

Using Risk Categories to Prescribe Diabetic Footwear

Different stages of diabetes require different shoe therapies.

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With the passage of the Medicare Therapeutic Shoe Bill (TSB), more people with diabetes are able to receive the benefits of therapeutic footwear. However, in order to truly serve these individuals, it is important to remember that they must be treated individually, with careful attention paid to specific foot problems. Rather than trying to fit patients into what is easily reimbursed by the TSB, we must assess each patient's foot condition and determine the appropriate therapeutic footwear. We can, however, as we will demonstrate in this article, use diabetic risk categories to provide guidelines for prescribing therapeutic footwear for patients with diabetes.

Shoe Fitting

While we have stated that prescribing therapeutic footwear must be individualized for each patient, there is one component that is essential for all patients with diabetes: a properly fitting shoe. Both shoe shape and shoe size must be considered in achieving proper fit. It is important to match the shape of the shoe, including both the sole and the upper, to the shape of the foot. To test how closely the shape of the sole matches a patient's foot shape, have the patient stand and draw an outline of his or her foot. Next, put the shoe over the outline. If parts of the foot outline extend outside the shoe, then the shoe shape does not match the foot shape, and the foot is being compressed to fit in the shoe. As an example of the importance of an appropriate shape for the shoe upper, a high toe box and a rounded, or oblique, toe provides the best fit by allowing the toes to fit comfortably inside the shoe. A shoe with a tapered toe box or a pointed toe is therefore, inappropriate for the diabetic foot, because it applies pressure to the toes and forces them into an unnatural shape, which may lead to calluses, ulcers, and eventual deformity.

In terms of shoe size, we need to look at both length and width. The proper shoe size is the one that accommodates the first metatarsophalangeal joint (i.e., the widest part of the foot) in the widest part of the shoe. The following is a set of guidelines that can be used to achieve proper shoe fit. (1-3)

1. Measure both feet with an appropriate measuring device; the Brannock measuring device is recommended. Measure both length and width. Remember that this is foot size only; use it as a starting point to find an appropriate shoe size.
2. Remember that shoe sizes are not standard; they vary among brands and styles. Look in a size range, based on the results of measuring.
3. Fit shoes on both feet while weight bearing.
4. Check for the proper position of the first metatarsophalangeal joint. It should be in the widest part of the shoe.
5. Check for the correct toe length. Allow 3/8 to 1/2 inch between the end of the shoe and the longest toe.
6. Check for the proper width, allowing adequate room across the ball of the foot.

7. Look for a snug fit around the heel.
8. Determine that proper fit over the instep has been achieved by an appropriately high vamp, preferably with laces or Velcro to allow adjustability.

In addition to shape and size, there are some other shoe characteristics that are appropriate for virtually all diabetes patients. A shoe upper should be made of a soft, breathable material, and the sole should offer stability as well as good shock absorption. A shoe with laces or Velcro is best because it allows for a better fit and is adjustable. The shoe should have a strong counter to provide support around the heel. A padded collar and tongue will add additional comfort. It is a good idea to avoid a lot of seams in the shoe upper; these can rub and lead to skin breakdown. A low heel is also strongly recommended to minimize pressure and shear on the vulnerable metatarsal heads.

Diabetic Risk Categories

The system of risk categorization that will be used is based on a prevention program developed at the Hansen's Disease Center in Carville, Louisiana, and is presented by Coleman.(4) It considers the following factors in determining a given patient's level of risk for foot injury: presence of disease that leads to insensitivity, presence of protective sensation, history of plantar ulceration, and presence of foot deformity. A patient with a higher risk has a greater need for therapeutic footwear and should be more closely monitored for possible foot complications.

Presence of protective sensation is determined using Semmes-Weinstein monofilaments, a set of progressively thicker nylon filaments each attached at right angles to a small handle. Sets of filaments which bend with forces of 1, 10, and 75 gm are generally used. Pressure is applied to the skin with the filament until it bends. Most people with normal sensation can feel the 1-gm filament. For the purposes of this classification system, loss of protective sensation occurs when the patient cannot feel the 10-gm filament. The 75-gm filament can determine if a patient with loss of protective sensation still has some remaining sensation. Hansen's Disease Center now distributes disposable 10-gm monofilaments through their LEAP (Lower Extremity Amputation Prevention) program, so that patients can be tested for protective sensation on a regular basis at home by a family member, friend, or caregiver (Fig. 1).

Patients with diabetes, no matter what their risk category, should be practicing preventive foot care. This includes performing regular foot inspections, preferably on a daily basis, looking for blisters, calluses, as well as any skin, nail, or other changes in their feet. Patients should also be encouraged to follow appropriate hygiene and injury prevention procedures, such as keeping their feet clean and dry and not walking barefoot. A foot examination should be performed at each doctor or clinic visit - ideally, at least four times per year. These people also need regular patient education so that they are properly informed about prevention measures, shoe selection, and shoe fitting.

Risk Category 0

Patients in Risk Category 0 have a disease which leads to insensitivity (i.e., diabetes), but still have protective sensation and no history of a plantar ulcer. Often, patients in this category do not need special therapeutic footwear and do not fall under the TSB. They can generally wear an off-the-shelf shoe with the characteristics described above. A yearly foot clinic visit is recommended to evaluate their footwear needs and to reinforce patient education concepts regarding proper footwear. These patients are also encouraged to use the LEAP monofilament self-test to detect any loss of sensation as early as possible.

Risk Category 1

Diabetes patients fall into Risk Category 1 when protective sensation has been lost, but they still have no history of a plantar ulcer and have no foot deformities (Fig. 2). Shoe-fitting becomes more critical in this category. The patient with a loss of sensation will tend to purchase a shoe that is too tight; the size that feels right is often too small because of the loss of sensation. (3,4) It is highly recommended that shoe fitting for these patients be done by someone who is professionally trained in shoe fitting. An in-depth shoe, which provides at least 3/16-inch of additional depth to accommodate an orthosis, is most often prescribed. Today's in-depth shoes include a variety of styles, such as athletic shoes, comfort shoes, walking shoes, and even some dressier styles.

Minimizing plantar pressure is a priority for patients in this category and is often accomplished with the use of a protective, accommodative orthosis. A pre-made orthosis can generally be used; however, the particular orthosis materials should be chosen based on the person's weight and activity level. A foot clinic visit is recommended every six months to make sure the footwear is providing the needed protection and to detect any possible deformity or potential ulcer site as early as possible. In addition to reinforcing the basic concepts described earlier, patient education in this category should focus on dealing with the loss of sensation. For example, these patients need to be taught to regularly inspect not only their feet, but to look at their shoes before putting them on to detect the presence of any foreign object which might have fallen into the shoes. Patients need to realize that once protective sensation is lost, they should never walk barefoot.

Risk Category 2

The majority of patients with diabetes fall into Category 0 or 1. By the time a patient reaches Risk Category 2, not only has protective sensation been lost, but a foot deformity is also present. The patient in Category 2, however, has not yet had a plantar ulcer. Common foot deformities seen in Category 2 patients include Charcot foot, pes cavus foot, hammertoes, prominent metatarsal heads, and plantar flexion contractures. In addition to minimizing plantar pressure, footwear for patients in this category must also be designed to accommodate the particular deformity (Fig. 3).

Most patients in Category 2 can probably be fitted with a regular in-depth shoe. In addition to providing room for an orthosis, the additional depth is also useful in accommodating deformities such as hammertoes and claw toes, as well as moderate medial and lateral bony prominences resulting from Charcot deformities. For more severe deformities, a shoe whose upper is made from stretchable or heat-moldable material can often be used; in some cases a custom-made shoe may be needed. It is especially important to pay attention to foot shape and to take advantage of the greater variety of shoe shapes available in prescription footwear to accommodate the deformity. The shape of the shoe can be further modified by a process called "re-lasting" in which the sole of the shoe is actually split and spread apart, resulting in a widening of the shoe. Performing this process on a regular in-depth shoe can allow a person with a more severe deformity to avoid the expense of a custom-made shoe (Fig. 4).

Shoes come in two basic types of throat openings: the blucher and the balmoral (Fig. 5). The blucher type is preferred over the balmoral because it allows for greater adjustability, easier entry, and is more compliant to foot shape. With rigid deformities such as Charcot foot or pes cavus foot, increased shock absorption is needed; a good shock-absorbing sole is crucial.

Depending on the severity of the deformity, orthoses for these patients may be either pre-made (that have been heat-molded) or custom-made over a model

of the patient's foot. In either case, care should be taken to use materials that provide shock absorption, minimize plantar pressure, reduce shock and shear, and accommodate the deformity.

A variety of external shoe modifications are used for patients in Category 2, primarily to accommodate the deformity present. One of the most common is the rocker sole. As its name suggests, the basic function of a rocker sole is to literally rock the foot from heel-strike to toe-off without bending the shoe. In general the biomechanical effects of a rocker sole are to restore lost motion in the foot and/or ankle, resulting in an overall improvement in gait, and to relieve pressure on a specific area of the plantar surface of the foot.(3,5,6) A rocker sole is appropriate to help replace lost motion resulting from a Charcot deformity, relieve pressure on prominent metatarsal heads or a midfoot prominence, and to help decrease the amount of shock present on heel strike. Care must be taken to get the right shape of the rocker sole, depending on its intended purpose, and to customize the rocker sole for the individual patient.

An extended steel shank, a strip of spring steel or carbon fiber inserted between the layers of the sole, extending from the heel to the toe of the shoe, is commonly used in combination with a rocker sole and helps maintain the shape and effectiveness of the rocker sole. An extended steel shank can also prevent the shoe from bending, limit toe and midfoot motion, aid propulsion on toe-off, and strengthen the entire shoe and sole, which may be necessary for overweight patients.

Another type of external shoe modification involves the addition of material to the medial or lateral portion of the shoe to stabilize some part of the foot. A flare is an extension to the heel of the shoe, the sole or both. Flares can be medial and/or lateral, and their purpose is to stabilize a hindfoot, midfoot, or forefoot instability. For example, a medial heel flare might be used to support a foot with a fixed valgus heel deformity. A stabilizer is an extension added to the side of the shoe, including both the sole and upper. Made from rigid foam or crepe, a stabilizer provides more extensive stabilization than a flare and is used for more severe medial or lateral instability of the hindfoot or midfoot, for example, with a medially collapsed Charcot foot.

If increased shock absorption is needed in the heel area, a cushion heel, which consists of a wedge of shock-absorbing material added at the heel area of the shoe, may be indicated. A plantar flexion contracture may benefit from a heel extension. The addition of a Velcro shoe closure not only offers greater adjustability but is easier than shoe laces for patients who are obese or who may have a loss of sensation in their hands. With regard to the TSB, external shoe modifications of custom-molded or in-depth shoes can be substituted for one of the three pairs of inserts allowed per year.

Patient education for patients in Risk Category 2 should continue to emphasize those concepts discussed above, as well as provide information specific to the patient's deformity. Foot clinic visits are recommended every three to four months, and possibly more often at times, to check that the footwear is accommodating the deformity.

Risk Category 3

Diabetes patients in Risk Category 3 are at the highest risk of possible injury. They do not have protective sensation, and they have a history of a plantar ulcer. Those who have had a toe or partial foot amputation also fall into this category. Exceptional care must be taken to protect the foot and prevent ulcer recurrence (Fig. 6).

In-depth, heat-moldable, and custom-made shoes may be prescribed for patients in category 3, depending on the shape of the foot and the severity of any deformity. Even those who have undergone an amputation may be able to wear

regular in-depth shoes with the use of an appropriate prosthesis, which can often be built into a custom-made orthosis. High-top shoes are helpful for more extensive amputations, and mis-mated sizes may also be needed (i.e., if the feet are significantly different in size). Custom-made shoes are now more easily obtainable since the passage of the TSB. Several manufacturers offer a variety of styles that can be made from a model of the patient's foot.

Another type of custom-made shoe used more commonly for patients in this category is the custom-made sandal. Made from multiple layers of polyethylene foam, with nylon straps and Velcro closures, the custom-made sandal has multiple uses: as a slipper, a shower or pool shoe, or as an interim shoe to be worn after wound healing and before a regular shoe can be worn. The custom-made sandal can even be dressed up with leather and worn as a regular sandal for casual wear.

It is generally recommended that orthoses for patients in Risk Category 3 be custom-made. Because a custom-made orthosis conforms more closely to the foot's individual contours, it can more effectively reduce areas of excessive plantar pressure. Specific material combinations can also be chosen to achieve the proper balance of accommodation and support. As mentioned earlier, a toe filler or more extensive prosthesis can be built into a custom-made orthosis to accommodate a toe or transmetatarsal amputation.

All of the external shoe modifications described above may be used on footwear in this category, depending on the individual foot condition. A custom-made rocker sole, possibly with an extended steel shank, can be especially helpful in relieving pressure on the area of the plantar surface that has previously been ulcerated.

Because of their high risk for potential re-ulceration, patients in Risk Category 3 should be seen every one to two months at a foot clinic. Both their feet and their footwear need to be closely monitored to prevent ulcer recurrence. They need to understand that having had an ulcer puts them at greater risk for another one, and that careful foot inspection and compliance with the prevention concepts are crucial.

Conclusion

Although it is still underutilized, the TSB has heightened the awareness among both patients and practitioners of the importance of therapeutic footwear in the prevention of diabetic foot complications, and it has made therapeutic footwear more obtainable for Medicare patients with diabetes. It is important, however, that we not let the TSB dictate which type of footwear a particular patient receives. There is no one correct shoe shape or style, nor one particular type of orthosis that is appropriate for all diabetes patients. Each patient's therapeutic footwear needs must be considered individually, based on a careful examination of his or her feet. The system of diabetic risk categories presented, by assessing the level of protective sensation, presence of a deformity, and history of previous plantar ulceration, can be a useful tool in prescribing the appropriate therapeutic footwear.

References

1. American Orthopaedic Foot and Ankle Society, National Shoe Retailers Association, Pedorthic Footwear Association: Shoe fit: What you need to know, Columbia, MD, Pedorthic Footwear Association, 1997.
2. Janisse DJ: The art and science of fitting shoes, *Foot Ankle* 13:257-262, 1992.
3. Janisse DJ: Pedorthic care of the diabetic foot. In Bowker JH, Pfeiffer MA (eds): Levin and O'Neal's *The Diabetic Foot*, 6th Edition, Mosby, St. Louis, 2001.

4. Coleman WC: Footwear for injury prevention: Correlation with risk category. In Bowker JH, Pfeiffer MA (eds): Levin and O'Neal's The Diabetic Foot, 6th Edition, Mosby, St. Louis, 2001.
5. Nawoczinski DA, Birke JA, Coleman WC: Effect of rocker sole design on plantar forefoot pressures, J Am Pod Med Assoc 78:455-460, 1988.
6. Ullman BC, Brncick M: Orthotic and pedorthic management of the diabetic foot. In Sammarco GJ, editor: The foot in diabetes, Philadelphia, Lea & Febiger, 1991.

Figure Legends

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| Fig. 1 | The LEAP monofilament for home testing for protective sensation. |
| Fig. 2 | Case study for Risk Category 1. |
| Fig. 3 | Case study for Risk Category 2. |
| Fig. 4 | A shoe which has been "re-lasted." |
| Fig. 5 | Blucher and balmoral shoe openings. |
| Fig. 6 | Case study for Risk Category 3. |