

# Preventing the First or Recurrent Ulcers

Lawrence A. Lavery, MPH, DPM<sup>a,\*</sup>, Javier La Fontaine, MS, DPM<sup>a</sup>,  
Paul J. Kim, MS, DPM<sup>b</sup>

## KEYWORDS

• Diabetes • Ulcer • Infection • Prevention

## KEY POINTS

- Prevention is best achieved within a multispecialty group of providers that have a common objective.
- The basic elements of prevention involve education, foot examination, risk classification, therapeutic shoes and insoles, and regular foot care.
- High-risk patients need additional assessment for vascular disease and intensive disease management, and corrective vascular and foot surgery when necessary.
- Basic interventions can reduce the incidence of foot ulcers by more than 50%.

## INTRODUCTION

Prevention in the diabetic foot is often neglected, even in very high-risk patients. The simple elements of the “standard of care” for prevention are not well understood by most clinicians, educators, or patients. The benefit of a team approach to prevent foot ulceration and reduce amputations has been described multiple times in the United States and Europe.<sup>1–4</sup> The standard approach to prevent ulceration requires little advanced technology or expensive testing procedures. The basic elements of prevention include screening, risk classification, regular foot care, protective shoes and insoles, and diabetic foot education. Most of the published work on prevention targets patients with diabetes that have had a previous ulcer. This is because their risk of experiencing another event is very high. Only about 3% to 4% of patients that have sensory neuropathy without a previous ulceration or peripheral arterial disease develop a foot ulcer in a year, so a large number of patients have to be evaluated

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<sup>a</sup> Department of Plastic Surgery, The University of Texas Southwestern Medical Center, 1801 Inwood Road, Dallas, TX 75390–9132, USA; <sup>b</sup> Department of Plastic Surgery, Georgetown University School of Medicine, Georgetown University Hospital, 3800 Reservoir Rd, Washington, DC 20007, USA

\* Corresponding author.

E-mail address: [Larry.Lavery@utsouthwestern.edu](mailto:Larry.Lavery@utsouthwestern.edu)

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to be able to measure the effects of treatment. Therefore, there is very little evidence about the ability to prevent the first foot ulcer in people with diabetes.

The cause of ulcerations in diabetes is associated with the presence of peripheral sensory neuropathy and repetitive trauma caused by normal walking activities to areas on the foot that are subject to moderate or high pressures and shear.<sup>5</sup> Pressure sites on the sole of the foot are often associated with limited joint mobility of the foot or ankle or structure deformities, such as hammer toes and hallux valgus deformity. The goal of prevention is to interrupt this pathway as often as possible.

## RISK CLASSIFICATION

The first challenge in prevention is to identify who to target first, or where to target resources. Classifying patients into groups based on risk status is a pivotal process to help identify the highest-risk patients and direct dwindling medical resources appropriately. Unfortunately, in most centers even basic foot risk assessment is not performed even though the criteria and procedures are inexpensive, practical, and easy to execute. A trained technician can perform the screening history and testing and place patients into the correct risk stratification.

There are several risk stratification tools that have been used to identify and treat high-risk patients. Some systems use a simple low- and high-risk scheme,<sup>4,6,7</sup> whereas others provide four to five specified risk categories and suggested prevention strategies for each. The International Working Group on the Diabetic Foot's (IWGDF) risk classification was designed from a consensus panel, and it has been adopted as an international tool. The most important factors for risk classification include assessment of sensory neuropathy; peripheral arterial disease; severe foot deformity; and history of foot pathology, such as ulceration, amputation, or Charcot neuroarthropathy.

Mayfield, Lavery, and Peters used risk classifications similar to the IWGDF risk classification to demonstrate that the frequency of foot complications increases as risk criteria increases.<sup>8-10</sup> The highest-risk groups to develop ulceration are patients with a previous ulcer or amputation. These patients have a 36-fold increased risk of developing a foot ulcer in the next year compared with patients without neuropathy or peripheral arterial disease.<sup>8,9,11</sup> Lavery and coworkers<sup>10</sup> evaluated a cohort of 1666 patients with diabetes that participated in a diabetes disease management program. In the program, patients received foot-specific education, therapeutic shoes and insoles, and regular foot care over a 2-year period. The IWGDF classification was expanded within current risk tiers to evaluate the contribution of various factors (Table 1). Lavery and coworkers<sup>10</sup> reported no difference in ulceration in patients with neuropathy, and neuropathy and foot deformity (risk group 1 and 2). There was a significant increase in the yearly incidence foot ulceration, reulceration, infection, amputation, and hospitalization in patients with peripheral arterial disease, compared with patients with neuropathy, and neuropathy and foot deformity. In addition, there were more ulcers in patients with a history of ulcers and amputations (risk group 3).<sup>10</sup> Overall, there were increasing trends in foot ulcers, infections, and amputations as risk tiers increased based on the criteria described in the IWGDF risk classification (see Table 1).

Targeting the correct risk group is important to provide cost-effective preventative care. In a prevention program with limited resources, the highest-risk groups should be the main focus for prevention services. Patients in risk group 3 can be easily identified from administrative data. This small minority (15%) accounts for a disproportionate number of wounds, infections, and hospitalizations (see Table 1). The

**Table 1**

The incidence of ulcers and amputation based on the International Working Group for the Diabetic Foot risk classification

N = 1666		Ulcer	Amputation
0	No sensory neuropathy No peripheral arterial disease No complication history	2%	0.04%
1	Sensory neuropathy No peripheral arterial disease No complication history	4.5%	0
2	Sensory neuropathy and foot deformity or limited joint mobility No complication history	3%	0.7%
	peripheral arterial disease No complication history	13.8%	3.7%
3	Ulcer history	31.7%	2.2%
	Amputation history	32.2%	20.7%

Data from Peters EJ, Lavery LA. Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care* 2001;24(8):1442–7.

benefit of intensive prevention services to patients in lower-risk groups has not been specifically addressed in the medical literature.

## EDUCATION

The diabetic foot is wrapped in mythology and misinformation for patients, their families, and clinicians. Education is a key component to get the patient and their family to participate in the prevention process. **By itself, education is unlikely to be effective. The high-risk patient needs to have education as one of the primary layers of prevention, but other elements, such as therapeutic shoes and insoles, professional foot care, and systemic disease modification, must be included.** It is difficult to evaluate education as a single intervention in a randomized clinical trial unless the other aspects of care are standardized. Several studies to evaluate diabetic foot education incorporate standard prevention strategies; however, many do not specify if these services are available or how they were provided.<sup>12,13</sup>

There are three randomized clinical studies that evaluated clinical outcomes with an education intervention.<sup>12,14,15</sup> Most studies evaluate a change in patient knowledge as the primary outcomes. It is unclear if better knowledge translates into sustained changes in behavior and a reduction in ulcers, infections, or amputations. Understanding the disease process is not enough. The diabetic foot is a mechanical problem more than a medical problem. **If the abnormal biomechanics of the foot are not addressed, the high-risk patient's understanding of the disease process alone will be insufficient to prevent repetitive ulcers, infections, and amputations. Usually, the education message to patients is to inspect their feet, avoid going barefoot, avoid hot surfaces, avoid hot water, and seek professional foot care on a regular basis. These instructions are not practical or effective for most high-risk patients. Many patients are obese with poor vision and limited mobility of their back, hip, knee, and ankle. Most patients are unable to provide any meaningful self-inspection.<sup>9</sup> Because of obesity or limited joint range of motion, they cannot physically position themselves to see the bottom of their feet. As a consequence of poor vision, they cannot see the bottom of their feet or recognize**

subtle changes that identify tissue damage. For instance, in a study by Lavery and colleagues<sup>9</sup> 48% of study patients had impaired vision and 41% lacked the flexibility to adequately position the foot so it could be examined. Locking-Cusolito and colleagues<sup>16</sup> evaluated similar criteria in a dialysis population and found that 25% of study patients had impaired vision and 45% lacked flexibility to correctly position the lower extremity so it could be visualized.<sup>9</sup> Perhaps a more rational approach is to assess the skills of the patient, and if they are unable to see the top and bottom of the foot, someone else in the family could help with this type of assessment.

If patients have good vision and they can position themselves to see their feet, they still may not be able to identify any changes that are meaningful. The early changes to the skin before an ulcer develops are too subtle for a patient or their caregiver to recognize. However, they may be able to identify an ulcer as soon as it develops. Lavery and colleagues<sup>17</sup> reported the results of a randomized clinical study where the control group received therapeutic shoes and insoles, education, and regular foot care. Patients were instructed to contact the study nurse if they identified any abnormalities during visual inspection. A list of local signs they should look for was provided, such as changes in color, or temperature, or swelling. An ulcer had already developed in most cases (97%) by the time the patient saw something that was "abnormal." Visual changes and self-inspection may not be effective for most patients to prevent foot ulcers if warning signs are too subtle to see.<sup>18</sup>

Malone and colleagues,<sup>14</sup> Lincoln and colleagues,<sup>15</sup> and Litzelman and colleagues<sup>12</sup> used education in randomized clinical trials of high-risk patients to prevent ulcers and amputations.<sup>19</sup> Malone and colleagues<sup>14</sup> randomized patients into an education group (N = 103) and a group with no education (N = 100). The educational intervention was based on a single education session. Provision of therapeutic shoes and insoles was not reported. However, during the follow-up period there were significantly few ulceration (education 8, no education 26;  $P < .005$ ) and amputation (education 7, no education 21;  $P = .025$ ).

Lincoln and colleagues<sup>15</sup> used a similar approach to that described by Malone and colleagues.<sup>14</sup> Lincoln randomized 172 patients with newly healed DFUs (diabetic foot ulcers) to receive usual care or one-to-one education. Patients that received the "education intervention" participated in a single session. Lincoln reported that subjects in the education group demonstrated improved knowledge compared with the control group. However, clinical outcomes were no different. There was no difference in foot ulcers or amputations among the treatment groups. The incidence of foot ulcers at 6 and 12 months was 30% and 41% in the education group and 21% and 41% in the control group.

Litzelman and colleagues<sup>12</sup> randomized 395 patients with diabetes to be assigned to either an education and prevention program or the standard care they would normally receive. The education intervention group received foot education, telephone follow-up calls, and reminders to their primary care providers to do diabetic foot examinations. Patients that received "community standard care" were more likely to develop a foot ulcer, not perform recommended self-care practices, or have their feet examined by their primary care physician (education group 68%; standard of care group 28%).

## THERAPEUTIC SHOES AND INSOLES

Special shoes and insoles are a mainstay of ulcer prevention in high-risk patients with diabetes. In the United States, the Therapeutic Shoe Bill has provided shoes and insoles for high-risk Medicare beneficiaries with diabetes since 1993. Unfortunately,

these services are dramatically underused. Only 7% to 16% of high-risk patients are prescribed therapeutic shoes and insoles. After they are prescribed, only about a third of patients wear the shoes for more than 12 hours a day.<sup>20,21</sup> Some reports suggest that 30% of high-risk patients prefer to go barefoot or wear slippers or stockings while at home.<sup>22</sup>

Several<sup>23,24</sup> studies have shown a significant reduction in foot ulcers in patients that receive therapeutic shoes compared with shoes patients would normally select themselves. There is little clinical evidence to help in understanding the effectiveness of the types of therapeutic shoes and insoles that are commonly used to prevent foot complications. There are a variety of insole materials and material combinations and different accommodations that can be built into the insole. Likewise, the type of shoe and outer sole accommodations are numerous. Most of the decisions for protective shoes and insoles are left to technicians that have little working knowledge of the medical literature. When patients reulcerate they do not return to the podiatrist or shoe maker for care, so these providers have no follow-up to determine if their approach is effective.

There are four randomized clinical trials and two prospective cohort studies that describe the benefit of various types of shoes and insoles for high-risk patients with diabetes (**Table 2**).<sup>25</sup> Most studies include patients with a previous foot ulcer and use a control group of patients with self-selected footwear. In some studies this is because they cannot afford therapeutic shoes,<sup>26</sup> they refuse recommended shoes,<sup>27</sup> or their insurance does not pay for shoes and insoles.<sup>28</sup> Reulceration is much higher

Reiber et al, <sup>32</sup> 2002	RCT 24 mo	121	Custom cork and neoprene	15%
		119	Prefabricated polyurethane insole	14%
		160	Self-selected shoes, no insole	17%
Uccioli et al, <sup>33</sup> 1995	RCT 12 mo	33	Custom-made shoe and insoles	28%
		36	Self-selected shoes, no insole	58%
Lavery et al, <sup>25</sup> 2012	RCT 18 mo	150	Standard design ethyl vinyl acetate insoles, therapeutic shoes	7%
		149	Shear design ethyl vinyl acetate insoles, therapeutic shoes	2%
Rizzo et al, <sup>30</sup> 2012	RCT 60 mo	150	Standard of care	23.5%
		148	Custom made orthosis with shoes	72%
Busch and Chantelau, <sup>28</sup> 2003	Prospective cohort 12 mo	60	Rocker sole shoe and standard insole	15%
		32	Self-selected shoes, no insole	60%
Dargis et al, <sup>29</sup> 1999	Prospective cohort 24 mo	56	Therapeutic shoes and insole	30%
		89	Self-selected shoes, no insole	58%

Abbreviation: RCT, randomized controlled trial.

among patients that do not use therapeutic shoes and insoles. About 60% of patients reulcerate with self-selected shoes. Among patients that receive therapeutic shoes and insoles, there is a twofold to fourfold reduction in reulceration compared with patients that use shoes they have selected. Even with standard preventative care, such as therapeutic shoes and insoles, education, and regular foot care, about 24% to 50% of patients develop another foot ulcer within the next year.<sup>18,29-31</sup>

The four randomized clinical studies that evaluate therapeutic shoes and insoles provide a glimpse into the complexity of evaluating this intervention to prevent ulcers. Reiber and colleagues<sup>32</sup> compared two insole constructs with off-the-shelf footwear with patient-selected shoes. Uccioli and colleagues<sup>33</sup> compared custom-made shoes and insoles with patient-selected shoes (Table 3). Lavery and colleagues<sup>34</sup> randomized patients to receive a shear-reducing insole compared with a standard insole and off-the-shelf shoe, and education and regular foot care. Rizzo and colleagues<sup>30</sup> assessed the impact of a structured follow-up program on the incidence of diabetic foot ulceration in high-risk patients with diabetes.

Reiber and colleagues<sup>32</sup> compared custom bilaminar cork and neoprene insoles (N = 121), prefabricated polyurethane insoles (N = 119), and a control group (N = 160) in which patients selected their own shoes. Reiber's study was the only negative study of therapeutic shoes and insole for high-risk patients with diabetes. The study population had a high proportion of subjects without sensory neuropathy measured with a 10-g Semmes-Weinstein monofilament.<sup>32</sup> Many patients would not be considered "high risk" by most risk classification criteria. It was also the study with the lowest ulceration rate in the control arm treated with self-selected shoes (17%). During the 2-year evaluation, 15% of patients developed ulcers in the custom insole group, 14% developed ulcers in the prefabricated insole group, and 17% developed ulcers in the self-selected shoe group. The rate of ulceration was lower in the control arm of Reiber's study than many of the therapeutic shoe treatment groups in other studies (see Table 2).

Uccioli and coworkers<sup>33</sup> conducted a multicenter randomized controlled trial of patients with previous foot ulceration for 1 year. Patients were randomized to custom made shoes and insoles (N = 33) or self-selected shoes (N = 36). Reulceration was

**Table 3**  
Foot surgery to prevent ulcer recurrence

Author	Study Population	Treatment Groups	Recurrent Foot Ulcers
Mueller et al, <sup>31</sup> 2003	Randomized controlled trial 7 mo follow-up	1. Achilles tendon lengthening, N = 30 2. Total contact cast, N = 33	15% 59%
Lin et al, <sup>45</sup> 1996	Retrospective cohort study 17 mo follow-up	1. Achilles tendon lengthening, N = 15 2. Total contact cast, N = 21	0% 19%
Armstrong et al, <sup>41</sup> 2003	Retrospective cohort study 6 mo follow-up	1. Arthroplasty of the great toe, N = 21 2. Standard care, N = 20	5% 35%
Lin et al, <sup>53</sup> 2000	Retrospective cohort study 4.2 mo follow-up	1. Arthroplasty of the great toe, N = 14 2. Total contact cast, N = 21	0% 0%

significantly lower in the custom shoe treatment group (27.7%) compared with patients that selected their own footwear (58.2%;  $P = .009$ ). Most patients that require therapeutic shoes and insoles do not require a custom-made shoe. Usually custom shoes are only necessary when the foot is so deformed that the foot does not fit in a ready-made shoe.

Lavery and colleagues<sup>25,34</sup> reported the results of a randomized clinical study that compared a standard insole and therapeutic shoe with a shear-reducing insole and shoe. In the study 299 patients with diabetic neuropathy, foot deformity, or history of foot ulceration were randomized into a standard therapy group that received therapeutic shoes and insoles, education, and regular foot care ( $N = 150$ ) or a shear-reducing insole instead of a standard accommodative insole ( $N = 149$ ). A multilaminar insole was constructed of a 35-durometer ethyl vinyl acetate upper pad 3 mm thick, a 45-durometer ethyl vinyl acetate lower pad 3 mm thick, and a 20-durometer Plastozote top cover 1.5 mm thick. The only difference between the groups was that the shear-reducing insole used elastic binders and two thin Teflon sheets, so the top layers could slide on the bottom layers, thereby reducing pressure and shear. The standard insole materials were glued together with adhesive. Insoles were changed every 4 months. During 18 months of evaluation there were fewer ulcers in the shear-reducing insole group ( $N = 3$ ; 2%) compared with the standard insole group ( $N = 10$ ; 6.7%). Standard therapy patients were 3.5 times more likely to develop an ulcer compared with the shear-reducing insole group (hazard ratio, 3.47; 95% confidence interval, 0.96–12.67).<sup>25</sup> The rate of ulceration was low in this study because only a small proportion of the study population had a history of foot ulceration (27.5% and 23.5%).

Rizzo and colleagues<sup>30</sup> reported the longest study in this area. A total of 1874 patients with diabetes referred to the Diabetic Foot Unit of the University of Pisa were ranked based on the ulcerative risk score proposed by the International Consensus on Diabetic Foot. A total of 334 patients (17.8%) were randomized into two groups: one group received standard treatment, and the second group received custom-made orthosis and shoes as a part of a structured prevention program. During the first 12-month follow-up, 11.5% of patients that received shoes and insoles developed a DFU compared with 38.6% in the standard therapy group ( $P < .0001$ ). In the extended follow-up, the cumulative incidence of ulceration in the standard therapy group was 61% and 17.6% in the group that received shoes as part of their intervention ( $P < .0001$ ) at 3 years and at 5 years 72% of subjects in the standard therapy group ulcerated compared with 23.5% in the treatment group ( $P < .0001$ ).

## TEMPERATURE SELF-ASSESSMENT

Temperature assessment has been used in clinical practice to diagnose neuropathy and soft tissue injury in patients with neuropathy, and it has been used as a tool for self-assessment and monitoring. Clinicians have used temperature assessment to evaluate foot ulcers and Charcot neuroarthropathy. The rationale to use temperature as part of a daily foot assessment is that temperatures could provide an objective measurement of tissue injury. A change in skin temperature could be used to identify tissue that is inflamed. It is a similar thought process as described in the National Pressure Ulcer Advisory Panel ulcer classification. A stage 1 pressure ulcer is recognized as having signs of tissue injury before there is a break in the epithelium. It can be characterized by changes in temperature, in color, or in texture of the skin.

There are three randomized clinical studies that compare standard prevention therapies consisting of therapeutic shoes and insoles; regular foot care by a podiatrist; and

a standard, foot-specific education to temperature home monitoring intervention in addition to standard care. All three studies demonstrated a 3- to 10-fold reduction in reulceration when patients used home temperature evaluation compared with standard prevention practices. All three studies used a similar approach. Patients used an infrared thermometer to record the temperatures from 10 sites on the foot and then compare temperatures at corresponding anatomic sites on the right and left feet to see if there was greater than 4°F difference. This temperature difference was used to define a high temperature that was believed to be associated with soft tissue injury that could lead to ulceration. Patients were to reduce their activity by 50% until temperatures normalized. If they did not return to a normal range in a set time frame, they called the study coordinator to be seen by the study physician.

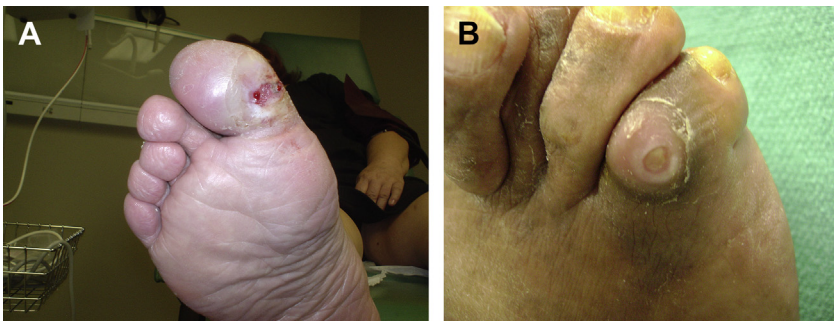
### FAT PAD AUGMENTATION

Several researches have explored the idea of reducing foot pressure with an “internal orthotic device” by injecting the subcutaneous tissue with material that increases the fat pad on the ball of the foot.<sup>35–37</sup> Balkin<sup>38,39</sup> reported the use of injectable silicon for the treatment of metatarsalgia, callus, scars, and diabetic foot ulcer since 1964. He reported data on a cohort of 1585 patients that were treated for metatarsalgia and diabetic foot ulcers. Balkin reported no long-term adverse events related to these injections based on close clinical monitoring and postmortem specimens.

Boulton’s group prospectively evaluated a cohort of patients with diabetes over a 2-year period. Twenty-eight patients with diabetes were randomized to active treatment with six injections of 0.2 mL liquid silicone in the plantar surface of the foot or sham treatment with saline. Patients treated with silicone oil had a significant increase in plantar tissue thickness compared with the placebo group (1.8 vs 0.1 mm) and a greater plantar pressures reduction (232 vs 25 kPa) at 3, 6, and 12 months.<sup>36,37</sup> There are several different materials that might be used instead of silicone; however, currently there are no randomized clinical studies to support the clinical effectiveness of this approach to reduce foot ulceration in high-risk patients.

### SURGERY TO HEAL ULCERS AND PREVENT RECURRENCE

Another option to prevent ulcer recurrence is to surgically correct the underlying biomechanical defect, such as hallux rigidus, hammer toe deformities, and equinus (**Fig. 1**). The goal of surgery is to reduce the long-term risk for reulceration by increasing joint motion where it is limited, reducing abnormal pressure points, and



**Fig. 1.** (A, B) Limitation of hallux dorsiflexion and contracture of lesser digits increases pressure and leads to ulceration.



repairing structural foot deformities when they are an underlying cause of ulceration. The literature has several reports of retrospective case series, but there is only one randomized clinical trial that reports clinical outcomes with this type of approach. In general, surgery seems to be safe and effective at healing recalcitrant ulcers and reducing the risk of reulceration.

The question for physicians and patients is whether the risks of surgery are better than the risk of having a chronic foot ulcer. The risks of infection and amputation from a nonhealing foot ulcer are high. Approximately 10% to 20% of diabetic foot ulcers end in amputation<sup>12,13</sup>; 56% are treated for infection; and 20% develop osteomyelitis.<sup>9–11</sup> Ulcer recurrence is about 30% per year when standard preventative therapies are provided. The incidence of ulceration is 50% to 80% when no additional prevention is provided. However, several authors have reported the results of planned surgical procedures to heal foot ulcers. These studies suggest a high rate of wound healing (91%–100%) and a low rate of ulcer recurrence after 2 years (0%–39%).<sup>40–42</sup> If surgery is simply viewed as a prevention tool, in the correct subpopulation, surgery has the lowest reulceration rate.

### ***Achilles Tendon Pathology***

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Several papers have reported results of percutaneous Achilles tendon lengthening to heal recalcitrant forefoot ulcers. Equinus deformity has been associated with high pressures on the sole of the foot and increased risk of foot ulceration in persons with diabetes.<sup>31,43,44</sup> Lengthening of the Achilles tendon reduces pressures on the forefoot and thereby decreases the risk of recurrent foot ulcers. Mueller and colleagues<sup>31</sup> and Lavery and coworkers<sup>43</sup> reported a 27% reduction in peak pressures on the ball of the foot in patients with diabetes after the Achilles tendon was lengthened. The procedure is very effective to heal recalcitrant forefoot ulcers, and there is a very low rate of ulcer recurrence.

Mueller and colleagues<sup>31</sup> conducted a randomized clinical study that compared Achilles tendon lengthening with immobilization in a total contact cast. Equinus was defined as ankle dorsiflexion less than five degrees. A higher proportion of patients healed in the surgery group (surgery 100% vs cast group 88%). Perhaps the greatest benefit to the surgery was the low rate of ulcer recurrence. The rate of reulceration was significantly lower in the surgery group at 7 months (surgery 15% vs cast group 59%) and at 24 months (surgery 38% vs cast group 83%). Lin reported similar results. After Achilles lengthening there were no cases of reulceration after 17 months.<sup>45</sup>

Achilles tendon surgery is not without complications. Deciding on an operational definition of equinus is difficult. A variety of different measurements and criteria have been reported.<sup>46–48</sup> There is no evidence-based criteria to help clinicians determine how much ankle joint motion is pathologic and how much correction is needed to make the procedure safe and effective. Over-lengthening the Achilles tendon is associated with ulcers on the heel. Holstein and coworkers<sup>49</sup> reported that 18% of patients with more than 10 degrees of ankle dorsiflexion after surgery developed a heel ulcer. Mueller and colleagues<sup>31</sup> reported similar findings; 16% of patients developed heel ulcers after undergoing an Achilles tendon lengthening procedure.<sup>50</sup> The average increase in ankle joint dorsiflexion was 15 degrees in Mueller and colleagues<sup>31</sup> randomized clinical study.

### ***Great Toe Ulcers Associated with Hallux Rigidus***

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Another example of selective foot surgery to reduce the risk of ulcer recurrence involves ulcers of the great toe. Foot ulcers of the great toe are commonly associated with hallux rigidus, or a reduced range of motion of the first metatarsophalangeal

joint.<sup>51,52</sup> One of the most common surgical approaches to address hallux rigidus in persons with diabetes is a resectional arthroplasty of the first metatarsophalangeal joint, or more specifically resection of a portion of the base of the proximal phalanx of the great toe. This is also referred to as a Keller bunionectomy. The Keller resectional arthroplasty removes the arthritic joint and allows a pseudoarthrosis to develop in its place. Like the surgery described to increase ankle joint range of motion by lengthening the Achilles tendon (**Fig. 2**), arthroplasty of the great toe has been reported to increase healing of ulcers that have failed other therapies with a much lower rate of ulcer recurrence.

Armstrong and coworkers<sup>41</sup> reported the results of a cohort study of 41 patients with diabetes with great toe ulcers. Patients received either resectional arthroplasty of the great toe or standard wound care. The surgery group had faster healing (24 vs 67 days) and few recurrent ulcers after the surgery (5% vs 35%). Lin and coworkers reported similar results.<sup>53</sup> He treated 14 patients with great toe ulcers that failed to heal with aggressive off-loading in a total contact cast. All of the ulcers healed after the resectional arthroplasty was performed, and none of the patients had an ulcer recurrence after 26 weeks.

#### ***Lesser Toe Ulcers Associated with Hammer toe Deformity***

Ulcers on the tip of the toe or on the top of the toe are often associated with hammer toe or mallet toe deformity (**Fig. 3**). Ulcers on the distal portion of the toe are especially prone to recurrence because the deformity causes the patient to bear weight on the tip of the toe.<sup>29,41</sup> Several authors have described a percutaneous flexor tenotomy of the long flexor tendon to heal recalcitrant ulcers and reduce ulcer recurrence.<sup>52,54,55</sup> Kearney and coworkers<sup>55</sup> described the results of 58 tenotomies for distal toe ulcers. Ninety-eight percent of ulcers healed and only 12% recurred after surgery after an



**Fig. 2.** A simple, percutaneous, lengthening of the Achilles tendon increases range of motion at the ankle joint and decreases forefoot pressure.



**Fig. 3.** Clawtoe deformity with neuropathy commonly leads to ulceration at the tip of the toe.

average of 28 months evaluation period. Two patients (3.4%) eventually had amputation of a portion of the toe.

Ulcers on the dorsum of the toe are usually associated with a hammer toe deformity. A joint resection of the proximal interphalangeal joint to correct the hammer toe deformity has been described to heal the ulcer and reduce the risk of reulceration. Armstrong and coworkers<sup>42</sup> compared the results of 31 patients with diabetes with hammer toe surgery. Ninety-six percent of ulcers healed; 14% of patients developed postoperative infections. However, after surgery none of the patients with an ulcer developed a recurrent foot ulcer in the next year.

These studies indicate that surgery to heal ulcers and prevent ulcer recurrence is safe in comparison with the natural course of the disease process. By increasing joint range of motion or correcting structural deformity, the pathway to ulcerations is more dramatically interrupted than with other interventions, such as therapeutic shoes and insoles or education. Many high-risk patients are not good candidates for surgery because of poor healing potential, poor glucose control, and inability to comply with the requirements of self-care after surgery. Patient selection is one of the most important aspects of successful surgery.

## **SUMMARY**

**Prevention is overlooked and underused, even in very high-risk patients.** Prevention is best achieved within a multispecialty group of providers that have a common objective. Ideally, the team approach should include educators; physical therapists; nurses; internist; pedorthists; and vascular, orthopedic, and podiatric surgeons. The basic

elements involve education, foot examination, risk classification, therapeutic shoes and insoles, and regular foot care. High-risk patients need additional assessment for vascular disease and intensive disease management, and corrective vascular and foot surgery when necessary. Basic interventions can reduce the incidence of foot ulcers by more than 50%.

## REFERENCES

1. Ronnema T, Hamalainen H, Toikka T, et al. Evaluation of the impact of podiatrist care in the primary prevention of foot problems in diabetic subjects. *Diabetes Care* 1997;20(12):1833–7.
2. Plank J, Haas W, Rakovac I, et al. Evaluation of the impact of chiroprapist care in the secondary prevention of foot ulcerations in diabetic subjects. *Diabetes Care* 2003;26(6):1691–5.
3. Armstrong DG, Harkless LB. Outcomes of preventative care in a diabetic foot specialty clinic. *J Foot Ankle Surg* 1998;37(6):460–6.
4. Leese GP, Stang D, Pearson DW. A national approach to diabetes foot risk stratification and foot care. *Scott Med J* 2011;56(3):151–5.
5. Brand P. The diabetic foot. In: Ellenberg M, Rifkin H, editors. *Diabetes mellitus, theory and practice*. New York: Medical Examination Publishing; 1983. p. 803–28.
6. Leese G, Schofield C, McMurray B, et al. Scottish foot ulcer risk score predicts foot ulcer healing in a regional specialist foot clinic. *Diabetes Care* 2007;30(8):2064–9.
7. Monteiro-Soares M, Boyko EJ, Ribeiro J, et al. Risk stratification systems for diabetic foot ulcers: a systematic review. *Diabetologia* 2011;54(5):1190–9.
8. Mayfield JA, Reiber GE, Nelson RG, et al. A foot risk classification system to predict diabetic amputation in Pima Indians. *Diabetes Care* 1996;19(7):704–9.
9. Lavery LA, Armstrong DG, Vela SA, et al. Practical criteria for screening patients at high risk for diabetic foot ulceration. *Arch Intern Med* 1998;158(2):157–62.
10. Lavery LA, Peters EJ, Williams JR, et al. Reevaluating the way we classify the diabetic foot: restructuring the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care* 2008;31(1):154–6.
11. Peters EJ, Lavery LA. Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care* 2001;24(8):1442–7.
12. Litzelman DK, Slemenda CW, Langefeld CD, et al. Reduction of lower extremity clinical abnormalities in patients with non-insulin-dependent diabetes mellitus. A randomized, controlled trial. *Ann Intern Med* 1993;119(1):36–41.
13. Donohoe ME, Fletton JA, Hook A, et al. Improving foot care for people with diabetes mellitus—a randomized controlled trial of an integrated care approach. *Diabet Med* 2000;17(8):581–7.
14. Malone JM, Snyder M, Anderson G, et al. Prevention of amputation by diabetic education. *Am J Surg* 1989;158(6):520–3 [discussion: 523–4].
15. Lincoln NB, Radford KA, Game FL, et al. Education for secondary prevention of foot ulcers in people with diabetes: a randomised controlled trial. *Diabetologia* 2008;51(11):1954–61.
16. Locking-Cusolito H, Harwood L, Wilson B, et al. Prevalence of risk factors predisposing to foot problems in patients on hemodialysis. *Nephrol Nurs J* 2005;32(4):373–84.

17. Lavery LA, Higgins KR, Lanctot DR, et al. Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care* 2004;27(11):2642–7.
18. Lavery LA, Higgins KR, Lanctot DR, et al. Preventing diabetic foot ulcer recurrence in high-risk patients: use of temperature monitoring as a self-assessment tool. *Diabetes Care* 2007;30(1):14–20.
19. Dorresteyn JA, Kriegsman DM, Assendelft WJ, et al. Patient education for preventing diabetic foot ulceration. *Cochrane Database Syst Rev* 2010;(5):CD001488.
20. Lavery LA, Armstrong DG. Temperature monitoring to assess, predict, and prevent diabetic foot complications. *Curr Diab Rep* 2007;7(6):416–9.
21. Armstrong DG, Holtz-Neiderer K, Wendel C, et al. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. *Am J Med* 2007;120(12):1042–6.
22. Reiber GE, Smith DG, Wallace CM, et al. Footwear used by individuals with diabetes and a history of foot ulcer. *J Rehabil Res Dev* 2002;39(5):615–22.
23. Ndip A, Rutter MK, Vileikyte L, et al. Dialysis treatment is an independent risk factor for foot ulceration in patients with diabetes and stage 4 or 5 chronic kidney disease. *Diabetes Care* 2010;33(8):1811–6.
24. Lavery LA, Hunt NA, Lafontaine J, et al. Diabetic foot prevention: a neglected opportunity in high-risk patients. *Diabetes Care* 2010;33(7):1460–2.
25. Lavery LA, LaFontaine J, Higgins KR, et al. Shear-reducing insoles to prevent foot ulceration in high-risk diabetic patients. *Adv Skin Wound Care* 2012;25(11):519–24 [quiz: 525–6].
26. Viswanathan V, Madhavan S, Gnanasundaram S, et al. Effectiveness of different types of footwear insoles for the diabetic neuropathic foot: a follow-up study. *Diabetes Care* 2004;27(2):474–7.
27. Edmonds ME, Blundell MP, Morris ME, et al. Improved survival of the diabetic foot: the role of a specialized foot clinic. *Q J Med* 1986;60(232):763–71.
28. Busch K, Chantelau E. Effectiveness of a new brand of stock 'diabetic' shoes to protect against diabetic foot ulcer relapse. A prospective cohort study. *Diabet Med* 2003;20(8):665–9.
29. Dargis V, Pantelejeva O, Jonushaite A, et al. Benefits of a multidisciplinary approach in the management of recurrent diabetic foot ulceration in Lithuania: a prospective study. *Diabetes Care* 1999;22(9):1428–31.
30. Rizzo L, Tedeschi A, Fallani E, et al. Custom-made orthosis and shoes in a structured follow-up program reduces the incidence of neuropathic ulcers in high-risk diabetic foot patients. *Int J Low Extrem Wounds* 2012;11(1):59–64.
31. Mueller MJ, Sinacore DR, Hastings MK, et al. Effect of Achilles tendon lengthening on neuropathic plantar ulcers. A randomized clinical trial. *J Bone Joint Surg Am* 2003;85-A(8):1436–45.
32. 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(19):2552–8.
33. Uccioli L, Faglia E, Monticone G, et al. Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 1995;18(10):1376–8.
34. Lavery LA, Lanctot DR, Constantinides G, et al. Wear and biomechanical characteristics of a novel shear-reducing insole with implications for high-risk persons with diabetes. *Diabetes Technol Ther* 2005;7(4):638–46.
35. Bowling FL, Metcalfe SA, Wu S, et al. Liquid silicone to mitigate plantar pedal pressure: a literature review. *J Diabetes Sci Technol* 2010;4(4):846–52.

36. van Schie CH, Whalley A, Armstrong DG, et al. The effect of silicone injections in the diabetic foot on peak plantar pressure and plantar tissue thickness: a 2-year follow-up. *Arch Phys Med Rehabil* 2002;83(7):919–23.
37. van Schie CH, Whalley A, Vileikyte L, et al. Efficacy of injected liquid silicone in the diabetic foot to reduce risk factors for ulceration: a randomized double-blind placebo-controlled trial. *Diabetes Care* 2000;23(5):634–8.
38. Balkin SW. Silicone injection for plantar keratoses. Preliminary report. *J Am Podiatry Assoc* 1966;56(1):1–11.
39. Balkin SW. Treatment of painful scars on soles and digits with injections of fluid silicone. *J Dermatol Surg Oncol* 1977;3(6):612–4.
40. Rosenblum BI, Giurini JM, Chrzan JS, et al. Preventing loss of the great toe with the hallux interphalangeal joint arthroplasty. *J Foot Ankle Surg* 1994;33(6):557–60.
41. Armstrong DG, Lavery LA, Vazquez JR, et al. Clinical efficacy of the first metatarsophalangeal joint arthroplasty as a curative procedure for hallux interphalangeal joint wounds in patients with diabetes. *Diabetes Care* 2003;26(12):3284–7.
42. Armstrong DG, Lavery LA, Stern S, et al. Is prophylactic diabetic foot surgery dangerous? *J Foot Ankle Surg* 1996;35(6):585–9.
43. Lavery LA, Armstrong DG, Boulton AJ. Ankle equinus deformity and its relationship to high plantar pressure in a large population with diabetes mellitus. *J Am Podiatr Med Assoc* 2002;92(9):479–82.
44. Armstrong DG, Stacpoole-Shea S, Nguyen H, et al. 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(4):535–8.
45. Lin SS, Lee TH, Wapner KL. Plantar forefoot ulceration with equinus deformity of the ankle in diabetic patients: the effect of tendo-Achilles lengthening and total contact casting. *Orthopedics* 1996;19(5):465–75.
46. DiGiovanni CW, Kuo R, Tejwani N, et al. Isolated gastrocnemius tightness. *J Bone Joint Surg Am* 2002;84-A(6):962–70.
47. Morton DJ. *The human foot*. New York: Columbia University Press; 1935.
48. Michael SD. Ankle equinus. In: Banks AS, Downey MS, Martin DE, et al, editors. *McGlamry's comprehensive textbook of foot and ankle surgery*. 3rd edition. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 715–60.
49. Holstein P, Lohmann M, Bitsch M, et al. Achilles tendon lengthening, the panacea for plantar forefoot ulceration? *Diabetes Metab Res Rev* 2004;20(Suppl 1):S37–40.
50. Barry DC, Sabacinski KA, Habershaw GM, et al. Tendo Achillis procedures for chronic ulcerations in diabetic patients with transmetatarsal amputations. *J Am Podiatr Med Assoc* 1993;83(2):96–100.
51. Boffeli TJ, Bean JK, Natwick JR. Biomechanical abnormalities and ulcers of the great toe in patients with diabetes. *J Foot Ankle Surg* 2002;41(6):359–64.
52. Laborde JM. Neuropathic toe ulcers treated with toe flexor tenotomies. *Foot Ankle Int* 2007;28(11):1160–4.
53. Lin SS, Bono CM, Lee TH. Total contact casting and Keller arthroplasty for diabetic great toe ulceration under the interphalangeal joint. *Foot Ankle Int* 2000;21(7):588–93.
54. Tamir E, McLaren AM, Gadgil A, et al. Outpatient percutaneous flexor tenotomies for management of diabetic claw toe deformities with ulcers: a preliminary report. *Can J Surg* 2008;51(1):41–4.
55. Kearney TP, Hunt NA, Lavery LA. Safety and effectiveness of flexor tenotomies to heal toe ulcers in persons with diabetes. *Diabetes Res Clin Pract* 2010;89(3):224–6.