

# Diabetic foot risk classification and shoe recommendations: lessons from SALSA at Rancho Los Amigos

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## Article points

1. The authors have created an updated guideline on footwear for people with diabetes.
2. Appropriate shoe prescriptions depend largely on the patient's level of risk for diabetic foot ulceration or amputation.
3. The guideline includes recommendations to guide healthcare professionals in selecting the most appropriate footwear to meet the specific needs for individuals with diabetes.

## Key words

- Diabetic foot ulcers
- Diabetes
- Footwear
- Guideline
- Prevention

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**The goal of this article is to create an updated guideline on footwear for people with diabetes that is accessible for interdisciplinary healthcare professionals involved in managing people with diabetes. The authors reviewed several footwear publications, including national and international guidelines, expert consensus documents and clinical knowledge in order to formulate updated recommendations. They recommend healthcare professionals managing people with diabetes should counsel their patients to wear shoe gear that fits, protects and accommodates the shape of their feet. They emphasise that appropriate shoe prescriptions depend largely on the patient's level of risk for diabetic foot ulceration or amputation. In the current Foot Risk Classification System, a risk- and treatment-based approach has been advocated that divides risks with appropriate prescription orders. They confine our recommendations regarding shoe prescriptions to patients in Categories 0–3: Category 0 include patients who are not likely to ulcerate; Category 1 include patients who have complete loss or have diminished protective sensation; Category 2 include patients with loss of protective sensation and presence of deformity with or without peripheral arterial disease (PAD); Category 3 include patients who have a history of previous ulceration(s) and/or amputation(s). Appropriate offloading devices can prevent and/or heal patients in respective categories. This guideline contains categories with respective offloading devices to protect and heal foot-related complications in patients with diabetes. It includes recommendations to guide healthcare professionals in selecting the most appropriate footwear to meet the specific needs for individuals with diabetes.**

**D**iabetes is a far-reaching malady from both an individual and a societal perspective. In 2015, 30.3 million Americans, or 9.4% of the population, had diabetes (Cannon et al, 2018). Diabetic foot ulcerations (DFUs) are a costly complication of diabetes that reduce a patient's quality of life and increase morbidity, mortality, and healthcare expenditure. It has been reported that the annual incidence of foot ulcers among diabetic patients may be as high as 6% (van Netten, 2018). Studies have estimated that DFUs are one of the major sources of hospitalisations among patients with diabetes, and that they precede

84% of lower limb amputations in these patients (Rinonapoli et al, 2014). Therefore, the prevention of such ulcerations is of significant importance.

The management of DFUs requires a multidisciplinary approach. These ulcers are typically caused by repetitive stresses, such as shear and pressure stresses, on the foot in the presence of the diabetes-related complications of peripheral neuropathy or peripheral artery disease (PAD), and their healing is often complicated by the development of infection.

The goal of the present review is to introduce foot risk classification and shoe recommendation

Table 1. Diabetic foot risk category.					
Foot risk category	LOPS	Deformity	PAD	Remission	Prescription
0	–	–	–	–	NO: Shoe advice
1	+	–	–	–	NOT NECESSARY: Well-fitting shoes with insoles recommended
2	+	+	-/+	–	YES: Shoes with insoles
3	+	+	+/-	+	YES: Shoes with insoles and outsole modifications
3(a)	+	+	+/-	+(history of ulceration)	YES: Shoes with insole and possible outsole modifications
3(b)	+	+	+/-	+(history of Charcot)	YES: CROW boot or shoes with insole and outsole modification based on location and degree of activity
3(c)	+	+	+/-	+(history of amputation)	YES: Shoes with fillers, insole and outsole modifications

in diabetic patients. Identifying the diabetic foot that is especially at risk, along with proper foot care, may prevent DFUs and thus reduce the risk of amputation.

Wearing improper footwear or walking barefoot typically increases the local mechanical repetitive stresses on the foot that are leading causes of the development of ulceration. It is recommended that people with diabetes wear appropriate footwear designed to reduce stresses at all times in order to prevent ulceration (van Netten et al, 2018).

In 1998, Armstrong and Lavery presented 10 recommendations for shoe fitting in patients with diabetes, based on levels of diabetic risk defined by the University of Texas Diabetic Foot Classification System (Armstrong and Lavery, 1998).

In 2013, the Australian Diabetes Foot Network was one of the first to publish nationwide practical guidelines on the provision of footwear for people with diabetes. Many new studies and international guidelines on shoes for the diabetic population have since been published (van Netten et al, 2018). The goal of this article is to update the previous guidelines and create a new foot risk classification and new shoe recommendations.

## Methods

### Procedure

The Australian Diabetes Foot Network 2018 practical guideline on footwear for diabetics was used as a reference for developing this updated

guideline (van Netten et al, 2018). The authors reviewed and incorporated new evidence-based footwear-related recommendations from the most recent International Working Group on the Diabetic Foot guidance and cost-effective analysis of optimal care for DFUs (Bus et al, 2016). In addition, the authors reviewed and incorporated recent findings from systematic reviews on shoe gear for people with diabetes (van Netten et al, 2016).

After methodically organising all findings, a table and figures were created, describing footwear requirements and offloading effects of footwear modifications in patients with DFUs. The table was organised in a clear fashion so that it is legible to healthcare professionals from various disciplines involved in the prevention of DFUs and amputations in people with diabetes.

### Determination of foot risk status

As the risk for developing DFUs increases, so does the importance of wearing appropriate footwear. There are a wide variety of classifications for foot risk status used in the literature.

The current foot risk classification is based on the University of Texas Diabetic Foot Classification System. The classification is divided into four categories based on loss of protective sensation (LOPS), foot deformity and PAD in people with diabetes. In order to determine foot risk status, annual foot screens performed by appropriate healthcare professional in individuals with diabetes

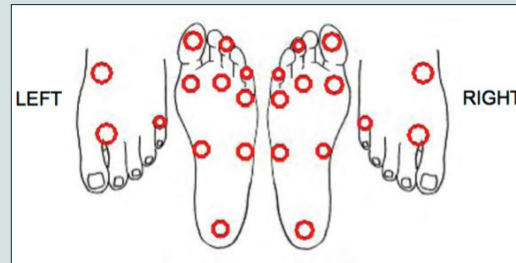


Figure 1. Level of sensation in the circles.

is crucial. This is particularly critical for patients who are in the high-risk category, who should be screened at least once every 3 or 6 months. The screening should include assessment of peripheral neuropathy (10g monofilament sensitivity and vibration perception), PAD (palpation of peripheral pulses, ankle-brachial pressure index and toe-brachial pressure index), foot deformity (Charcot foot deformity, bony prominence, hammer or claw toes and limited joint mobility) and assessment of a history of foot ulcer(s) or lower-extremity amputation.

## Results

### Foot risk classification and shoe recommendations

Appropriate shoe prescriptions depend largely on the patient's level of risk for ulceration or amputation. In the current Foot Risk Classification System, a risk- and treatment-based approach to prevention assesses risk in line with appropriate prescription orders (Table 1). We confine our recommendations regarding shoe prescriptions to patients in Categories 0–3.

Diabetic Foot Risk Category 0 is where a patient's protective sensation is intact, and these patients are not likely to ulcerate. In this category, treatment involves education and palliative foot care as necessary. During this stage, we recommend two or three annual visits for reinforcement of education, as well as routine diabetic foot care.

Patients can choose the type of shoes they prefer to wear. It is important when educating these patients to acknowledge that they may one day lose protective sensation. We therefore encourage them to wear athletic footwear or comfort-type shoes.

Category 1 includes people with LOPS. Although protective sensation is lost in these patients, there is no significant foot deformity and no history of ulceration or amputation. It is important to make

these patients aware that they have about twice the risk for ulceration as patients in Category 0.

LOPS is best defined as the absence of sensation in four or more foot sites out of 10 in response to the Semmes-Weinstein monofilament (SWMF) wire test. The sites for testing include distal plantar aspect of the first, third and fifth toes; the first, third and fifth sub-metatarsal heads; plantar aspect of medial and lateral midfoot; plantar aspect of heel; and dorsal aspect of first web space of each foot. It has been shown that testing for protective sensation using SWMF alone has 97% sensitivity and 80% specificity in identifying patients at risk for ulceration (Figure 1). However, when combined with a calibrated vibratory measurement instrument, sensitivities can reach up to 100%.

An even more practical tool is the Ipswich Touch Test, which allows the clinician to use an index finger to assess protective sensation (Rayman et al, 2011). This has been shown to be nearly comparable to vibration perception threshold and SWMF (Armstrong et al, 2017).

In Category 1, treatment involves education about appropriate shoe gear, in addition to three or four annual visits for routine diabetic foot care. Studies have shown that when fitted with prescription multilaminar inserts, certain over-the-counter comfort-type shoes reduced pressure better than considerably more expensive prescription shoes (Lavery et al, 1997). Higher-risk patients with significant deformity require more room in the toe box.

Category 2 includes people with LOPS and deformity with or without PAD. Patients in Category 2 are up to 12 times more likely to develop DFU than those in Category 0 (Armstrong and Lavery, 1998). Deformity in these patients is defined as any contractures that clinicians cannot completely reduce manually. These patients generally have limited joint mobility with less than 50° of dorsiflexion when non-weightbearing (seated in an exam chair) at the first metatarsophalangeal joint.

Prescription for Category 2 patients should include prompt fitting for prescriptive shoes to accommodate their deformity and protect them against higher repetitive plantar pressures resulting from their deformity (Figure 2a).

These patients generally require the extra room in the toe box that only a prescription shoe can offer.



Figure 2a. Diabetic insert – functional with accommodative total contact plastazote top cover. Figure 2b. Diabetic shoe – high top with toe rocker.



Figure 3a. Posterior relief ankle foot orthosis. Figure 3b. Removable cast walker boot.

In addition, these in-depth shoes are made with proportionately smaller soft prescription insoles that are typically multilayered and of different density. The lower the density of the insole, the more cushion is present at the foot–insole interface. These insoles are generally heat-moulded to contour the patient’s foot, providing additional reduction in pressure. Modifications on the outer sole of an in-depth shoe are often made to further reduce pressure (*Figure 2b*).

Many patients need rocker bottom fitting with a rigid shank and a curved or angled rubber sole. This allows the shoe to provide the motion and absorb the forces that would normally be accepted by the joints of the foot. This type of modification allows the patient to roll over the curved outer portion instead of bending the joints of the forefoot. The rocker sole placement at specific regions of the

forefoot to decrease pressure in high-risk individuals has not been well documented, but placements are suggested at the metatarsal heads, proximal to the metatarsal heads, distal to the midpoint of the shoe, or at the midpoint of the shoe. After being fitted for in-depth shoes, patients should be seen every 2–3 months by a foot specialist.

Patients in Category 3 have a history of previous pathology. They are up to 36 times as likely to develop a foot ulcer than patients in Category 0 (Armstrong and Lavery, 1998). Total contact casts and removable cast walker boots are common off-loading strategies to facilitate ulcer healing and prevent future ulcerations (*Figures 3a and 3b*).

We subdivided this category into three parts:

- 3(a) remission from previous ulceration
- 3(b) remission from Charcot (*Figure 4*)
- 3(c) remission from amputation.



Figure 4. Charcot restraint orthosis walker.

The patients, within each or a combination of these subcategories, require prescription shoes with custom modifications and fillers (Figure 5). Prescription shoes and regular visits every 1–2 months to a diabetic foot clinic are vital to ensure that these patients remain in remission.

### Discussion

Prescription shoe choice based on the patient's foot risk should provide a considerable benefit to patients with diabetes who are at risk for ulceration and/or amputation, to private and public health insurance carriers as well as to physicians. This new DFU foot risk classification reflects evidence from international guidelines and studies from investigating footwear interventions. We presented four categories to guide healthcare professionals in selecting the most appropriate footwear to meet the specific foot risk needs for a person with diabetes.

Further considerations in order to provide proper footwear to people with diabetes should incorporate a person's gait pattern, activity levels, occupation, level of mobility, living situation, personal goals and preferences. These factors may influence the possible options for appropriate footwear. The neuropathic foot is characterised by loss of peripheral nerve function, which can be sensory, motor, autonomic, or combination of these. This loss of function alters the form and function of the foot, leading to ulceration and severe deformity, which may eventually lead to amputation. Therefore, protection



Figure 5. Temporary wound relief shoe.

of the foot is of the greatest importance.

Another important consideration when prescribing footwear to people with diabetes is their adherence to wearing the appropriate footwear. This can be achieved with early education for foot health for all people with diabetes. However, this education needs to continue on a life-long basis, especially if an individual's risk of DFU is high.

### Conclusion

Incorporating appropriate footwear for all people with diabetes in order to prevent DFUs and reduce the threat of diabetic foot disease is a requirement of patient care. More evidence-based reports on the effectiveness of therapeutic shoes, especially in the high-risk population, are essential. We believe that it is important for the diabetic patient population to incorporate preventative therapies for substantial reduction in foot ulceration and subsequent lower extremity amputation. ■

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## Online CPD activity

Visit [www.diabetesonthenet.com/cpd](http://www.diabetesonthenet.com/cpd) to record your answers and gain a certificate of participation

Participants should read the preceding article before answering the multiple choice questions below. There is ONE correct answer to each question. After submitting your answers online, you will be immediately notified of your score. A pass mark of 70% is required to obtain a certificate of successful participation; however, it is possible to take the test a maximum of three times. A short explanation of the correct answer is provided. Before accessing your certificate, you will be given the opportunity to evaluate the activity and reflect on the module, stating how you will use what you have learnt in practice. The new CPD centre keeps a record of your CPD activities and provides the option to add items to an action plan, which will help you to collate evidence for your annual appraisal.

- According to Cannon et al (2018), what approximate proportion (%) of the United States population had diabetes in 2015? Select ONE option only.

A. 5  
B. 10  
C. 15  
D. 20  
E. 25
- According to van Netten (2018), what is the highest estimate of the current annual incidence (%) of foot ulcers in people with diabetes? Select ONE option only.

A. 6  
B. 12  
C. 18  
D. 24  
E. 30
- A 57-year-old woman with type 2 diabetes has a history of a single episode of diabetic foot ulceration 3 years ago. On examination, pedal pulses are normal, but she has a loss of protective sensation (LOPS) and claw toes.

According to the Texas Diabetic Foot Classification System, what is her foot risk category? Select ONE option only.

A. 0  
B. 1  
C. 2  
D. 3  
E. 3a  
F. 3b  
G. 3c
- A 49-year-old man with type 2 diabetes has a history of a Charcot right foot. He has no current foot ulceration, pedal pulses are normal, but he has a residual foot deformity and LOPS.

According to Tadinada et al (2020), which is the single most appropriate footwear to prescribe, if any? Select ONE option only.

A. CROW boot  
B. Non-prescription simple footwear advice  
C. Shoes with fillers  
D. Shoes with outsole modifications  
E. Well-fitting shoes with insoles
- A 31-year old woman with type 2 diabetes has a current diabetes foot risk categorisation of zero.

According to Tadinada et al (2020), which of the following is the most appropriate routine footwear to recommend? Select ONE option only.

A. Athletic shoes  
B. Flip-flops  
C. Higher heeled shoes  
D. Open-toed sandals  
E. Platform shoes
- According to Tadinada et al (2020), LOPS is tested using the Semmes-Weinstein monofilament (SWMF) on 10 different foot sites.

What is the threshold number of tested sites without sensation, at which LOPS is diagnosed? Select ONE option only.

A. 2  
B. 4  
C. 6  
D. 8  
E. 10
- According to Tadinada et al (2020), the SWMF has '97% sensitivity and 80% specificity' in identifying patients at risk of ulceration.

Using this information, what is the false positive rate (%) of using the SWMF? Select ONE option only.

A. 3  
B. 20  
C. 80
- Which one of the following is used by the Ipswich Touch Test method to assess for the presence or absence of protective foot sensation? Select ONE option only.

A. Cotton wool  
B. Index finger  
C. SWMF  
D. Tuning fork  
E. VibraTip
- Which one of the following shoe modifications best reduces forefoot joint flexion and extension? Select ONE option only.

A. Accommodative Plastazote insole top cover  
B. High-topped shoes  
C. Multi-layered soft prescription insoles  
D. Posterior relief ankle foot orthosis  
E. Rocker bottom with a rigid shank and angled rubber sole
- Which one of the following people with type 2 diabetes and no current or previous foot ulceration is most likely to need a removable cast walker boot? Select ONE option only.

A. A 47-year-old man with hypertension and chronic renal failure  
B. A 55-year-old woman with peripheral arterial disease  
C. A 64-year-old man with with LOPS on SWMF testing  
D. A 72-year-old woman in recent remission from Charcot  
E. An 81-year-old woman with LOPS and hammer toes