Diabetes mellitus is a major public health problem in the United States. The American Diabetes Association estimates that at least 14 million people in the United States are diabetic. Affecting approximately 5% of the population, the disease is the third leading cause of death. The incidence of diabetes appears to be increasing by 6% per year. At this rate, the number of people with diabetes will double every 15 years. The rate of increase is even greater in the elderly population.

The authors evaluated the time to healing and prevalence of complications in patients undergoing mechanically assisted, delayed primary closure of diabetic foot wounds compared with a similar population who received standard wound care. A total of 55 patients were enrolled for study, with 25 in the experimental group and 30 in the control group. Patients in the experimental (stretch) group underwent mechanically assisted primary closure of their wounds using a skin-stretching device. There was no difference between the stretch and control groups with regard to any descriptive characteristics, including wound chronicity. Although the wounds were over three times as large on average in the stretch group (P < .001), the stretch group reached full epithelialization approximately 40% sooner than the control group (26.4 ± 16.0 versus 42.5 ± 19.9 days; P < .002). Eighty-eight percent of patients in the stretch group experienced wound dehiscence, at a mean time of 1.8 ± 0.6 weeks following mechanically assisted closure. However, patients who experienced dehiscence in the stretch group healed significantly faster than patients in the control group (27.4 ± 16.7 versus 42.5 ± 19.9 days; P < .007). The results of this study suggest that mechanically assisted closure of diabetic foot wounds may result in reduced healing time compared with healing by secondary intention. (J Am Podiatr Med Assoc 88(10): 483-488, 1998)
Diabetes, neuropathy and vasculopathy, result in major damage to the foot. Vasculopathy results in reduced circulation that impairs wound healing and can lead to gangrene in the diabetic extremity, necessitating amputation. Patients with vascular disease concomitant with an infected ulceration are up to 90 times more likely to suffer a high-level amputation than subjects without ischemia.4 Neuropathy causes a loss of acute sensation of pain and thus plays a role in the pathogenesis of foot lesions.6 It also renders diabetic patients vulnerable to arthropathy and joint dislocation (Charcot’s joint).11-13 Other significant risk factors that may contribute to lower-extremity complications and impaired healing are poor control of blood glucose and mechanical stress due to structural foot deformity.5,8

Foot ulcers on the sole of the foot are one of the most common complications of diabetes and a major cause of disability and morbidity.4 It has been estimated that 10% to 18% of people with diabetes will develop pedal ulcers at some point.14 Nearly nine in ten lower-extremity amputations in patients with diabetes are a result of failed healing of pedal ulcers.7 Patients who have had an amputation at any level on the lower extremity are up to 36 times more likely to experience an ulceration.5 At least half of these patients will have a contralateral amputation within 5 years.15-17

The authors hypothesized that surgical primary closure of diabetic foot wounds may result in substantially faster healing and a less complex treatment course than secondary wound closure.18-20 Many wounds are problematic because their size precludes primary closure. These large diabetic foot wounds require a long time for epithelialization, substantially increasing the risk of infection and amputation.4 The purpose of this study was to evaluate the time to healing and prevalence of complications encountered in patients undergoing mechanically assisted, delayed primary closure of diabetic foot wounds compared with a similar population who received standard wound care.

Materials and Methods

A total of 55 patients were enrolled in the study. The authors prospectively evaluated 25 consecutive patients with diabetes and foot wounds who presented for care at a multidisciplinary, tertiary-care diabetic foot care center and who had their wounds treated with mechanically assisted closure. This group was called the stretch group for purposes of this study. A group of 30 patients with neuropathic ulcers or open wounds who were treated with standard wound-treatment protocols was used as a comparison group to evaluate healing time and complications. This group formed the control group. All subjects presented with a wound below the ankle. As part of protocol, patients treated in the high-risk diabetic foot clinic for foot complications have a standardized evaluation to assess wound depth, sensory neuropathy, vascular insufficiency, and infection. Descriptive data for the study population are shown in Table 1.

Mechanically assisted wound closure was performed using the same device (Sure Closure Skin Stretching System®1) and technique described by Armstrong et al.18 All of these procedures were performed in a clinical setting under local anesthesia. Figures 1 through 5 demonstrate use of the skin-stretching device in a patient (not a participant in the present study) who underwent a transmetatarsal amputation.

With the exception of the aforementioned intervention, all wounds were treated using similar care. All wounds were off-loaded with the same removable walking cast (DH Pressure Relief Walker®2). Patients were evaluated on a weekly basis, and wound debridement was performed as needed at the discretion of the attending physician. Complete healing was defined as complete epithelialization of any deficit (stretch and control groups) or when the sutures were removed without dehiscence (stretch group).

The diagnosis of diabetes mellitus was verified for all patients using the criteria set forth by the World Health Organization, which include treatment with insulin or an oral hypoglycemic agent, two random glucose measurements greater than 200 mg/dL, or a fasting glucose level greater than 140 mg/dL.4 Sensory neuropathy was evaluated with a 10-g Semmes-Weinstein monofilament wire and a Biothesiometer®3 using the method and criteria described by Arm-

Table 1. Descriptive Characteristics of the Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stretch (n = 25)</th>
<th>Control (n = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>56.0</td>
<td>56.7</td>
</tr>
<tr>
<td>Age (years)</td>
<td>53.2 ± 10.0</td>
<td>52.1 ± 11.0</td>
</tr>
<tr>
<td>Diabetes mellitus duration (years)</td>
<td>14.5 ± 6.5</td>
<td>14.3 ± 7.3</td>
</tr>
<tr>
<td>Glycohemoglobin (%)</td>
<td>11.1 ± 1.5</td>
<td>9.5 ± 1.9</td>
</tr>
<tr>
<td>Vibratory perception threshold (volts)</td>
<td>45.0 ± 5.8</td>
<td>45.9 ± 5.1</td>
</tr>
</tbody>
</table>

Note: Plus-minus values are mean ± SD.
All subjects had clinical loss of protective sensation using these criteria.

The diagnosis of infection was made using clinical criteria. Wounds with frank purulence and/or two or more of the following local signs were classified as “infected”: warmth, erythema, lymphangitis, lymphadenopathy, edema, pain, and loss of function. For all wounds, depth was evaluated using a sterile blunt nasal probe. If bone or an open joint was palpable using a sterile blunt probe and there was local or systemic infection, a bone biopsy was performed, and examination by both microbiologic and histologic analysis was conducted to diagnose or exclude osteomyelitis. A working diagnosis of lower-extremity ischemia was made by a combination of clinical and noninvasive vascular studies. Clinical signs were based on the absence of one or more foot pulses of the involved foot. Noninvasive criteria included an ankle-brachial index less than 0.80. Clinical signs and/or the presence of abnormal, noninvasive values provided a diagnosis of lower-extremity vascular insufficiency.

Wounds were classified by one of the principal investigators using the University of Texas Diabetic Wound Classification System. Figure 6 shows the location of wounds of the study population. The classification uses a matrix of wound grade on the horizontal axis and wound stage on the vertical axis to categorize wounds by severity. Wounds were graded by depth according to the following criteria: Grade 0 represented a preulcerative site or postulcerative site that had healed. Grade 1 wounds were superficial wounds through the epidermis or epidermis and dermis that did not penetrate to tendon, capsule, or bone. Grade 2 wounds penetrated to tendon or capsule. Grade 3 wounds penetrated to bone or into the joint. Within each wound grade there are four stages: clean wounds (A); nonischemic, infected wounds (B); ischemic, noninfected wounds (C); and infected, ischemic wounds (D). Patients presenting initially with infected or ischemic wounds (stages B to D) were excluded from enrollment in this study. All of the control patients were classified as having 1A wounds. The stretch-group patients were classified as follows: 64%, 1A; 20%, 2A; and 16%, 3A. Wound area was measured in square centimeters using a digital camera and computerized planimetry (VIRGe Videometer).

Vista Medical, Winnipeg, Manitoba, Canada.
A chi-square test with odds ratio and 95% confidence interval was used to assess the association between prevalence of infection during the treatment course and other dichotomous variables. Differences in age, ankle-brachial index, vibratory perception threshold, wound duration prior to treatment, time to complete epithelialization, and all other continuous variables were assessed using a t-test for independent samples. For all analyses, an alpha of .05 was used.27

**Results**

Details regarding wound characteristics are shown in Table 2. There was no difference in chronicity of wounds, vascular perfusion, or any other descriptive characteristics between the stretch and control groups. There was, however, a significant difference in wound size between the stretch and control groups (27.0 ± 24.4 versus 7.9 ± 3.5 cm²; *P* < .001). Furthermore, even though the wounds were more than three times as large on average in the stretch group, this group reached full epithelialization approximately 40% sooner than the control group (26.4 ± 16.0 versus 42.5 ± 19.9 days; *P* < .002).

The prevalence of complications was also evaluated. No patient in the stretch group had infection during the healing period, compared with 10% in the control group (*P* > .05). Nearly nine in ten patients in the
The stretch group experienced dehiscence (88%) (Table 3). This occurred at a mean of 1.8 ± 0.6 weeks following mechanically assisted closure. As a subgroup, patients who experienced dehiscence in the stretch group also healed significantly faster than those in the control group (27.4 ± 16.7 versus 42.5 ± 19.9 days; P < .007).

Discussion

The results of this study suggest that mechanically assisted closure of diabetic foot wounds may result in more rapid healing compared with healing by secondary intention. While the majority of the wounds of this study group that were primarily closed experienced dehiscence, the mean time to complete epithelialization was still approximately 40% shorter than in those patients not undergoing this procedure. This is made more significant by the fact that wounds in the stretch group were, on average, three times as large as those in the control group. In fact, many patients were selected to have mechanically assisted wound closure because of the severity and the size of their wounds. Therefore, selection bias in this study favored smaller, less severe wounds in the comparison group that received standard therapy alone. Perhaps the main shortcoming of this project was that the study did not assign treatment randomly. The patients prospectively evaluated in the stretch group were included as part of a project to evaluate safety and efficacy of the device in patients with diabetes. Control-group patients were obtained retrospectively from patients evaluated at the high-risk diabetic foot clinic.

Ideally, aggressive off-loading of the affected foot, debridement, and meticulous wound care should be performed concomitantly with skin stretching to achieve optimal long-term results. Mechanically assisted closure should be viewed as an adjunct to standard care. However, as indicated by the results of this study, mechanically assisted closure seems to provide a significant benefit when used with standard protocols and good judgment. Perhaps the most gratifying cases have been open, partial-foot amputations or debridements of large plantar-space infections that otherwise would have required several months to heal by secondary intention or would have necessitated a more proximal amputation. In the past, many of these patients would have had split-thickness skin grafts and/or muscle flaps that, in general, have not held up to the rigorous demands made of plantar and distal pedal skin. One of the reasons the technique presented in this article is so favorable is that it allows defects on the sole of the foot to be closed with native plantar integument.

The average healing time of patients treated with standard therapy was similar to that reported in previous studies of patients treated with total contact casting.8, 28-31 Although the size of the average wound was very large, most of the wounds were superficial, relatively well vascularized, and not infected. These are essentially the same criteria as described in many descriptive studies of total contact casts,8 platelet-derived growth factors,32, 33 and living skin equivalents.34 The technique was not associated with untoward results. There were no postoperative infections or other complications that resulted in proximal amputation or wound deterioration in the stretch group. While the prevalence of postoperative infections was not statistically significant, 10% of the patients in the control group had superficial infections. Safety and improved healing times may result in less morbidity and more cost-effective results. More work must be done to evaluate the efficacy of this type of therapy for treating classic neuropathic ulcers on the sole of the foot, but the results presented here are encouraging and clearly provide a rationale for additional research.

| Table 2. Wound Characteristics of the Study Population |
|---------------------------------|----------------|----------------|
| Characteristic                  | Study Group    |                |
|                                 | Stretch (n = 25) | Control (n = 30) |
| Ankle-brachial index            | 0.99 ± 0.16     | 0.98 ± 0.13    |
| Area (cm²)                      | 27.0 ± 24.4     | 7.9 ± 3.5     |
| Time to complete epithelialization (days) | 26.4 ± 16.0 | 42.5 ± 19.9 |
| Ulcer duration (days)           | 90.6 ± 87.6     | 80.9 ± 92.0    |

Note: All data are expressed as mean ± SD.

| Table 3. Prevalence of Complications |
|-------------------------------------|----------------|----------------|
| Complication                       | Study Group    |                |
| Infection (%)                      | Stretch (n = 25) | Control (n = 30) |
| Mean (± SD) wound size before dehiscence (cm²) | 27.0 ± 24.4 | NA |
| Mean (± SD) wound size after dehiscence (cm²) | 4.2 ± 1.8 | NA |

Abbreviation: NA, not available.
References