



# The Diabetic Foot in Remission

These medical and  
surgical management strategies  
can extend ulcer-free days.

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## Goals and Objectives

After completing this CME the  
reader should be able to:

- 1) Understand the impact of diabetes-related foot ulcers on the global health system
- 2) Review current conservative and surgical methods for preventing repeat ulcerative episodes
- 3) Consider advanced surgical techniques such as silicone implants and fat transplants for maintaining ulcer remission
- 4) Review the benefits of a multi-disciplinary practice in treating ulcerations and preventing repeat episodes

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Following this article, an answer sheet and full set of instructions are provided (pg. 124).—*Editor*

### Incidence and Cost of Diabetic Foot infections

Developed and developing nations alike loom on the edge of a global diabetes epidemic. Diabetes-related ulcerations continue to challenge healthcare systems by re-

maining common, costly, and recalcitrant. In the past 30 years, the incidence of diabetes among the world's adult population has nearly quadrupled, rising to over 422 million adults worldwide. During this same time global prevalence increased from

4.7% to 8.5%.<sup>1</sup> Within the diabetic population the incidence of diabetic foot ulcers (DFUs) has been reported to be 4-10%, with a one-in-four risk of ulceration during an individual's lifetime.<sup>2,3</sup>

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Diabetes-related foot ulcers and amputations cost the U.S. healthcare system up to \$17 billion annually, surpassing the direct costs of the five most expensive cancers.<sup>4,7</sup> Of the sum of diabetic inpatient care charges, foot ulcerations are a significant source of expenditures, often leading to admissions totaling upwards of \$100,000 in charges.<sup>8-10</sup> It has been reported that as much as 25-50% of all costs related to inpatient care among the diabetic population may be directly related to diabetic foot ulcers.<sup>11</sup> These costs inflate with the presence of peripheral arterial disease to nearly four times the cost of purely neuropathic wounds.<sup>12</sup>

Annual recurrence rates of diabetic ulcerations have been reported as high as 34%, 61%, and 70% at one, three, and five years, respectively, with recurrence rates as high as 20% to 58% within one year.<sup>13,14</sup> Existing prevention methods have the potential to decrease the risk of amputation for diabetic patients with a history of ulcer by 50%.<sup>15</sup> It has also been demonstrated that a 25% reduction in the incidence of foot ulcers through the implementation of basic preventative clinical care would negate the cost of program implementation of such a program.<sup>16</sup> It is to this



Figure 1: Plantar-flexed metatarsal heads are common manifestations of high-pressure areas that lead to ulceration. Conservative and surgical methods to prophylactically offload these areas are crucial to the prevention of return ulcerations to the patient in remission.



Figure 2: Wound secondary to peak forces sub-3rd metatarsal head. Without proper offloading, plantar wounds will persist indefinitely and often result in infection requiring amputation.

evaluate a patient's continued risk for ulceration by evaluating a patient's neurological and vascular status as well as reviewing prior history of foot ulcers to create an overall picture of ulcerative risk.<sup>18,19</sup>



Figure 3: Rigid digital contractions produce numerous high-friction areas in footwear for the creation of ulcers. Preventative management of these deformities by conservative and surgical methods is crucial to avoid foot ulcers.

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end that we outline innovations in the management of the diabetic foot ulcer (DFU) and discuss the course of diabetic foot remission.

### Current Screening Strategies

The American Diabetes Association recommends that all patients with diabetes see a lower extremity specialist for foot screenings at routine intervals depending on need; at least every six months for the most basic evaluation or at least every two months for those at greater risk for DFUs.<sup>17</sup> At these visitations, clinicians

Clinical application of risk stratification guidelines such as the Society for Vascular Surgery's WIfI (wound, ischemia, and foot infection) classification<sup>20</sup> aid this process by correlating certain risk parameters with end-outcome probabilities. This information proves particularly useful during patient education and clarification of how they fit the spectrum of amputation and mortal risk. This information is not only requisite in understanding clinical prognosis, but may be further motivation to take early action towards

the promotion of their own health.

Due to the astonishingly high recurrence of DFU, often comparable to rates of cancer, language when discussing preventative treatment of DFUs should be as clear and stark as that of cancers.<sup>21</sup> Healed DFUs should be explained to be in "remission", as

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abatement of recurrence and “active prevention” becomes the focus of care once a DFU has healed.<sup>21</sup>

With this mindset, increasing patient knowledge regarding the importance of self-care and daily foot exams is key to their overall success

calcitrant plantar metatarsal wound, as seen in Figure 2. This threshold was obtained from patients with previous ulcer sites that have remained healed.<sup>27</sup> However, use of plantar pressure data to predict ulceration is problematic when used alone, as activity and activity collection likely play just as important a role.<sup>22,23,28-31</sup>

high peak plantar pressure.<sup>24,37</sup> However, that practice does not parallel the podiatric standard of care as only 2-11% of care centers and podiatry practitioners surveyed utilize TCCs for primary off-loading.<sup>38-40</sup> Additionally, despite proven efficacy, Cavanagh and Bus<sup>26</sup> also found clinicians worldwide resisting the implementation of TCC devices in these cases, presumably because of the increased time, cost, and expertise required for proper application.

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#### Surgical Methods of Off-loading

Common neurologic and musculoskeletal sequelae of the diabetic process lead to multiple areas of abnormal foot structure that cause areas of higher pressure, which in turn are at great risk for re-ulceration.<sup>41-43</sup> The most common deformities in the diabetic patient include local nerve entrapment, tightness of the Achilles tendon, and hammer and claw-toe deformities. With rates of infection status-post digital surgeries in patients with diabetes similar to those of patients without diabetes, surgical options in any patient with obstreperous wound recurrence should be considered.<sup>44</sup> Critical to the success of the patient in remission is adequate pre-operative amputation planning. Figures 4a and 4b demonstrate a patient in

in maintaining DFU remission. Current patient guidelines for daily care include inspection of the feet, use of diabetic socks to reduce friction, foot exercises to promote circulation, and application of any topical antifungal or hydrating lotions as necessary. At-risk patients should be informed to avoid self-damaging behaviors such as barefoot walking, using ill-fitting footwear, poor glycemic control, or delaying regular medical professional foot inspection and nail care.<sup>18</sup>

#### The Use of Custom Footwear for Off-loading

Diabetic shoes have proven effective at reducing ulcer recurrence by reducing peak plantar pressures and shear forces.<sup>32,33</sup> Uccioli, et al.<sup>34</sup> found ulcer recurrence rates in patients using normal footwear to be more than 200% higher than with patients using diabetic shoes. These findings were later confirmed by Busch and Chantelau,<sup>35</sup> who found that therapeutic footwear significantly reduced

#### Reducing Peak Plantar Pressures

Among the strongest risk factors for ulcer development are repetitive stresses on the feet. This, in combination with the presence of neuropathy, bony prominences or peripheral artery disease, augments risk of DFUs as seen in Figure 1. Lack of sensation and decreased metabolic response render patients unable to organically detect repetitive stress and trauma to their plantar tissues. Confounding this presentation, patients with diabetes are shown to regularly have elevated peak plantar pressures which further propagate the risk of ulceration.<sup>17,22-25</sup>

Plantar pressure redistribution is regarded as the most important therapy for managing a patient in remission.<sup>26</sup> The in-shoe peak plantar pressure threshold of 200 kPa has been suggested as a reference to prevent foot ulceration, particularly the re-

rate of re-ulceration. Therefore, it is strongly recommended that any diabetic with confirmed lower extremity polyneuropathy be transitioned to these devices.<sup>21,36</sup>

#### Casting Methods for Off-loading

Current literature refers to the total contact casts as the gold standard for wound off-loading in the treatment of ulcerations caused by

which a violation of the ‘too few toes principle’ for digital amputation planning likely led to his re-ulceration.

#### Nerve Decompression

A small demographic of diabetic patients who have symptoms of nerve entrapment may benefit from nerve release surgery with a main hypothesis of correction being the

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re-establishment of plantar protective sensation following surgical release.<sup>45</sup> Although not indicated in all patients, nerve decompression procedures have demonstrated reduction in ulcer recurrence in patients with diabetic neuropathy and signs of entrapment.<sup>46,47</sup>

**Achilles Tendon Lengthening**

The performance of an Achilles tendon lengthening in tandem with TCC application reduced rates of re-ulceration from 59% to just 15%, when compared to TCC application alone in a study by Mueller, et al.<sup>48</sup> In addition to reduced re-ulceration rates, a mean reduction in peak plantar pressure by 28% with percutaneous Achilles tendon lengthening alone has also been reported.<sup>10</sup>

**Surgical Correction of Skeletal Abnormalities**

Ulcer recurrence in the diabetic foot is highly linked to progressive deformities of the foot's natural bony architecture. In areas where bony prominence, such as the dorsal digit with hammertoes (as in Figure 3),

or the distal digit in cases of claw toe deformity, increase risk for ulceration, surgical debridement of the offending bone should be considered to facilitate prolonged ulcerative remission.<sup>44,49</sup> Surgical procedures in these instances are considered prophylactic in the scheme of "Diabetic Foot Surgery Classifications."<sup>50</sup> These surgeries benefit diabetic patients in a pre-ulcerative state as well as post-ulcerative one by ameliorating areas of peak pressure responsible

distal digital ulcerations.<sup>44,51</sup> Comparison of DFU recurrence demonstrated a 14% overall recurrence in re-ulceration in patients with prior DFU who underwent prophylactic surgical off-loading, versus a 42% rate of recurrence in patients whose treatments were limited to non-surgical therapies alone.<sup>52</sup>

**Plantar Fat Pad Augmentation**

Bony prominence in the setting of a diabetic foot and plantar fat pad

### Evidence suggests that use of custom-molded shoes may reduce ulcer recurrence in the patient in remission.

for ulceration, and may also aid in reducing recurrence.

Plantar hallux interphalangeal joint ulceration recurrence after surgical intervention demonstrated a rate of 4.8% in one study, when compared to non-surgical prophylactic therapies.<sup>49</sup> Simple and safe flexor tenotomy procedures have been used for recurrence prophylaxis to healed

atrophy, even with efforts of off-loading, often progress to soft tissue breakdown and lesions, or pre-ulceration. Soft tissue that has healed after ulceration can remain with significant deficit and sometimes worryingly thin substance protecting the area. Considering the fundamental principle that plantar pressure is a direct result of plantar soft tissue thickness, recent focus has returned to addressing this in the healed diabetic foot.<sup>53,54</sup> Prior reports of silicone injection treatment to add bulk to soft tissue associated with ulceration or pre-ulceration have thoroughly indicated its safe utility in prevention and maintenance of wound remission.<sup>55,56</sup> Additionally, current efforts are being made to optimize the use of one's own adipocytes to increase soft tissue depth and promote autogenous sourcing of graft material in preventing recurrence of DFUs.

**Silicone**

Beginning in 1975, Balkin, also the first attributable author for injecting silicone in areas of prominence in the plantar foot, reports injections of over 1,500 patients with painful corns and calluses to evaluate the efficacy and safety of silicone injections.<sup>55,57</sup> Of those patients, there were also 41 diabetic foot ulcerations and 16 pre-ulcerative lesions. After a series of silicone injections, all 41 ul-



Figure 4: Anterior (a) and posterior (b) views of a patient with unstable biomechanical status following multiple amputations. Irregular bony prominences left this patient susceptible to areas of excessive force and tissue breakdown, which may have been preventable with more robust pre-operative planning.

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cerations and pre-ulcerative lesions healed. Remarkably, 73% of lesions remained healed during a six-year follow-up period. Long-term in-vivo analysis revealed no significant adverse reactions to the injections. Post-mortem analysis of injection sites were also devoid of adverse inflammation, infection, or granulomatous reactive formations.<sup>55,57</sup>

Another report, in a randomized double-blind placebo-controlled trial of 28 patients with diabetic neuropathy demonstrated reduced barefoot plantar pressures in pedobarographic evaluations.<sup>58</sup> They relate significantly increased plantar tissue thickness, with decreased plantar pressures in the patients who underwent silicone injections versus placebo.<sup>58</sup>

Injected silicone filler has been found safe, and long-term patient reviews as well as histopathologic evaluation of injection sites have demonstrated no serious complications. Despite these findings, there are current limitations to the utility and availability of “injectable-grade” silicone products, mainly attributed to prior adverse reactions, a result of impure and large quantity injections. Further investigations into non-silicone in-

not well outlined. Subsequent anecdotal findings questioned the ability of plantar fat grafts to provide lasting therapeutic relief to areas of prominence.<sup>59</sup> Further reports of post-traumatic regional fat augmentation,

There is currently a single randomized control trial launched in the U.S. with the goal of evaluating the efficacy of lipofilling/fat grafting for plantar heel pain.<sup>61,62</sup> Further investigation into the

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### Patients with diabetes mellitus and vascular disease have approximately a ten times increased likelihood of ulcer recurrence.

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or “lipofilling” by Nicoletti, et al.<sup>60</sup> demonstrated the ability to provide improved plantar load distribution and local soft tissue stability utilizing autologous fat grafts.

Concerning the application of autologous fat grafting for the treatment of DFUs, Statsch, et al.<sup>61</sup> performed autologous lipotransfer to increase soft tissue thickness and incite wound healing after debridement of 26 chronic non-healing wounds. They report an 88% healing rate, with a reduction of all wound sizes by 50% at an average of four weeks. This report demonstrated efficacy in the healing of chronic DFUs with the use of autologous fat transfer.

A single case report publication

efficacy of autograft application in the promotion of wound remission may reveal further insight as to its safety, simplicity, and efficacy.

#### Monitoring Strategies and Technological Innovations

Currently, calor, erythema, and high peak plantar pressure are some of the earliest clinical indications of inflammation that marks initiation of ulcer development.<sup>63</sup> A 2007 randomized controlled trial from *Diabetes Care* found that patients not trained in plantar foot temperature monitoring were four times more likely to develop foot ulcer recurrence than those who were appropriately trained to do so.<sup>64</sup> In addition to temperature monitoring, pressure monitoring is advancing. Although custom diabetic shoes with appropriately fashioned trilaminar insoles or custom orthotics are the minimal requirement for preventing the recurrence of ulcers, not every device can be created perfectly to each patient’s unique anatomy. Electronic monitoring reduces the subjective findings of neuropathic patients concerning shoe fit and comfort in exchange for objective data to fabricate patient-specific devices.<sup>65</sup>

In the near future, constant monitoring systems will seamlessly integrate themselves into patients’ daily lives by means of wearable sensors and medical telemetry. “Intelligent” insoles or “smart” socks could perpetually monitor warmth and pressure without any user interaction required and subsequently alert the user or medical staff of a need for intervention. This advancing technology perpetuates the concept of

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### In Dr. Balkin’s study following the outcomes of patients receiving silicone injections to prominent areas of the plantar foot, 73 percent of ulcerative lesions remained healed at 6 years.

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jectable materials such as poly-L-lactic acid (Sculptra™, Sanofi-Aventis) and hyaluronic acid may prove remarkable in the treatment and prevention of recurrence of DFUs.

#### Autologous Fat Grafting

A report by Chairman in 1994 was the first to outline the grafting of autologous fat to the plantar foot during concomitant bone procedures.<sup>59</sup> This report of 50 patients demonstrated good “subjective” results; however, the exact process of graft harvesting and application were

in-press by Dr. Luu and colleagues in the *Journal of Plastic Surgery* reports the use of plantar foot injection of autologous fat into an area of recurrent ulceration at the plantar styloid process of the 5th metatarsal and plantar forefoot. They report injecting 25mL of autograft harvested from the anterior abdomen with clinical evidence of graft “take” at three weeks post-operatively. At six-weeks post-operative evaluation, MRI demonstrated graft preservation without new wounds or recurrence of the lesion.

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ulcerative “remission” by allowing real-time analysis of the efficacy of therapy efforts towards critical provider and patient goals for care.<sup>21</sup>

**The Role of the Multidisciplinary Team**

Between 10% to 40% of patients with diabetes also have a form of vascular disease, a comorbid factor that increases the likelihood of ulcerative recurrence by a factor of 10.<sup>33</sup> Furthermore, patients with vascular disease compounded by peripheral neuropathy also have higher re-ulceration and amputation rates than those with neuropathy alone.<sup>66</sup>

As the predominance of neuropathic ulcers continues to shift toward the neuroischemic, the increasing adoption of the “toe and flow” multidisciplinary model, where podiatry and vascular surgeons personify the backbone of a diabetes wound management team, will see accelerated implementation.<sup>67</sup>

A coordinated team approach has been shown to decrease the frequency of limb loss and perpetuation of diabetic foot remission worldwide.<sup>68-70</sup> A prospective study from 2008 found a 70% reduction in the total number of diabetes-related amputations from 1995 to 2005 in the United Kingdom because of the introduction of the multidisciplinary team.<sup>71</sup> Reports from Lithuania found that patients receiving multidisciplinary care had a re-ulceration occurrence rate of 30.4% in comparison with a 58.4% rate of recurrence in the control group receiving individualized physician care.<sup>72</sup>

Furthermore, recent data suggest that the removal of foot care from statewide reimbursement systems led to significant and sustained increases in hospital admission (37%), charges (38%), length of stay (23%), and severe aggregate outcomes including amputation, sepsis, and death (49%).<sup>73</sup> The inclusion of occupational therapists, physical therapists, and registered nutritionists further facilitates the respective home environment augmentation, mobility, dietary, and health style modifications necessary to reach the

personalized goals of the high-risk diabetic patient.<sup>74-76</sup>

**Pearls and Lasting Comments on Ulcerative Remission**

Maintaining a state of remission in a high-risk diabetic foot is one

use for improving patient care and extending the duration of wound remission. Physician practices and care strategies still demonstrate the best results when centered on interpersonal connections and interdisciplinary approaches. In the realm of main-

**“Intelligent” insoles or “smart” socks could perpetually monitor warmth and pressure without any user interaction required and subsequently alert the user or medical staff of a need for intervention.**

of the most complex aspects related to the management of diabetic foot complications. Initial occurrence and subsequent recurrence of DFUs are multifactorial in terms of etiologies and confounding factors; included in the list are biomechanics as well as sociomechanics.<sup>21,77</sup>

It must always be considered that any lasting medical treatment or healing course is doomed without patient and support team involvement. Recruiting the emotional and intellectual engagement of patients and other members of the patients’ support team is challenging, yet patients are more adherent to treatment guidelines and follow-up visits when clearly presented with the reasoning and logic behind the physician’s treatment course.<sup>78</sup> It has also been proven that when others participate in a patient’s care, it not only has a positive psychological impact on the patient, but also on other individuals involved.<sup>79</sup>

Much of the aims in the future of personalized medicine rest firmly on catered medical and surgical treatments.<sup>80</sup> We believe that an analogy to cancer is apt in terms of personal and fiscal impact; therefore, patient involvement should be central to prevention.<sup>81</sup> Just as a regular breast cancer screening examination may be important in identifying benign or sinister lesions, so too could regular foot examinations in detecting equally co-morbid pre-ulcerative calluses.<sup>82</sup>

Many of the interventions mentioned in this article hold great prom-

taining remission, patient education and active participation in prevention promotion trump surgical prophylaxis alone. **PM**

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# WOUND MANAGEMENT

## Remission (from page 122)

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## CME EXAMINATION

SEE ANSWER SHEET ON PAGE 125.

1) What is the current estimated population of adults diagnosed with diabetes mellitus in the world?

- A) ~ 5 million persons
- B) ~ 30 million persons
- C) ~ 100 million persons
- D) ~ 400 million persons

2) How often does the American Diabetes Association recommend a patient with diabetes see a lower extremity specialist for routine screening?

- A) Only as needed
- B) At least every 6 months
- C) At least every 5 years
- D) At least every 10 years

3) The WiFI wound classification system quantifies which of the following parameters?

- A) Vascular status
- B) Presence or absence of infection
- C) Wound size/depth
- D) All of the above

4) Which of the following regarding the use of custom-molded shoes in the diabetic patient is true?

- A) Evidence suggests they should be a first-line treatment for active diabetic wounds.
- B) Evidence suggests their use may reduce ulcer recurrence in the patient in 'remission'.
- C) Evidence suggests that custom-molded shoes should not be used in patients with a prior history of foot ulceration.
- D) Presence of neuropathy, ischemia, and/or deformity would not indicate use of custom-molded shoes in a patient with diabetes.

5) In Dr. Balkin's study following the outcomes of patients receiving silicone injections to prominent areas of the plantar foot, what percentage of ulcerative lesions remained healed at 6-years?

- A) 20%
- B) 45%
- C) 60%
- D) 73%

Continued on page 124

- 6) Benefits of using lipofilling/fat grafting for coverage of high plantar pressure areas in the foot include:
- A) Use of an autologous substance
  - B) Increasing the thickness of soft tissue covering prominent bone
  - C) Improving plantar pressure load distribution
  - D) All of the above
- 7) A recent decision to remove the coverage of foot care in state-wide reimbursement systems lead to increases in which of the following?
- A) Foot related hospital admissions (37%)
  - B) Foot related medical charges (38%)
  - C) Length of stay for foot related admissions (23%)
  - D) All of the above
- 8) Patients with diabetes mellitus and vascular disease have an increased likelihood of ulcer recurrence by approximately what factor?
- A) Decreased likelihood for recurrence
  - B) No increase in likelihood
  - C) Ten times the likelihood
  - D) Fifty times the likelihood
- 9) 'Intelligent' insoles or 'smart' socks may offer future benefit in the prevention of re-ulceration by:
- A) Constant monitoring of warmth, pressure or other parameters critical to early detection of potential ulcerations
  - B) Actively preventing the formation of new wounds through electrical stimulation
  - C) Decreasing plantar pressures by modulating material densities
  - D) Changing the temperature and humidity within shoes to maintain a protective environment
- 10) Plantar re-ulceration rates may be best reduced with the addition of \_\_\_\_\_ following the use of serial total contact casting to achieve complete wound healing.
- A) Increasing weight-bearing exercises
  - B) Achilles tendon lengthening
  - C) Early return to weight-bearing activities
  - D) Use of assistive walking devices such as crutches or a cane

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**(Miller, Hatch and Armstrong)**

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| 1. A B C D | 6. A B C D  |
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