Guidelines for the prevention of diabetic ulcers

David L. Steed, MD[1,2]; Christopher Attinger, MD[3]; Harold Brem, MD[4]; Theodore Colaizzi, CPed, COF[5]; Mary Crossland, RN[6]; Michael Franz, MD[7]; Lawrence Harkless, DPM[8]; Andrew Johnson, BS[9]; Hans Moosa, MD[10]; Martin Robson, MD[11]; Thomas Serena, MD[12]; Peter Sheehan, MD[13]; Aristidis Veves, MD[14]; Laurel Wiersma-Bryant, RN, BC, ANP[15]

1. Chaired this panel,
2. University of Pittsburgh/UPMC, Pittsburgh, Pennsylvania,
3. Georgetown University Hospital, Washington, DC,
4. Columbia University College of Physicians and Surgeons, Department of Surgery, New York, New York,
5. Colaizzi Pedorthic Center, Pittsburgh, Pennsylvania,
6. HCA Richmond Retreat Hospital, Richmond, Virginia,
7. University of Michigan Hospital, Ann Arbor, Michigan,
8. University of Texas Health Science Center, San Antonio, Texas,
9. Covance, Princeton, New Jersey,
10. St. Joseph's Hospital, Belleville, Illinois,
11. University of South Florida, Tampa, Florida,
12. Penn North Centers for Advanced Wound Care, Warren, Pennsylvania,
13. Cabrini Medical Center, New York, New York,
14. Beth Israel Deaconess Medical Center, Boston, Massachusetts, and
15. Barnes-Jewish Hospital at Washington University Medical Center, St. Louis, Missouri

The Wound Healing Society (WHS) is a professional society of physicians, nurses, physical therapists, podiatrists, and other wound care specialists, basic scientists, clinical researchers, and industrial researchers dedicated to assuring that every patient receives optimal wound care. Its mission is to advance the science and practice of wound healing. To that end, the following comprehensive, evidence- and consensus-based guidelines were developed to address *The Prevention of Diabetic Ulcers*. The guidelines are presented in generic terms; the details of specific tests, therapies, and procedures are at the discretion of an interdisciplinary team of health care professionals who establish, implement, and evaluate policies and procedures directed at prevention of diabetic ulcers.

METHODS

PubMed, EMBASE, CINAHL, and the Cochrane Database of Systematic Reviews were searched and reviewed for evidence on arterial insufficiency ulcer prevention. In addition, a search of health care databases for current evidence-based guidelines addressing the prevention of diabetic ulcers was conducted using electronic and online resources. The panel classified studies based on whether the intervention being evaluated addressed diabetic ulcer risk screening and assessment, diabetic ulcer prevention plans of care (including interdisciplinary approaches), or patient and caregiver education.

Evidence references for each standard are listed and coded. The code abbreviations for the evidence citations were as follows:

STAT	Statistical analysis, meta-analysis, consensus statement by commissioned panel of experts
RCT	Randomized clinical trial
LIT REV	Literature review
CLIN S	Clinical case series
RETRO S	Retrospective series review
EXP	Experimental laboratory or animal study
TECH	Technique or methodology description
PATH S	Pathological series review

Classification of evidence

The strength of evidence supporting a guideline is listed as Level I, Level II, or Level III, using the following definitions:

- *Level I:* Meta-analysis of multiple RCTs or at least two RCTs supporting the intervention in the guideline or multiple laboratory or animal experiments with at least two clinical series supporting the laboratory results.
- *Level II:* Less evidence than Level I, but at least one RCT and at least two significant clinical series or expert opinion papers with literature reviews supporting the intervention. Experimental evidence that is quite convincing but without support by adequate human experience.
- *Level III:* Suggestive data of proof-of-principle, but lacking sufficient data such as meta-analysis, RCT or multiple clinical series.

REFERENCES

1. Cowie CC, Rust KF, Byrd-Holt DD, Eberhardt MS, Flegal KM, Engelgau MM, Saydah SH, Williams DE, Geiss LS, Gregg EW. Prevalence of diabetes and impaired fasting glucose in adults in the U.S. population: National Health and Nutrition Examination Survey. *Diabetes Care* 2006; 29: 1263–8.

2. Chetty VK, Bruce Zellner B. Use of survey and clinical data for screening and diagnosis. *Stat Med* 2007; 26: 3213–28 [Epub].
3. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005; 293: 217–28.

GUIDELINES

Preamble: Patients with diabetes develop wounds as a result of neuropathy, peripheral vascular disease with ischemia, or both. In 2002, there were 19.3 million people with diabetes mellitus, for a crude incidence of 9.3%. The diagnosis of diabetes had been established in 6.5%, with 2.8% undiagnosed. There are now an estimated 20.8 million people in the United States with diabetes. As many as 25% of these patients are at risk for ulceration during their lifetimes. Preventing wounds may reduce the likelihood of amputation. Establishing the proper diagnosis is imperative, as is evaluation of the patient for the complications of diabetes. Prevention of wounds in these patients involves addressing these complications before ulceration.

1. Identifying Complications of Diabetes Leading to Ulceration:

Guideline #1.1: In patients with diabetes, clinically significant arterial disease should be ruled out by establishing that pedal pulses are clearly palpable or that the ankle:brachial index (ABI) is > 0.9. An ABI > 1.3 suggests noncompressible arteries. In elderly patients or patients with an ABI > 1.2, a normal Doppler derived wave form, a toe:brachial index of > 0.7 or a transcutaneous oxygen pressure of > 40 mmHg may help to suggest an adequate arterial flow. Color duplex ultrasound scanning provides anatomic and physiologic data confirming atherosclerotic occlusive disease.

Level of Evidence: I.

Principle: Diabetic ulcers can result from minor trauma in patients with arterial insufficiency. Although clinical history and physical examination can be suggestive of ischemia of the lower extremity in a patient with diabetes, a definitive diagnosis must be established.

Evidence:

1. Sahli D, Eliasson B, Svensson M, Blohme G, Eliasson M, Samuelsson P, Ojbrandt K, Eriksson J. Assessment of toe blood pressure is an effective screening method to identify diabetes patients with lower extremity arterial disease. *Angiology* 2004; 55: 641–51 [CLIN S].
2. Teodorescu V, Chen C, Morrissey N, Faries P, Marin M, Hollier L. Detailed protocol of ischemia and the use of noninvasive vascular laboratory testing in diabetic foot ulcers. *Am J Surg* 2004; 187(5A): 75S–80S [LIT REV].
3. Hirsch A, Criqui M, Treat-Jacobson D, Regensteiner J, Creager M, Olin J, Krook S, Hunninghake D, Comerota A, Walsh M, McDermott M, Hiatt W. Peripheral arterial disease detection, awareness, and treatment in primary care. *JAMA* 2001; 286: 1317–24 [CLIN S].
4. Ascher E, Hingorani A, Markevich N, Yorkovich W, Schutzer R, Hou A, Jacob T, Nahata S, Kallakuri S. Role of duplex arteriography as the sole preoperative imaging modality prior to lower extremity revascularization surgery in diabetic and renal patients. *Ann Vasc Surg* 2004; 18: 433–9 [CLIN S].
5. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, Hiratzka LF, Murphy WRC, Olin JW, Puschett JB, Rosenfield KA, Sacks D, Stanley JC, Taylor LM Jr, White CJ, White J, White RA. ACC/AHA guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the american association for vascular surgery/society for vascular surgery, society for cardiovascular angiography and interventions, society of interventional radiology, society for vascular medicine and biology, and the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to develop guidelines for the management of patients with peripheral arterial disease). American College of Cardiology Web Site. Available at: http://www.acc.org/clinical/guidelines/pad/index.pdf [STAT].
6. Padberg FT, Back TL, Thompson PN, Hobson RW. Transcutaneous oxygen ($TcPO_2$) estimates probability of healing in the ischemic extremity. *J Surg Res* 1996; 60: 365–9 [CLIN S].

Guideline #1.2: The presence of significant neuropathy that can render a patient at risk of foot ulceration can be determined by testing with a 10 g (5.07) Semmes–Weinstein monofilament. Monofilament testing should be combined with a clinical examination of the lower extremity that focuses on the possible existence of foot deformity and a symmetric sensory level below which there is reduced sensation to pain, touch and vibration in both limbs.

Level of Evidence: II.

Principle: The most important causative factor of diabetic foot ulcers is peripheral neuropathy. Neuropathy leads to foot deformity with abnormal pressure on the foot, especially the plantar surface. Lack of protective sensation allows ulceration in areas of high pressure. Autonomic neuropathy may increase the likelihood of skin breakdown.

Evidence:

1. Singh N, Armstrong D, Lipsky B. Preventing foot ulcers in patients with diabetes. *JAMA* 2005; 293: 217–28 [LIT REV].
2. Kamei N, Yamane K, Nakanishi S, Yamashita Y, Tamura T, Ohshita K, Watanabe H, Fujikawa R, Okubo M, Kohno N. Effectiveness of Semmes–Weinstein monofilament examination for diabetic peripheral neuropathy screening. *J Diabetes Complications* 2005; 19: 47–53 [CLIN S].
3. Foltz K, Fallat L, Schwartz S. Usefulness of a brief assessment battery for early detection of Charcot foot

deformity in patients with diabetes. *J Foot Ankle Surg* 2004; 43: 87–92 [CLIN S].
4. Jirkovska A, Boucek P, Woskova V, Bartos V, Skibova J. Identification of patients at risk for diabetic foot: a comparison of standardized noninvasive testing with routine practice at community diabetes clinics. *J Diabetes Complications* 2001; 15: 63–8 [CLIN S].
5. Mayfield J, Sugarman J. The use of the Semmes–Weinstein monofilament and other threshold tests for preventing foot ulceration and amputation in persons with diabetes. *J Fam Pract* 2000; 49 (11 Suppl.): S17–29 [LIT REV].
6. Pham H, Armstrong D, Harvey C, Harkless L, Giurini J, Veves A. Screening techniques to identify people at high risk for diabetic foot ulceration: a prospective multicenter trial. *Diabetes Care* 2000; 23: 606–11 [CLIN S].
7. Smieja M, Hunt D, Edelman D, Etchells E, Cornuz J, Simel D. Clinical examination for the detection of protective sensation in the feet of diabetic patients. International Cooperative Group for Clinical Examination Research. *J Gen Intern Med* 1999; 14: 418–24 [CLIN S].
8. Kumar S, Fernando D, Veves A, Knowles E, Young M, Boulton A. Semmes-Weinstein monofilaments: a simple, effective and inexpensive screening device for identifying diabetic patients at risk of foot ulceration. *Diabetes Res Clin Pract* 1991; 13: 63–7 [CLIN S].
9. Holewski J, Stess R, Graf P, Grunfeld C. Aesthesiometry. Quantification of cutaneous pressure sensation in diabetic peripheral neuropathy. *J Rehabil Res Dev* 1988; 25: 1–10 [CLIN S].
10. Lavery LA, Armstrong DG, Vela SA, Quebedeaux TL, Fleischli JC. Practical criteria for screening patients at high risk for diabetic foot ulceration. *Arch Int Med* 1998; 158: 157–62 [CLIN S].
11. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJ. Predictive value of foot pressure assessment as part of a population-based diabetes disease management program. *Diab Care* 2003; 26: 1069–73 [CLIN S].
12. Litzelman DK, Marriott DJ, Vinicor F. Independent physiological predictors of foot lesions in patients with NIDDM. *Diab Care* 1997; 20: 1273–8 [RCT].

Guideline #1.3: In patients with diabetes, laboratory values such as hemoglobin A1c should be monitored.

Level of Evidence: II.

Principle: High glucose concentrations in the blood lead to increased glycation of the hemoglobin molecules to form hemoglobin A1C, which persists in circulation for up to 6 weeks. Therefore, measurement of plasma hemoglobin A1C is the accepted standard for monitoring long-term glucose control. Elevated hemoglobin A1C levels have been correlated with a variety of comorbidities of diabetes, such as cardiovascular and/or coronary heart disease, retinopathy, neuropathy, and nephropathy/renal failure. Elevated hemoglobin A1C has been shown to be a predictive factor in the development of diabetic foot ulcers but further research is still required.

Evidence:

1. Valeri D, Pozzilli P, Leslie D. Glucose control in diabetes. *Diabetes Metab Res Rev* 2004; 20 (Suppl. 2): S1–8 [LIT REV].
2. Roberts SR, Hamedani B. Benefits and methods of achieving strict glycemic control in the ICU. *Crit Care Nurs Clin North Am* 2004; 16: 537–45 [LIT REV].
3. Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan DM, Peterson CM, American Diabetes Association. Tests of glycemia in diabetes. *Diabetes Care* 2004; 27 (Suppl. 1): S91–3 [STAT].
4. Stratton IM, Adler AI, Neil HA, Matthews DA, Manley SA, Cull CA, Hadden D, Turner RC, Holman RP. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ* 2000; 321: 405–12 [CLIN S].
5. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993; 329: 977–86 [RCT].
6. Schellhase KG, Koepsell TD, Weiss NS. Glycemic control and the risk of multiple microvascular diabetic complications. *Fam Med* 2005; 37: 125–30 [RETRO S].
7. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet* 1998; 352: 854–65 [RCT].
8. Boyko EJ, Ahroni JH, Cohen V, Nelson KM, Heagerty PJ. Prediction of diabetic foot ulcer occurrence using commonly available clinical information: the Seattle Diabetic Foot Study. *Diabetes Care* 2006; 29: 1202–27 [CLIN S].

2. Perform Foot Exam for Clinical Manifestations of Diabetes that Increase Risk of Ulceration:

Guideline #2.1: Patients with diabetes should have an annual foot exam.

Level of Evidence: I.

Principle: Published guidelines uniformly recommend that all diabetic patients have an annual foot examination that includes assessment for anatomic deformities, skin breaks, nail disorders, loss of protective sensation, diminished arterial supply, and improper footwear. People with higher risk for foot ulceration should have more frequent foot exams.

Evidence:

1. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005; 293: 217–28 [LIT REV].
2. Frykberg RG, Armstrong DG, Giurini JM, Edwards A, Kravette M, Kravitz S, Ross C, Stavosky J, Stuck R, Vanore J, American College of Foot and Ankle Surgeons. Diabetic foot disorders: a clinical practice guideline. *J Foot Ankle Surg* 2000; 39: S1–60 [STAT].

3. Hutchinson A, McIntosh A, Feder G, Home PD, Young R. Clinical guidelines for type 2 diabetes: prevention and management of foot problems. London, UK: *J Roy Col Gen Practitioners*, 2000 [STAT].
4. International Consensus on the Diabetic Foot: Practical Guidelines [book on CD-ROM]. Noordwijkerhout, the Netherlands: International Working Group on the Diabetic Foot, 1999 [STAT].
5. Supplement to the International Consensus on the Diabetic Foot: Practical Guidelines [book on CD-ROM]. Noordwijkerhout, the Netherlands: International Working Group on the Diabetic Foot, 2003 [STAT].
6. U.S. Veterans Health Administration/Department of Defense. *Clinical practice guidelines: diabetes mellitus algorithms—Module F: Foot Care*. Washington, DC: Veterans Health Administration, 2003 [STAT].
7. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM, American Diabetes Association. Preventive foot care in people with diabetes. *Diabetes Care* 2004; 27 (Suppl. 1): S31–2 [STAT].

Guideline #2.2: Patients with diabetes should be examined for callus formation.

Level of Evidence: III.

Principle: Callus formation, particularly with hemorrhage, is a sign of impending skin breakdown and ulceration. Removal of the callus results in lowered plantar pressures.

Evidence:

1. Brem H, Sheehan P, Rosenberg HJ, Schneider JS, Boulton AJM. Evidence-based protocol for diabetic foot ulcers. *Plast Reconstr Surg* 2006; 117 (7 Suppl.): S193–209 [LIT REV].
2. Boulton AJ, Meneses P, Ennis WJ. Diabetic foot ulcers: a framework for prevention and care. *Wound Repair Regen* 1999; 7: 7–16 [LIT REV].

Guideline #2.3: Patients with diabetes should be examined for fungal toenails.

Level of Evidence: III.

Principle: Onychomycosis, a fungal infection of the nails, affects approximately one-third of patients with diabetes and is the source of extensive morbidity. Fungal toenails often harbor bacteria that can cause infection after injury to the skin, often initiated by the sharp and brittle nails themselves. Treatment options include oral antifungal agents, topical therapy, and mechanical intervention.

Evidence:

1. Gupta AK, Konnikov N, MacDonald P, Rich P, Rodgers NW, Edmonds MW, McManus R, Summerbell RC. Prevalence and epidemiology of toenail onychomycosis: a multicentre survey. *Br J Dermatol* 1998; 139: 665–71 [CLIN S].
2. Bristow IR, Baran R. Topical and oral combination therapy for toenail onychomycosis. *J Am Podiatr Med Assoc* 2006; 96: 116–9 [LIT REV].
3. Drake LA, Patrick DL, Fleckman P, Andr J, Baran R, Haneke E, Sapede C, Tosti A. The impact of onychomycosis on quality of life: development of an international onychomycosis-specific questionnaire to measure patient quality of life. *J Am Acad Dermatol* 1999; 41: 189–96 [CLIN S].
4. Gupta AK, Humke S. The prevalence and management of onychomycosis in diabetic patients. *Eur J Dermatol* 2000; 10: 379–84 [LIT REV].
5. Rich P. Onychomycosis and tinea pedis in patients with diabetes. *J Am Acad Dermatol* 2000; 43: S130–4 [LIT REV].
6. Robbins JM. Treatment of onychomycosis in the diabetic patient population. *J Diabetes Complications* 2003; 17: 98–104 [LIT REV].
7. Bell-Syer SE, Hart R, Crawford F, Torgerson DJ, Tyrrell W, Russell I. Oral treatments for fungal infections of the skin and of the foot. *Cochrane Database Syst Rev* 2002; CD003584 [STAT].
8. Gupta AK, Einarson TR, Summerbell RC, Sherr NH. An overview of topical antifungal therapy in dermatomycoses: a North American perspective. *Drugs* 1998; 55: 645–74 [LIT REV].

3. Surgery to Prevent Ulceration:

Guideline #3.1: Increased pressure on areas of the diabetic foot results in callus formation, which can then lead to ulceration. Removal of callus will reduce the likelihood of ulceration.

Level of Evidence: I.

Principle: Paring callus will reduce pressure in areas at increased risk for ulceration; therefore, all calluses should be removed with few exceptions.

Evidence:

1. Murray HJ, Young MJ, Hollis S, Boulton AJ. The association between callus formation, high pressures, and neuropathy in diabetic ulceration. *Diabet Med* 1996; 13: 979–82 [CLIN S].
2. Duffin AC, Kidd R, Chan A, Donaghue KC. High plantar pressure and callus in diabetic adolescents. *J Am Podiatr Med Assoc* 2003; 93: 214–20 [CLIN S].
3. Slater RA, Hershkowitz I, Ramot Y, Buchs A, Rapoport MJ. Reduction in digital plantar pressure by debridement and silicone orthosis. *Diabetes Res Clin Pract* 2006; 74: 263–6 [CLIN S].
4. Pataky Z, Golay A, Faravel L, DaSilva J, Makoundou V, Peter-Riesch B, Assal JP. The impact of callosities on the magnitude and duration of plantar pressure in patients with diabetes mellitus. A callus may cause 18,600 kilograms of excess plantar pressure per day. *Diabetes Metab* 2002; 28: 356–61 [CLIN S].
5. Young MJ, Cavanagh PR, Thomas G, Johnson MM, Murray H, Boulton AJ. The effect of callus removal on dynamic plantar foot pressures in diabetic patients. *Diabet Med* 1992; 9: 55–7 [CLIN S].
6. Pitei DL, Foster A, Edmonds M. The effect of regular callus removal on foot pressures. *J Foot Ankle Surg* 1999; 38: 251–5 [CLIN S].

7. Brem H, Sheehan P, Rosenberg HJ, Schneider JS, Boulton AJM. Evidence-based protocol for diabetic foot ulcers. *Plast Reconstr Surg* 2006; 117 (7 Suppl.): 193S–209S [LIT REV].

Guideline #3.2: Achilles tendon lengthening decreases forefoot plantar pressure. This procedure may be recommended only for patients with history of repeated foot ulceration in whom all other non-interventional care has failed.

Level of Evidence: II.

Principle: Decreasing elevated forefoot plantar pressure is associated with a decrease in risk of ulceration.

Evidence:

1. Maluf KS, Meuller MJ, Steube JJ, Engsberg JR, Johnson JE. Tendon Achilles lengthening for the treatment of neuropathic ulcers cause of temporary reduction in forefoot pressure associated with changes in plantar flexor power rather than ankle motion during gait. *J Biomech* 2004; 37: 897–906 [RCT].
2. Mueller MJ, Sinacore DR, Hastings MK, Strube MJ, Johnson JE. Effect of Achilles tendon lengthening on neuropathic plantar ulcers. A randomized clinical trial. *J Bone Joint Surg Am* 2003; 85-A: 1436–45 [RCT].
3. Armstrong DG, Stacpoole-Shea S, Nguyen H, Harkless LB. Lengthening of the Achilles tendon in diabetic patients who are at high risk for ulceration of the foot. *J Bone Joint Surg Am* 1999; 81: 535–8 [CLIN S].
4. Hastins MK, Mueller MJ, Minacore DR, Salsich GB, Engsberg JR, Johnson JE. Effects of a tendo-Achilles lengthening procedure on muscle function and gait characteristics in a patient with diabetes mellitus. *J Orthop Sports Phys Ther* 2000; 30: 85–90 [CLIN S].
5. Nishimoto GS, Attinger CE, Cooper PS. Lengthening the Achilles tendon for the treatment of diabetic plantar forefoot ulceration. *Surg Clin North Am* 2003; 83: 707–26 [LIT REV].

4. Protect the Diabetic Foot:

Guideline #4.1: Protective footwear should be prescribed in any patient at risk for ulceration (significant arterial insufficiency, significant neuropathy, or previous amputation).

Level of Evidence: II.

Principle: Diabetic ulceration may result from an increase in pressure in the diabetic foot because of foot deformity and neuropathy. Offloading reduces the area of high pressure. The incidence of ulceration in diabetic patients at risk can be reduced by using protective footwear. Protective footwear should be prescribed in any patient at risk for amputation (such as significant arterial insufficiency, significant neuropathy, previous amputation, previous ulcer formation, pre-ulcerative callus, foot deformity, or evidence of callus formation).

Evidence:

1. Janisse D. The Therapeutic Shoe Bill: medicare coverage for prescription footwear for diabetic patients. *Foot Ankle Int* 2005; 26: 42–5 [CLIN S].
2. Pinzur M, Slovenkai M, Trepman E, Shields N. Diabetes Committee of American Orthopaedic Foot and Ankle Society. Guidelines for diabetic foot care: recommendations endorsed by the Diabetes Committee of the American Orthopaedic Foot and Ankle Society. *Foot Ankle Int* 2005; 26: 113–9 [LIT REV].
3. Reiber GE, Smith DG, Wallace C, Sullivan K, Hayes S, Vath C, Maciejewski ML, Yu O, Heagerty PJ, LeMaster J. Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial. *JAMA* 2002; 287: 2552–8 [RCT].
4. Maciejewski ML, Reiber GE, Smith DG, Wallace C, Hayes S, Boyko EJ. Effectiveness of diabetic therapeutic footwear in preventing reulceration. *Diabetes Care* 2004; 27: 1774–82 [LIT REV].
5. Chantelau E, Kushner T, Spraul M. How effective is cushioned therapeutic footwear in protecting diabetic feet? A clinical study. *Diabet Med* 1990; 7: 355–59 [CLIN S].
6. Chantelau E, Haage P. An audit of cushioned diabetic footwear: relation to patient compliance. *Diabet Med* 1994; 11: 114–6 [CLIN S].
7. Uccioli L, Faglia E, Monticone G, Favales F, Durola L, Aldeghi A, Quarantiello A, Calia P, Menzinger G. Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 1995; 18: 1376–8 [RCT].
8. Donaghue VM, Sarnow MR, Giurini JM, Chrzan JS, Habershaw GM, Veves A. Longitudinal in-shoe foot pressure relief achieved by specially designed footwear in high risk diabetic patients. *Diabetes Res Clin Pract* 1996; 31: 109–14 [CLIN S].
9. Sarnow MR, Veves A, Giurini JM, Rosenblum BI, Chrzan JS, Habershaw GM. In-shoe foot pressure measurements in diabetic patients with at risk feet and healthy subjects. *Diabetes Care* 1994; 17: 1002–6 [CLIN S].

Guideline #4.2: Patients with healed diabetic ulcers should use protective footwear to prevent recurrence.

Level of Evidence: II.

Principle: Diabetic ulcers of the lower extremity are a chronic problem. Recurrence rates are 8–59%. Therefore, long-term maintenance must be addressed even for healed ulcers. Most treatments do not eliminate the underlying increased pressure on the foot, so offloading is necessary long term.

Evidence:

1. Maciejewski M, Reiber G, Smith D, Wallace C, Hayes S, Boyko E. Effectiveness of diabetic therapeutic footwear in preventing reulceration. *Diabetes Care* 2004; 27: 3024–5 [LIT REV].
2. Cavanagh PR. Therapeutic footwear for people with diabetes. *Diabetes Metab Res Rev* 2004; 20 (Suppl. 1): S51–5 [LIT REV].

3. Boulton AJ. Pressure and the diabetic foot: clinical science and off-loading techniques. *Am J Surg* 2004; 187(5A): 17S–24S [LIT REV].
4. Pinzur MS, Dart HC. Pedorthic management of the diabetic foot. *Foot Ankle Clin* 2001; 612: 205–14 [LIT REV].
5. Lobmann R, Kayser R, Kasten G, Kasten U, Kluge K, Neumann W, Lehnert H. Effects of preventive footwear on foot pressures as determined by pedibarography in diabetic patients: a prospective study. *Diabet Med* 2001; 18: 314–9 [RCT].
6. Uccioli L, Faglia E, Monticone G, Favales F, Durola L, Aldeghi A, Quarantiello A, Calia P, Menzinger G. Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 1995; 18: 1376–8 [RCT].
7. Colagiuri S, Marsden L, Naidu V, Taylor L. Use of orthotic devices to correct planter callus in people with diabetes. *Diabetes Res Clin Pract* 1995; 28: 29–34 [CLIN S].
8. Mueller MJ, Diamond JE, Sinacore DR, Delitto A, Blair VP 3rd, Drury DA, Rose SJ. Total contact casting in treatment of diabetic plantar ulcers. Controlled clinical trial. *Diabetes Care* 1989; 12: 384–8 [CLIN S].
9. Reiber GE, Smith DG, Wallace C, et al. Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial. *JAMA* 2002; 287: 2552–8 [RCT].

5. Good Foot Care:

Guideline #5.1: Good foot care and daily inspection of the feet will reduce the incidence of diabetic ulceration. It may be necessary for a family member or caregiver to help with these tasks.

Level of Evidence: II.

Principle: Good foot care, including proper bathing and nail trimming, and the use of proper footwear, will reduce ulceration in diabetic feet.

Evidence:

1. Pinzur M, Slovenkai M, Trepman E, Shields N: Diabetes Committee of American Orthopaedic Foot and Ankle Society. Guidelines for diabetic foot care: recommendations endorsed by the Diabetes Committee of the American Orthopaedic Foot and Ankle Society. *Foot Ankle Int* 2005; 26: 113–9 [LIT REV].
2. Jeffcoate W, Price P, Harding K: International Working Group on Wound Healing and Treatments for People with Diabetic Foot Ulcers. Wound healing and treatments for people with diabetic foot ulcers. *Diabetes Metab Res Rev* 2004; 20 (Suppl 1): S78–89 [LIT REV].
3. Pinzur M. The diabetic foot. *Compr Ther* 2002; 28: 232–7 [LIT REV].
4. Suico JG, Marriott DJ, Vinicor F, Litzelman DK. Behaviors predicting foot lesions in patients with non-insulin dependent diabetes mellitus. *J Gen Intern Med* 1998; 13: 482–4 [STAT].
5. Litzelman DK, Marriott DJ, Vinicor F. Independent physiological predictors of foot lesions in patients with NIDDM. *Diab Care* 1997; 20: 1273–8 [STAT].
6. Humphrey AR, Dowse GK, Thoma K, Zimmet PZ. Diabetes and nontraumatic lower extremity amputations. Incidence, risk factors, and prevention—a 12-year follow-up study in Nauru. *Diab Care* 1996; 19: 710–4 [CLIN S].

6. Education:

Guideline #6.1: Education of patients with diabetes, aimed at preventing foot wounds, may reduce the incidence of ulceration and amputation, especially in high-risk patients.

Level of Evidence: II.

Principle: Education of patients, using a diabetes educator if available, may help them to practice good foot care behavior.

Evidence:

1. Valk GD, Kriegsman DM, Assendelft WJ. Patient education for preventing diabetic foot ulceration. *Cochrane Database Syst Rev* 2005: CD 001488 [STAT].
2. Del Aquila MA, Reiber GE, Koepsell TD. How does provider and patient awareness of high-risk states for lower extremity amputation influence foot care practice? *Diab Care* 1994; 17: 1050–4 [CLIN S].
3. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005; 293: 217–28 [LIT REV].
4. Pinzur MS, Slovenkai MP, Trepman E, Shields NN, Diabetes Committee of the American Orthopaedic Foot and Ankle Society. Guidelines for diabetic foot care: recommendations endorsed by the Diabetic Committee of the American Orthopaedic Foot and Ankle Society. *Foot Ankle Int* 2005; 26: 113–9 [STAT].
5. Bokyo EJ, Ahroni JH, Stensel V, Forsberg RC, Davignon DR, Smith DG. A prospective study of risk factors for diabetic foot ulcer: the Seattle Diabetic Foot Study. *Diabetes Care* 1999; 22: 1036–42 [CLIN S].
6. Chaturvedi N, Abbott CA, Whalley A, Widdows P, Leggetter SY, Boulton AJ. Risk of diabetes-related amputation in South Asians vs. Europeans in the UK. *Diabet Med* 2002; 19: 99–104 [CLIN S].
7. Jbour AS, Jarrah NS, Radaideh AM, Shegem NS, Bader IM, Batieha AM, Ajlouni KM. Prevalence and predictors of diabetic foot syndrome in type 2 diabetes mellitus in Jordan. *Saudi Med J* 2003; 24: 761–4 [CLIN S].

Guideline #6.2: Education of clinicians about patients with elevated risk for lower extremity amputation may reduce the risk of ulceration.

Level of Evidence: III.

Principle: Clinicians who are aware of patients with increased risk of foot ulceration are more likely to prescribe preventive foot care behaviors.

Evidence:

1. Del Aquila MA, Reiber GE, Koepsell TD. How does provider and patient awareness of high-risk status for lower-extremity amputation influence foot-care practice? *Diab Care* 1994; 17:1050–4 [CLIN S].