



BY JARROD SHAPIRO, DPM

Preventing Preventable Diabetes Foot Disease

It's more than just educating patients.

Practice Perfect is a continuing every-issue column in which Dr. Shapiro offers his unique personal perspective on the ins and outs of running a podiatric practice.

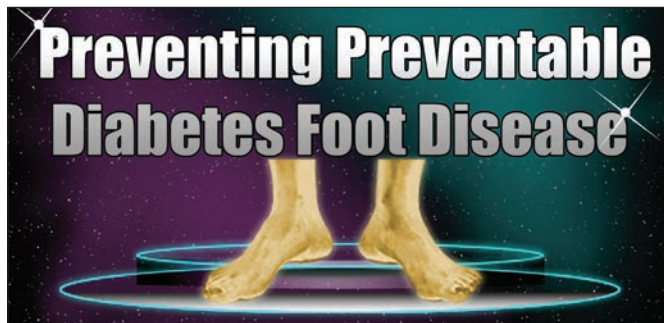
On a Friday night at 5:00 PM, you are about to go home after clinic, when one of your residents calls with a new patient consultation at the hospital: a septic diabetic patient with an abscess. Isn't that always the way it goes? As a very astute attending commented, "pus doesn't take a holiday." Tonight, it seemed that for this patient situation, pus actually did take a holiday and decided to come back just at the right time—on Friday night at 5:00 PM. Unfortunately for this patient, this needed to go to the operating room.

It's tough to have an emergent case at just the wrong time, but this situation is much sadder than any personal inconvenience. In reality, the poor patient's dilemma demonstrates how unnecessary diabetic foot infections are. The vast majority of diabetic foot infections are the result of chronic, low-grade issues that could have been avoided with appropriate preventative care. Take a look at the patient's clinical images (see Figures 1A and 1B on page 72).

You'll note the dry gangrenous fifth toe with the associated erythema

and ascending lymphangitis plantarly, along with the hemorrhagic bulla. Take a look at the radiographs and CT scan. To be clear, the CT was ordered by someone else, and your resident didn't have the opportunity to cancel the order. However, it's interesting for our sake to demonstrate the soft tissue emphysema (see Figures 2A, 2B, 2C, and 2D on page 74).

Now, what's important for our discussion is that the clinical picture being presented for you is one of a chronic process that became acute. And, again, it was entirely preventable.



Let's take a step back and consider some of the well-known statistics on the diabetic foot.

- Between 15% and 25% of diabetics will develop a foot ulcer at some time.
- 2-6% of diabetics develop a wound yearly.¹
- 84% of non-traumatic limb amputations in diabetes are preceded by an ulcer.²
- The odds ratio for amputation after the index ulceration is 5.7.³

- 34% of patients develop a new ulcer within one year of healing their first ulcer (70% at 5 years).⁴

- There is a 50% risk of contralateral foot ulcer after a major limb amputation and 50% contralateral limb amputation within 2-5 years.⁵

- The survival rate after a major limb amputation is 50% after three years and 40% after five years.⁶

To put these stats in perspective: the odds are simply terrible. Is that enough perspective for you?

If you're a diabetic and you get an ulcer, you're highly likely to have a future one. If you ulcerate, you're much more likely to have a major limb amputation. If that occurs, your life expectancy is much lower (not because of the amputation itself—we don't have proof of that yet—but due to the associated cardiac comorbidities). Not good.

Another statistic pertinent to our discussion is that lower extremity infection is the most common reason for a diabetic to be admitted to a hospital. We're also well aware that contiguous spread (normal bacterial skin flora spreading to the deep tissues through an opening in the skin) is the manner in which these infections occur. Diabetics rarely get hematogenous spread infections to the feet (luckily for us!).

With this entire picture in mind,
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one can understand one's frustration with situations like this patient's. This is an entirely preventable situation, yet one which the medical community has such an incredibly difficult time preventing. There are a number of opportunities in the process in which we may effectively intervene:

Diabetic Foot Complication Disease Progression Line

Prevent the diabetes > halt the neuropathy > prevent the ulcer > stop the infection > limit the amputation > targeted limited foot amputations > active rehab after a major limb amputation.

There is a greater-than symbol between each step, because the earlier in the disease line we intervene, the more effective we are. The converse of this is also true: the later that we intervene, the less effective we are. Preventing a foot amputation after ulceration is less effective overall than preventing the ulcer in the first place.

Is Education Effective?

Most of us spend significant time educating our patients about their various illnesses, and this remains an important part of medical care. However, with all that time we spend, does the research bear out the effectiveness of education?

In December of 2014, the *Cochrane Review* published an analysis to assess the effectiveness of education in preventing diabetic foot ulcers.⁷ Their meta-analysis included 12 randomized controlled trials (five of which had education effects as a primary endpoint). Two of these studies were found to be sufficiently powered, and only one of the 12 studies was found to be at low risk for bias. Overall, the reviewers found that education alone does not reduce ulcer or amputation rates. In fairness, it should be mentioned that some of the studies did show some decrease in ulcer and amputation with education, though they had significant methodological problems. Clearly more research needs to be done.

There are several reasons why education might not prevent ulceration. For example, preventing or treating diabetic foot ulcers is, in many cases, a complex process in which patients might not truly understand the significance of a foot ulcer after education.

Additionally, various other barriers such as lack of clinical time to fully explain the problem, foreign language, and social issues may

also play a role. A patient with a right foot ulcer who lives alone and must drive himself to get food will be unable to comply with off-loading measures such as a total contact cast. Despite this, it would be ridiculous to suggest we not educate our patients.

Shoes for Prevention

Do shoes prevent ulceration? Is the federal government correct in continuing to fund the diabetic shoe program? A

Prescription therapeutic shoes do indeed prevent foot ulcers compared with non-prescription shoes.

recent systematic review by researchers on behalf of the International Working Group on the Diabetic Foot looked at the current literature in reference to four interventions: casting, footwear, surgical offloading, and others (such as bed rest or wheelchairs).⁸ Their primary outcomes were ulcer prevention, ulcer healing, and pressure reduction. We'll focus our discussion here on ulcer prevention with shoes. They found 20 research studies (seven RCTs, four cohort studies, and nine non-controlled studies) that looked at therapeutic shoes.

The researchers found the following general two conclusions:

- 1) Prescription therapeutic shoes do indeed prevent foot ulcers compared with nonprescription shoes.
- 2) Prescription shoes work better when they are worn by patients for most of their steps during a day.

These results seem obvious, but it is important for all of us to have well-designed studies that actually demonstrate the efficacy of therapeutic shoes for ulcer prevention (especially considering how much money is spent on them). The crux of the matter, though, really is in detail #2: patients actually have to wear the shoes.

Armstrong and associates performed a prospective longitudinal study of 20 diabetic patients with either neuropathy and deformity or a prior ulcer history. Patients wore a pedometer for seven days, logged times entered and exited their homes, and filled out a questionnaire. They found that 85% of patients wore prescribed shoes when outside the home. It sounds okay right? Wrong. It turns out that only 15% of patients wore their prescribed shoes when inside the home.⁹ To put this in perspective, they took more steps per day when in the home. The

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Figure 1A



Figure 1B

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shoes clearly don't do any good if the patients don't wear them during the times they are most ambulatory.

In the sections above, we reviewed the statistics that demonstrate the seriousness of the problem and the need for prevention, and covered two options, including education and prescription footwear. The research has yet to demonstrate that education prevents ulcers and amputations, but it seems foolish not to teach our patients how to protect themselves. Knowledge is power, as we know. Prescription shoes, though, have proved their benefits, but only when patients actually wear them, which is usually not often enough. The methods described so far rely on the patient to effect successful prevention. What if physicians employed methods that essentially eliminated the need for patient cooperation from the picture? Would this improve outcomes?

Podiatrist-Administered Prophylactic Foot Care

Let's first talk about something highly common for most podiatrists: regular foot care. For many podiatrists, this "bread and butter" practice component consists of toenail and callus debridement. When my students work with me in clinic, they often present these patients as "just nail trimming." This drives me crazy. Let's view these regular visits as "diabetic surveillance," a chance to intervene earlier in the process. Is that not what you're really doing when these patients come in? While debriding nails and calluses, we have the opportunity to make sure that there are no developing physical is-

suces such as wounds, but also to educate and remind our patients how best to care for their feet.

A few comments are worthwhile here. First, podiatrists don't trim nails—that's the purview of pedicurists. We debride nails, which includes not only shortening the length but also thinning the nail plate. This typically requires a device such as an electric burr or Podospray device. If this is not done, your patient is receiving substandard care. A thick toenail will increase pressure on the nail bed, leading

Evidence shows increased ulceration at areas of increased pressure and shear.

to a subungual ulcer in a location that has almost no soft tissue between the nail and the bone. We should also be treating the nail fungus that is so prevalent in these patients.

Second, and perhaps more importantly, the podiatric visit should truly be focused on deformity and calluses. Callus and deformity are the body's advertising methods that say, "Hey, you, podiatrist. Here's where the next ulcer is going to happen!" These areas need to be offloaded and that offloading can literally change the course of the patient's life.

Back in 1996, Murray and colleagues were the first to demonstrate that the presence of callus strongly predicts future ulcer formation.¹⁰ They prospectively watched 63 diabetic neuropathic patients over a 15-month period. They found a relative risk of ulcer of 4.7 at locations of increased plantar pressure, 11.0 at callus locations, and 56.8 with a prior ulcer in the same area. This makes perfect intuitive sense, since increased focal pressure with resultant hyperkeratosis is the exact mechanism of both callus and neuropathic ulcer formation.

Similarly, shear has also been found to be a significant factor. Zou, et al. and Mueller, et al. demonstrated this to be true. Superficial subsurface shear at the forefoot correlates well with increased plantar pressures.^{11,12}

This is one avenue of prevention in which the podiatrist can be especially effective. Given our biomechanical expertise, we have an understanding of methods to off-load those callused, pre-ulcerative areas and, if necessary, surgically alter the foot to reduce pressures. Which brings us to our next option....

Prophylactic Surgery

Unfortunately, there is no definitive study that demonstrates prophylactic surgery should be pursued to pre-

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Figure 2A



Figure 2B



Figure 2D



Figure 2C

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vent foot ulcerations. However, there is a strong argument to be made from some of the medical evidence. First, it is intuitively logical that if deformity causes the pressure which leads to the ulcer, then eliminating the deformity will decrease the ulcer risk.

Since there is a paucity of evidence about directly preventing ulcerations, let's look quickly at a couple of studies about surgical treatment of foot ulcers. Piagessi and colleagues compared non-surgical versus surgical treatment of forefoot and digital ulcers with a six-month follow-up. They found that 79.2% healed with non-surgical care (with a healing time of 128.9 +/- 86.6 days) versus 95.5% healing with surgical care (and a healing time of 46.73 +/- 38.94 days).¹³

In this study, the surgical group was more successful and obtained a faster healing rate, though it's important to note one particular method-

ological flaw: the nonsurgical ulcer care was wet-to-dry, which is not our current standard of care.

A more recent study by Armstrong and colleagues retrospectively examined a cohort of 40 diabetic patients with a plantar 5th metatarsal head neuropathic ulcer. Their nonsurgical group of 18 patients received local wound care and debridement, while the surgical group of 22 patients received a 5th metatarsal head resection. They found a healing time of about 40% less with surgical therapy with a significantly decreased six-month recurrence rate (4.5% with surgical care versus 27.8% with nonsurgical care);¹⁴ faster healing and lower recurrence. Sounds like an excellent combination, huh?

Other studies also exist that demonstrate the ability of surgery to successfully heal foot ulcers. The key here is to be rational about performing surgery in this high-risk population. Recognize the increased infection risk,

the demand to be certain of adequate blood flow and normalized blood glucose. In the right patient population, we can extrapolate the improved prevention outcomes from the surgical literature.

To conclude, we'll quickly summarize:

1) The diabetic foot is a high-risk structure in which damage portends terrible long-term outcomes, including limb loss and decreased mortality.

2) Physicians have multiple points during the progression toward limb loss in which to intervene, and the later in the process, the less chance to effect improvements.

3) Education alone does not seem to decrease the risk of ulcer and amputation, though more research with strong methodology is necessary.

4) Prescription therapeutic shoes prevent foot ulcers compared with non-prescription shoes.

5) Prescription shoes work better

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when they are worn by patients for most of their steps during a day.

6) Regular foot care with an emphasis on surveillance and minimizing ulcer risk factors is a powerful tool for the podiatrist.

7) Prophylactic surgery has a very powerful potential role in prevention, though more research needs to be done.

The diabetic foot has been one of the areas in which podiatrists have historically been able to participate and create highly successful outcomes for patients. Of all the professions, we are the ones with the full perspective and ability to intervene at multiple levels. In essence, we have all of the tools in the toolbox in which to help our diabetic patients continue walking. In the words of Dr. Lawrence Harkless, one of the pioneers of this field, we can Keep America Walking. **PM**

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