>D1</td>
<td>Superficial wound, not involving tendon, capsule, or bone with infection and ischemia</td>
</tr>
<tr>
<td>D2</td>
<td>Wound penetrating to tendon or capsule with infection and ischemia</td>
</tr>
<tr>
<td>D3</td>
<td>Wound penetrating to bone or joint with infection and ischemia</td>
</tr>
</tbody>
</table>

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Treatment of the Diabetic Foot Ulcer

Because prolonged healing times increase the risk for morbidities, infections, hospitalization, and amputation, expeditious wound closure is the primary goal in DFU treatment. Early adoption of advanced or appropriate care may be more cost effective than traditional standard-care practices for decreasing the incidence of lower-extremity amputation.8,50

Appropriate Preparation of the Wound Bed

Chronic wounds differ biochemically from acute ones and are commonly complicated by impediments to healing such as local ischemia, necrotic tissue, and heavy bacterial loads. Continued recruitment of macrophages and neutrophils fosters a prolonged inflammatory response leading to the production of excessive inflammatory cytokines and matrix metalloproteinases (MMPs).51 This noxious environment perpetuates cellular senescence, growth factor deficiencies, faulty receptor site function, and poor cell proliferation.

Preparing the wound for healing may include debridement, control of infection and inflammation, moisture control, and excision of wound edges and periwound callus, when appropriate.

Debridement

The rationale behind debridement in the preparation of the wound bed is to change the wound physiology from chronic to acute. This involves the removal of nonviable tissue, MMPs and biofilm, and the excision of wound edges and periwound callus to stimulate the production of growth factors. Ironically, evidence supporting debridement as a primary treatment regimen to improve healing rates is sparse, consisting primarily of self-reports from treating physicians and post hoc analysis of randomized clinical trials.52-54

Debridement may be surgical, enzymatic (collagenase), autolytic (ie, occlusive), mechanical (wet-to-dry dressing, lavage), or biologic (larval). Of these types of debridement, surgical debridement is the gold standard and is the most studied. Surgical debridement may be excisional or selective in nature. Excisional debridement involves the surgical removal of clearly identifiable tissue (ie, skin, subcutaneous tissue, tendon, fascia, muscle, or bone) by cutting outside or beyond the wound margin in whole or in part. Selective debridement involves the removal of devitalized tissue including slough, fibrin, exudates, crusts, and other non-tissue materials from wounds. Selective debridement also includes the removal of specific, targeted areas of unidentifiable devitalized tissue along the wound margin.

Steed and colleagues52 evaluated debridement frequency as a secondary endpoint to a double-blind, randomized controlled trial in patients with chronic neuropathic DFUs (N = 118) treated with platelet-derived growth factor. All patients had aggressive, sharp debridement of DFUs before randomization and repeat debridement of callus and necrotic tissue as needed. Across the 6 treatment centers, 83% of patients who received frequent debridement (81% of visits) healed compared with only 20% who received less frequent debridement (15% of visits). In a randomized, controlled trial of a bilayered human skin equivalent, Saap and Falanga53 rated the adequacy and performance of surgical debridement with a novel scale, the Debridement Performance Index (Table 4). Researchers found that patients with higher scores (3–6) on the Debridement Performance Index were 2.4 times more likely to heal than those who had lower scores (0–2).53

Wound debridement is traditionally performed initially and then may be performed at weekly intervals (maintenance debridement).55 If the ulcer bed is clean, shows beefy red granulation tissue, and is free of infection, maintenance debridement may not be required.
Infection Control

Bacterial contamination or colonization of a DFU does not necessarily mean it is infected. All wounds are colonized and there is no operational guide to what level of bacteria leads to pathology. DFU infection should be diagnosed clinically based on the presence of purulent secretions or at least 2 principal symptoms of inflammation (eg, redness, warmth, swelling, and pain or tenderness). However, as patients with diabetes are typically immunocompromised and often fail to mount a physiologic response to infection, clinicians should look for secondary signs of infection including exudates, delayed healing, friable granulation tissue, discolored granulation tissue, foul odor, pocketing at the wound base, and wound breakdown.45

Infections in DFUs are usually polymicrobial, predominantly comprising aerobic, gram-positive, cocci.56 *Staphylococcus aureus* is the most common pathogen found in chronic, nonhealing DFUs.56,57 Optimal treatment decisions can be made only after determining the causative organism(s). Tissue cultures have remained the gold standard of bacterial identification for many years. Deep tissue specimens produce better results than superficial swabs, especially when osteomyelitis is suspected.56,58 Quantitative biopsy of deep tissue specimens is not always practical or available. Sharp debridement followed by culture using the Levine technique (culture is performed on fluid drawn out of the wound via pressure on the wound) has been shown to be accurate and consistent with quantitative biopsy.59 The culture itself is not meant as a means to diagnose infection, but rather as a method to identify species of organisms and antibiotic sensitivities.

Newer but not universally available diagnostic tests with greater sensitivity have been developed that can better identify infections or pathogens within hours instead of days.56 For instance, a polymerase chain reaction assay can detect gram-positive, gram-negative, and anaerobic organisms. An oligonucleotide array can detect genes involved with resistance and toxins and can also identify some specific species by their genotype. Finally, MRI is an emerging technique for detecting infections in soft tissue and bone. Osteomyelitis often underlies an infected DFU. The bone can be cultured, but less invasive diagnostic techniques are available, such as x-ray, MRI, or computed axial tomography scans,58 with MRI considered the best non-invasive test. Osteomyelitis can be difficult to cure. Whenever feasible the bone should be debrided and a 2- to 4-week course of intravenous antibiotic therapy should follow. In some cases, 6 or more weeks of treatment may be necessary.58

### Table 4. Debridement Performance Index (DPI)

<table>
<thead>
<tr>
<th>Category</th>
<th>Needed but not done</th>
<th>Needed and done</th>
<th>Not needed</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Callus</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0 to 2</td>
</tr>
<tr>
<td>Skin undermining</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0 to 2</td>
</tr>
<tr>
<td>Wound bed necrotic tissue</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0 to 2</td>
</tr>
</tbody>
</table>

DPI = Total score

Note: Score range 0-6; higher score is optimal. Adapted from reference 53 with permission.
Off-Loading

The use of effective off-loading modalities is a very important part of DFU treatment and their value should not be underestimated. High-level evidence is lacking that wheelchairs, bed rest, crutches, custom shoes, therapeutic shoes, pads, or custom-made insoles can heal wounds. In some cases devices can interfere with healing; a completely circular felt donut pad can occlude the entire superficial blood supply to the wound via the “edge effect.”

True off-loading is crucial to decreasing pressure and strain rate. Pressure is the force applied uniformly over a surface, measured as force per unit of area. Strain rate is force divided by time; the duration of stress is very important in determining strain. The relation between the shear stress and the rate of strain is linear. Many patients with DFUs are obese and suffer from attendant comorbidities. Obese patients with DFUs put 2 to 2.5 times their body weight on the wound with each step, and a 400-pound patient exceeds the maximum skin elasticity by about 3-fold with each step.

Decreasing the strain rate, not just pressure, is the key to healing wounds. The easiest way to decrease force over time is to decelerate the foot onto the ground and shorten the time the foot is on the ground. However, most patients with DFUs have significant neuropathy and they strike the ground more rapidly than those without neuropathy. For a device to be effective in decreasing the rate and absorbing the force, it must extend above the ankle.

The literature supports the following devices as having reproducible ability to heal wounds: cast walkers (eg, DH Pressure Relief Walker, Bledsoe Conformer Diabetic Boot, ThreeD Dura Steppers [3-D], CAM Walkers), Charcot Restraint Orthotic Walkers (CROW)/total contact brace, patellar tendon-bearing (PTB) braces, ankle-foot orthoses (AFOs) in shoes, and regular or instant total contact casting (TCC). These methods work because they decelerate the foot onto the ground, and decrease weight bearing if they are used for walking. See Figure 2 for examples of off-loading devices.

The key to effective off-loading is to have an ankle brace that is fixed to the foot bed. Total contact casting is associated with highest healing rates. Molding the bottom of the cast to the bottom of the foot causes the entire sole to participate in the force distribution, resulting in lower pressures. One study of treatment of DFUs compared 1350 wounds treated with either TCC, 3-D walkers with custom insoles, or custom healing sandals. The percentages of closures within 5 weeks for each device were as follows: TCC, 88% closure; 3-D with custom insole, 63% closure; and custom sandals with 3 layers of foam, 55% closure. Although this study showed TCC to be superior to the other off-loading methods tested, the other off-loading modalities provided rates of healing better than those seen without off-loading.

Clinician proficiency with TCC application is a barrier to its acceptance, but training in-services can smooth the transition to everyday practice. Clinical experience suggests that it takes about 10 casts to achieve a level of competency. The key in TCC application is to resist the intuitive urge to increase the padding, but keep to a well-molded cast that does not have contact with the interface; to allow for no ankle motion so as to transfer all forces to the tibia; and to construct a cast that will be less likely to create secondary ulcerations.

Reimbursement issues are potentially another barrier to adoption; however, time and effort are saved by ensuring that patients heal faster. If TCC is not available for any reason, there are ways to improvise and make removable casts nonremovable, to ensure compliance. Sometimes referred to as an instant TCC (iTCC), plaster application over a properly fitted CAM walker can be very effective. Another option is to staple together the ends of hook and loop closures to ensure patient compliance; if the staples are removed, the patient has removed the device.
### Figure 2. Off-loading options

<table>
<thead>
<tr>
<th></th>
<th>Dorsal Digit</th>
<th>Plantar Digit</th>
<th>Plantar Metatarsal</th>
<th>Medial Metatarsal</th>
<th>Lateral Metatarsal</th>
<th>Heel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Contact Cast</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>CROW Boot</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Prefabricated Walker</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Ortho Wedge</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>PostOp Shoe</td>
<td>●</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healing Sandal</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Heel Wedge Shoe</td>
<td>●</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>L’nard Splint</td>
<td>●</td>
<td>●</td>
<td></td>
<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>PTB Brace</td>
<td>●</td>
<td>●</td>
<td></td>
<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>MABAL Shoe</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

Adapted from reference 84 with permission.
CROW=Charcot Restraint Orthotic Walker; PTB=patellar tendon bearing.
Not all patients are appropriate candidates for TCCs. TCCs are large and heavy and may not be appropriate for frail individuals, patients with motor difficulties, or morbidly obese patients. An option for these individuals is an AFO with felted foam. Also, clinicians who aren’t entirely proficient with TCC or iTCC applications can prescribe removable devices such as a CAM walker that can be obtained from any durable medical equipment supplier.

The primary disadvantage of these removable devices is that they are just that – removable. There is a probability that these removable devices will be worn while the patient works (likely seated) during the day, then taken off when the patient is at home at night – the time of day when most weight-bearing will occur – rendering the removable device useless. In addition, if the patient improperly dons a removable device, the wearing of it may not be effective.

Adjuvant Therapies – Advancing the Standard of Care

Good wound care practices are necessary to promote timely and complete DFU healing. Despite management with good wound care, many DFUs do not heal completely, become chronic, or infected.6,17 Major costs associated with managing DFUs include hospitalizations due to osteomyelitis and amputation; therefore, the economics of treatment point to healing the ulcer and preventing these complications.

Prognostic factors for wound healing

As noted above, Margolis and colleagues17 evaluated the rate of neuropathic ulcer healing in 10 control groups from prospective clinical trials via meta-analysis. Control groups used good wound care, which included debridement and off-loading, and either saline-moistened gauze or placebo gel and gauze. Six hundred twenty-two patients were assessed. Weighted mean healing rates were 24.2% (95% CI, 19.5–28.8%) for the 12-week end point and 30.9% (95% CI, 26.6–35.1%) for the 20-week end point.

These suboptimal healing rates elucidate the challenges of healing chronic wounds despite appropriate conservative wound management and fosters the notion that advanced wound therapies may be required to treat ulcers that fail to heal with good wound care alone. The importance of utilizing adjuvant therapies / advanced products such as human skin equivalents, wound modulators, and growth factors is well documented.6,58,69,70 Clinicians, however, continue to use these therapies as a “last resort” and may not be sure when it is appropriate to use them earlier in the wound healing process.

It has been increasingly suggested that after 4 weeks of good, standard DFU care, wounds should be reassessed for progress, and reduction in ulcer size should be used as a predictive marker.6,70 Sheehan et al70 assessed the ability of the 4-week healing rate to predict complete healing over a 12-week period in a post hoc analysis of data collected in a large prospective multicenter trial of 203 diabetic patients with DFUs. The midpoint between the percentage area reductions (PARs) from baseline at 4 weeks in patients healed vs those not healed at 12 weeks was 53%. Subjects with a PAR in ulcer size greater than 53% in 4 weeks had a 12-week healing rate of 58%, whereas those with reduction in ulcer area less than 53% in 4 weeks had a healing rate of only 9% (P < .01). It was concluded that the PAR in foot ulcer area after 4 weeks is a robust predictor of healing at 12 weeks and could serve as a pivotal clinical decision point in the treatment algorithm of DFUs for early identification of patients who may not respond to standard care and may require adjuvant therapies. Foremost, this study created a negative predictive value for those ulcers that would not heal in 12 weeks.70

Snyder et al71 found similar results by conducting post hoc analyses of control participant data extracted from 2 previously published randomized, controlled trials of a human fibroblast–derived dermal substitute for treating DFUs. Analyses showed ≥ 50% PAR at 4 weeks was significantly associated with healing at 12 weeks and independent of baseline ulcer area (P < .001). Additional analyses indicated that less than one-tenth of DFUs with PAR < 50% at weeks 2 and 3 were healed by week 12, whereas more than half of DFUs with at least 50% PAR measurements at weeks 2 to 4 were healed by week 12.
Thus, previous recommendations to reevaluate wound care at 4 weeks continue to hold true. In addition, it has been recommended that the failure to reduce the size of an ulcer after 4 weeks, despite standard wound care, should prompt consideration of adjuvant therapy.\(^6\)

In addition to percent area reduction, several other wound-specific characteristics have been predictive of DFU healing (duration of wound, baseline wound size, and location of the wound).\(^7\) The value of understanding the possible outcomes associated with prognostic factors should not be underestimated. A recent study\(^73\) demonstrated improved DFU healing rates by merely providing clinicians with computer-generated prognostic data based on the ulcer baseline measurements and 4-week changes in wound size – no guidance for adjusting treatment was given with the prognostic data.

**Place of adjuvant therapies in DFU treatment**

In a recent review of optimal treatment strategies for DFUs, Armstrong and colleagues\(^74\) argued that use of an active therapy such as a bioengineered skin substitute to stimulate healing in nonresponding wounds after 4 weeks’ treatment is the optimal care. Only a small number of wound-care products have proven their value in accelerating DFU healing in prospective, randomized registration trials. These include becaplermin (Regranex®; Ortho-McNeil, Raritan, NJ), a topical gel containing recombinant human platelet-derived growth factor, and 2 living skin equivalents: a bilayered skin substitute (Apligraf®; Organogenesis, Inc., Canton, MA) and a human fibroblast–derived dermal substitute (Dermagraft®; Advanced BioHealing, Inc., La Jolla, CA). Before an adjuvant agent is applied, the wound should be open, debrided, and clean. Other modalities that are available but lack rigorous trial data include vacuum-assisted wound closure, hyperbaric oxygen, and electrical stimulation.

**Screening for hyperbaric oxygen therapy**

There is evidence for the use and applicability of HBO therapy in persistently ischemic or infected DFUs, but HBO should be used in combination with optimization of perfusion, aggressive local wound care, and systemic antibiotic therapy, when indicated. Selecting patients for HBO requires demonstration of local periwound hypoxia by TcPO\(_2\) study (TcPO\(_2\) < 50 mmHg with ≤ 30 mmHg defining critical limb ischemia) and demonstrating during HBO treatment that there is sufficient periwound blood flow to raise the TcPO\(_2\) level to ≥ 200 mmHg.\(^75\)\(^76\) Medicare has established the following guidelines for covering HBO for patients with DFUs. The patient must be diagnosed with type 1 or type 2 diabetes mellitus; must have a lower-extremity wound due to diabetes mellitus, which is Wagner Grade III or higher; and must have failed standard wound care (no measurable signs of healing for 30 days). If treated with HBO, the wound must be reevaluated every 30 days during the course of therapy. Continued HBO therapy will not be covered if there are no measurable signs of healing during the 30-day period.\(^77\)

Cost is often cited as a concern with the use of advanced therapies. Cost-effectiveness studies of advanced-care agents for DFUs have been conducted. In a comprehensive review of 9 studies, Chow et al\(^78\) evaluated the cost-effectiveness of becaplermin, and the bilayered skin substitute (Apligraf®) and human fibroblast–derived dermal substitute (Dermagraft). Higher direct costs of using advanced-care therapies often were offset by the avoidance of serious adverse events and resections or amputations. One study conducted over a 1-year period used a living-skin equivalent and found use of the advanced therapy plus standard wound care had 12% lower costs, 24% more ulcer-free days, 67% less time with an infected ulcer, and 63% lower risk of amputation than the group that received standard wound care alone.\(^79\) Any incremental improvement in healing the wound and avoiding serious complications – especially amputation – can have a dramatic impact on overall healthcare utilization costs.

**Amputation**

The decision to amputate when a wound has penetrated through the dermis and affects tendon or bone is a difficult one; 5-year mortality rates after lower-extremity amputation range from 50% to 76%.\(^80\)\(^81\) Approximately 85% of lower-limb amputations in patients with diabetes are preceded by ulceration.\(^8\)\(^11\)

Amputation, whether it is minor (eg, occurring distal or through the tarsometatarsal joint) or major (eg, proximal to the tarsometatarsal joint), may in some instances be the...
The Standard of Care for Evaluation and Treatment of Diabetic Foot Ulcers

The most common causal pathway for development of a DFU is the triad of peripheral neuropathy, foot deformity, and minor trauma. Other risk factors include peripheral ischemia, edema, and callus. The recognition of risk factors for DFU and prophylactic foot care could prevent or delay formation of DFUs in many patients. Healthcare professionals caring for diabetic patients at risk should employ patient education and strategies outlined in Table 5. Patients must be educated about the implications of loss of protective sensation and how to perform foot self-care activities such as

Table 5. Strategies that may prevent or delay development of DFU

<table>
<thead>
<tr>
<th>Component cause</th>
<th>Prevention strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral neuropathy</td>
<td>• Patient instruction on how lack of protective sensation requires special care and</td>
</tr>
<tr>
<td></td>
<td>diligence by patient, family, and healthcare provider</td>
</tr>
<tr>
<td></td>
<td>• Protective footwear</td>
</tr>
<tr>
<td></td>
<td>• Good glycemic control</td>
</tr>
<tr>
<td>Deformity</td>
<td>• Appropriate shoes/inserts to accommodate contours of the foot and relieve pressure</td>
</tr>
<tr>
<td>Minor trauma</td>
<td>• Protective footwear</td>
</tr>
<tr>
<td></td>
<td>• Review of living environment for safety</td>
</tr>
<tr>
<td>Peripheral ischemia</td>
<td>• Alter risk factors for atherosclerosis (smoking, hypertension, lipoprotein abnormalities)</td>
</tr>
<tr>
<td></td>
<td>• Revascularize for critical ischemia</td>
</tr>
<tr>
<td>Callus</td>
<td>• Regular removal of callus</td>
</tr>
<tr>
<td></td>
<td>• Footwear to minimize callus development</td>
</tr>
<tr>
<td>Peripheral edema</td>
<td>• Footwear to accommodate presence/absence of edema</td>
</tr>
<tr>
<td></td>
<td>• Resolution of edema based on etiology (pharmacologic approaches, compression stockings, bedrest)</td>
</tr>
</tbody>
</table>

Adapted from reference 83 with permission.
frequent inspection, appropriate daily foot hygiene, and use of protective footwear. At a minimum, off-the-shelf footwear should have broad, round toes and adjustable laces or velcro closures. To protect against trauma, protective house slippers should be worn in the home when shoes are not worn. Patients with severe neuropathy or foot deformity may require extra depth and width shoes and custom insoles. For patients with multiple risk factors, regular and frequent podiatric visits for callus removal and toenail maintenance should be advocated. Resources for patient-oriented information can be found in Table 6.

Table 6. Resources for patient education on diabetic foot care

<table>
<thead>
<tr>
<th>Resource</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.diabeticfoot.org.uk/">http://www.diabeticfoot.org.uk/</a></td>
</tr>
<tr>
<td><a href="http://ndep.nih.gov/media/Feet_broch_Eng.pdf">http://ndep.nih.gov/media/Feet_broch_Eng.pdf</a></td>
</tr>
</tbody>
</table>

Summary

Neuropathic DFUs are one of the most common complications in patients with diabetes. The economic burden of DFUs is high and secondary complications of infection and amputation contribute most to the costs. Expeditious and complete wound healing is the definitive goal in treating DFUs, and standard management strategies include preparation of the wound bed, debridement, infection control, and off-loading. Despite the use of these strategies, healing rates of DFUs remain low.

Assessment of a DFU should include a comprehensive foot and ulcer evaluation with key components of a patient history and physical examination, laboratory screening, nutritional evaluation, and a neuropathy and vascular assessment. Wound status history and a complete and accurate description of the wound, including measurements of length, width, and depth, need to be included in the evaluation. Treatment should include appropriate preparation and maintenance of the wound bed with special attention to debridement, off-loading, and infection control. Clinicians must take a holistic approach to healing DFUs, and decision-making is a proactive process that requires ongoing reassessment. Rates of wound closure early in the course of treatment predict later healing. Early adoption of advanced therapies is advocated to speed wound healing and decrease complications.
The Standard of Care for Evaluation and Treatment of Diabetic Foot Ulcers

References


8. Apelqvist J, Larsson J. What is the most effective way to reduce incidence of amputation in the diabetic foot? *Diabetes Metab Res Rev*. 2000;16 (suppl 1):S75-S83.


The Standard of Care for Evaluation and Treatment of Diabetic Foot Ulcers


Self-Assessment Examination

1. Which of the following statements is false?
   a. The development of diabetic foot ulcers (DFUs) typically results from peripheral neuropathy and/or large vessel vascular disease.
   b. Approximately 7% of DFUs result in lower-extremity amputation.
   c. A history of DFU is a significant independent predictor of mortality in patients with diabetes.
   d. None of the above.

2. Standard wound care is effective in healing 95% of neuropathic ulcers in patients with diabetes.
   a. True
   b. False

3. As part of foot and ulcer examination, the healthcare team should:
   a. Assess dermatologic changes in the surrounding skin, including callus, musculoskeletal deformity, and muscle wasting.
   b. Document ulcer characteristics including location, shape, and size of the wound.
   c. Determine the condition of the wound edges, wound bed, wound base, periwound skin, and exudates.
   d. All of the above

4. Preparing a DFU for healing may include debridement, control of infection and inflammation, moisture control, and excision of wound edges and periwound callus.
   a. True
   b. False

5. In one double-blind, randomized, controlled trial in patients with chronic neuropathic DFUs treated with an advanced therapy, subjects who received _______ had higher healing rates than those who did not.
   a. Frequent debridement of callus and necrotic tissue
   b. Intensive antibiotic treatment
   c. Physical therapy
   d. None of the above

6. Bacterial colonization of a DFU requires antibiotic treatment prior to additional wound healing measures.
   a. True
   b. False

7. In terms of off-loading, decreasing the ____________ in addition to reducing pressure is the key to healing DFUs.
   a. Overall weight of the patient
   b. Glucose level
   c. Strain rate
   d. Risk for infection

8. Which of the following is a predictor of DFU healing?
   a. Wound depth
   b. Baseline wound size
   c. Location of the wound
   d. All of the above

9. The direct costs of using advanced-care agents for DFUs are offset by which of the following?
   a. Improved glycemic control
   b. Avoidance of serious adverse events and resections or amputations
   c. Both a and b
   d. Neither a nor b

10. Patient education regarding foot self-care should include:
    a. The need for frequent inspection
    b. Appropriate daily foot hygiene
    c. The use of protective footwear
    d. All of the above
## Answer and Evaluation Form

### The Standard of Care for Evaluation and Treatment of Diabetic Foot Ulcers

You may take the post-test online at [www.cme-dfu.com](http://www.cme-dfu.com). If you receive a passing score you will be able to download and print a certificate for physician or nursing credit. For podiatric credit, a Certificate of Completion and a copy of the Barry University CME transcript will be mailed to you within 4 weeks. A minimum score of 70% is required for certification.

If you choose to mail or fax your post-test, the information provided below will be used for the customization and distribution of certificates. Please print clearly and ensure that all information provided is complete and accurate. Certificates will be mailed within 4 weeks. All forms must be received by January 30, 2012. Return via fax (815-301-5470) or mail to:

The JB Ashton Group, Inc.
DFU CE Monograph
47075 Five Mile Rd.
Plymouth, MI 48170

For further information contact Cindy Brown: cbrown@jashtin.com
734-459-3144 x 208

| *CE CREDIT DESIGNATION: Check Only One* |  |
|-----------------------------------------|  |
| ❑ Podiatrist                            |  |
| Podiatrists only: State and license number (for certificate purposes)______________________ |  |
| ❑ Physician                             |  |
| ❑ Nurse                                |  |

### ANSWERS.

Refer to self-assessment examination. Circle one answer for each question.

1) a b c d  
2) a b  
3) a b c d  
4) a b  
5) a b c d  
6) a b  
7) a b c d  
8) a b c d  
9) a b c d  
10) a b c d  

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Email Address: ____________________________

Confirm Email Address: ____________________________

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The overall purpose of this module is to share current clinical treatment and research related to the care of diabetic foot ulcers. Please answer the following questions by circling the appropriate rating:


To what extent did the program meet the educational objective: “Summarize examination, evaluation, and classification of diabetic foot ulcers (DFUs)”?

5 4 3 2 1

To what extent did the program meet the educational objective: “Identify the medical, quality-of-life, and cost implications of DFUs”?

5 4 3 2 1

To what extent did the program meet the educational objective: “Analyze the treatment considerations, including debridement, off-loading, and infection control, for DFUs”?

5 4 3 2 1

To what extent did the program meet the educational objective: “Describe the role of adjuvant therapies in the treatment of DFUs”?

5 4 3 2 1

Rate the effectiveness of how well the program avoided commercial bias/influence:

5 4 3 2 1

Rate the effectiveness of how well the program related to your practice needs:

5 4 3 2 1

Rate the effectiveness of how well the program will help you improve patient care:

5 4 3 2 1

Rate the overall quality of the program:

5 4 3 2 1

Do you currently care for patients with diabetic foot ulcers?

Yes No

Additional comments:

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________
This self-study activity for physicians, podiatrists, and nurses is cosponsored by The University of Michigan Medical School, The University of Michigan Health System’s Educational Services for Nursing, and Barry University School of Podiatric Medicine.

This program is supported by an unrestricted educational grant from Advanced BioHealing, Inc.

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