Strategies to Prevent and Heal Diabetic Foot Ulcers: A Joint Publication of APMA and SVS

SPECIAL COMMUNICATION

Off-loading the Diabetic Foot for Ulcer Prevention and Healing

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Retrospective and prospective studies have shown that elevated plantar pressure is a causative factor in the development of many plantar ulcers in diabetic patients and that ulceration is often a precursor of lower-extremity amputation. Herein, we review the evidence that relieving areas of elevated plantar pressure (off-loading) can prevent and heal plantar ulceration.

There is no consensus in the literature concerning the role of off-loading through footwear in the primary or secondary prevention of ulcers. This is likely due to the diversity of intervention and control conditions tested, the lack of information about off-loading efficacy of the footwear used, and the absence of a target pressure threshold for off-loading. Uncomplicated plantar ulcers should heal in 6 to 8 weeks with adequate off-loading. Total-contact casts and other nonremovable devices are most effective because they eliminate the problem of nonadherence to recommendations for using a removable device. Conventional or standard therapeutic footwear is not effective in ulcer healing. Recent US and European surveys show that there is a large discrepancy between guidelines and clinical practice in off-loading diabetic foot ulcers. Many clinics continue to use methods that are known to be ineffective or that have not been proved to be effective while ignoring methods that have demonstrated efficacy.

A variety of strategies are proposed to address this situation, notably the adoption and implementation of recently established international guidelines, which are evidence based and specific, by professional societies in the United States and Europe. Such an approach would improve the often poor current expectations for healing diabetic plantar ulcers. (J Am Podiatr Med Assoc 100(5): 360-368, 2010)

What Is Off-loading and How Can It Be Measured?

In the sensate foot, for example, in a patient with rheumatoid arthritis, relieving the local pressure (off-loading) at painful regions of the foot is driven and evaluated by the patient’s perceived pain.1 However, up to approximately 50% of people with diabetes mellitus (depending on ethnicity2) eventually have loss of sensation in the feet secondary to peripheral neuropathy that is sufficient to allow them to injure the soft tissues of the plantar surface (a condition that has been termed loss of protective sensation).3 These areas need to be off-loaded, but because the patient has inadequate sensation, his or her feedback is not useful in judging whether pressure relief has been obtained.4

The design of footwear and in-shoe devices to off-load at-risk areas of the diabetic foot has traditionally been considered to be an art rather than a science despite the fact that one of the first articles to actually measure the pressure relief from therapeutic footwear was published almost 50 years ago.5 Pressure measurement inside footwear is now more widespread; because of economic and reimbursement issues, it is more common in research settings than in clinical practice. An example of what the technique can demonstrate is shown in Figure 1. The substantial difference in off-loading seen between the two footwear conditions is
apparent, but the practitioner would not be able to determine this difference without the benefit of the measuring device. This is one reason why off-loading the diabetic foot is so difficult and prone to failure.

Why Is Off-loading Needed?

Retrospective and prospective studies have shown that elevated plantar pressure is a causative factor in the development of plantar ulcers in diabetic patients and that ulceration is often a precursor of lower-extremity amputation. Many structural abnormalities in the foot have been associated with increased levels of plantar pressure. In a person with diabetes, claw toe deformity and Charcot’s neuroarthropathy are among the most important abnormalities that can cause significant disruption to the architecture of the foot and elevated local foot pressures. The combination of foot deformity, loss of protective sensation, and inadequate off-loading leads to tissue damage and ulceration. Once an ulcer has formed, the studies described herein indicate that unless the ulcerated area is off-loaded, healing may be chronically delayed, even in an adequately perfused limb. After an ulcer is healed, the risk of recurrence is high (40% in a median of 4 months in one recent study), showing the need for continuous off-loading in these patients.

In this article, we demonstrate that effective off-loading of diabetic feet is important for ulcer healing and the prevention of ulcer recurrence. There is not yet sufficient evidence to support primary prevention of ulcers by off-loading, although clinical opinion strongly favors such an approach. Many new potential solutions for healing diabetic foot ulcers, such as topically applied growth factors, bioengineered skin, and stem cells, have been proposed. What all of the solutions have in common is that they require a mechanical environment that will not destroy the healing construct. This must be achieved by a device that effectively removes mechanical stress from the wound and its immediate environment. The effectiveness of off-loading must be judged by the relief of stress and by the patient’s adherence to the treatment.

The Evidence Base: What Works and What Does Not Work?

Pressure Off-loading

Total-contact casts and removable walkers have been shown to be extremely effective in off-loading
the diabetic foot, with reported peak pressure reduction in the forefoot of up to 87% compared with a control condition (Fig. 2).\textsuperscript{16-19} This effect may be achieved, among other mechanisms, by limiting ankle motion and redistributing load to the device itself.\textsuperscript{20} For these reasons, devices that extend only to the ankle, such as cast shoes and forefoot off-loading shoes, may be less effective in off-loading the foot than devices that extend above the ankle, as do total-contact casts and walkers. Reported off-loading values for such devices range from 44% to 64% compared with controls.\textsuperscript{18-22} Various therapeutic footwear designs can effectively off-load at-risk foot regions. Among these designs, rocker-bottom outsoles, custom-made insoles, and some shoe inserts (eg, metatarsal pads and medial arch supports) may reduce forefoot peak pressure 16% to 52% compared with controls.\textsuperscript{18, 23-28} However, the design and placement of such devices is critical and, without pressure measurement, difficult to establish. The surgical approaches to Achilles tendon lengthening and liquid silicone injections under the metatarsal heads may only temporarily reduce pressure underneath the forefoot.\textsuperscript{29, 30} Callus removal can reduce pressures by as much as 30%, although the durability of such relief is unknown.\textsuperscript{31, 32} Different interventions exhibit great variations in off-loading capacity (Fig. 2), and this likely influences their efficacy in preventing or healing foot ulcers in diabetic patients.

**Ulcer Healing**

The largest evidence base on off-loading available is for the treatment of primarily uncomplicated neuropathic plantar foot ulcers (Fig. 3). A variety of different metrics are used in wound-healing studies to characterize progress toward healing, including percentage of wound closure in a given time and time to complete healing. It is generally assumed that in clinical practice, time to complete healing is the most important consideration because

![Figure 2. The off-loading capacities of different modalities used for the prevention and treatment of diabetic plantar foot ulcers is expressed as percentage of peak pressure reduction at the first metatarsal head region compared with a control condition. Dark gray bars show the minimum and light gray bars the range in percentage peak pressure reduction found in different studies. TCC indicates total-contact cast. Aircast is manufactured by DJO Inc, Vista, California; CAM Walker by Zinco Industries Inc, Pasadena, California; DH Pressure Relief by Royce Medical Co, Camarillo, California; Mabal is a device described by Hissink et al\textsuperscript{5}; and VACOdiaped by OPED Inc, Framingham, Massachusetts.](image-url)
this affects treatment costs and presumably lowers the risk of infection.

Several randomized controlled trials have shown that the total-contact cast is more effective than removable devices in terms of healing proportions (Fig. 3) and time to healing.\(^{33-36}\) One recent randomized controlled trial\(^{37}\) showed similar healing rates between the total-contact cast and an ankle-high removable walker. A meta-analysis (JS Ulbrecht, MD, written personal communication, 2010) of 11 studies using the total-contact cast\(^{33, 34, 38-46}\) showed that 92% of the 277 treated ulcers healed in a mean of 42 days (range, 31–79 days). These ulcers had existed for an average of 282 days before treatment was initiated. However, adverse effects with total-contact casts may occur and include reduced activity level, difficulty with sleeping or driving a car, and iatrogenic ulcers due to poor casting technique. Alternatively, below-the-knee removable walkers that have been made nonremovable may be as effective as total-contact casts and more effective than standard removable walkers in healing plantar foot ulcers.\(^{47-49}\)

Ulcer healing using removable devices is complicated by patients not adhering to recommendations for using their prescription device. One study\(^{50}\) found that patients used their prescribed removable device for an average of only 29% of their total daily number of steps. This may explain the lower effectiveness of removable devices and points to the importance of continued pressure relief to promote healing. Half shoes, forefoot off-loading shoes, and cast shoes may be effective in healing neuropathic forefoot ulcers (healing proportions: 58%–91%), although their efficacy requires confirmation in prospective trials.\(^{34, 51-54}\)

Conventional or standard therapeutic footwear is not effective in ulcer healing, and the role of custom footwear in this context is not yet clear.\(^{55}\) Several prospective controlled studies have shown that surgical interventions, such as Achilles tendon lengthening, metatarsophalangeal joint arthroplasty, and metatarsal head resection, may have only limited additional value in ulcer healing compared with conservative treatment.\(^{56-60}\)

Neuroischemic or infected wounds can also be treated with off-loading, although success rates are much lower.

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**Figure 3.** Histogram showing the proportion of healed ulcers expressed in percentages (black bars) and time to healing expressed in number of days (dark gray bars) for different off-loading modalities used to treat noncomplicated neuropathic plantar foot ulcers in diabetic patients. The light gray bars show the range in the proportion of healed ulcers or time to healing found in different studies.
lower than for purely neuropathic wounds. In summary, the data on ulcer healing support the use of nonremovable off-loading modalities, whereas the role of certain removable devices and surgical procedures requires further definition in prospective controlled studies.

Ulcer Prevention

Several prospective studies have shown a beneficial effect of the use of therapeutic footwear compared with standard footwear in preventing ulcer recurrence. However, one randomized controlled trials showed no effect. These contrasting results are likely attributable to the wide diversity of intervention and control conditions tested and the lack of information about off-loading efficacy of the footwear used. This lack of standardization complicates the comparison of studies and limits the definition of the role of special footwear in ulcer prevention. In this context, a recent prospective 5-year analysis on the use of a previously defined footwear prescription algorithm showed much lower primary and secondary ulceration rates compared with the rates in the preceding 5 years in the same study center. This demonstrates the usefulness of such a structured approach for ulcer prevention. Surgical interventions may reduce ulcer recurrence rates in selected patients compared with conservative treatment. However, complications may occur with these procedures such as transfer ulcers and impaired balance during walking. Overall, the evidence base to support the safe use of therapeutic footwear and surgical procedures for ulcer prevention is still weak, although some recent studies show promising results in this regard.

We do not yet know the exact pressure threshold that will prevent plantar tissue damage from occurring. Recently, researchers examined patients who had remained healed after plantar ulceration and found a mean pressure of approximately 200 kPa at the previous ulcer site. It may be that such a threshold is unique to each individual, but the 200-kPa value can serve as a goal for plantar off-loading until better evidence is available.

Clinical Recommendations

Recently, efforts have been made by the International Working Group on the Diabetic Foot to develop specific evidence-based guidelines on the use of footwear and off-loading for ulcer prevention and healing in the diabetic foot. Recommendations for the use of off-loading in treating uncomplicated neuropathic plantar foot ulcers are as follows: 1) relieving pressure on ulcers should always be a part of the treatment plan; 2) total-contact casts and nonremovable walkers are the preferred interventions (the clinician should, however, be aware of possible adverse effects of these devices); 3) forefoot off-loading shoes or cast shoes may be used when above-the-ankle devices are contraindicated or not tolerated by the patient; and 4) conventional or standard therapeutic footwear should not be used because many other devices are more effective.

Recommendations for the use of off-loading in ulcer prevention in patients with an at-risk foot are as follows: 1) regular callus removal should be provided by a skilled health-care professional, 2) patients should be urged not to walk barefoot, and 3) therapeutic footwear, including a custom-molded insole in a shoe with adequate depth, is the preferred intervention.

Although surgical procedures may be effective for ulcer healing or secondary prevention in selected patients, more studies are needed to better define the role of surgery compared with conservative treatment before it can be recommended for widespread use.

Discussion

We have presented strong evidence that uncomplicated plantar ulcers can be healed in approximately 6 to 8 weeks. This time frame is in sharp contrast to reported clinical experience in the “standard of care” arms of US clinical trials in which only 24% and 31% of uncomplicated ulcers were healed after 12 and 20 weeks, respectively. We believe that inadequate use of off-loading explains this difference. The guidelines discussed herein are clear: nonremovable off-loading is the gold standard. However, Wu et al found that 41% of 895 US clinics responding to a survey attempted to off-load patients with shoes, whereas less than 2% used total-contact casts. Similarly, Fife et al reported that only 6% of patients with ulcer received a total-contact cast. However, of patients who received a total-contact cast, the average cost of treatment was half that incurred by patients who did not. In Europe, the situation is not markedly different. Prompers et al found that an average of only 35% of plantar foot ulcers treated in 14 specialized centers across the continent received casting (range, 0%–68%, of which only half was with a total-contact cast). Clearly, a large discrepancy
exists between guidelines and clinical practice in off-loading diabetic foot ulcers.

How can this gap between recommendations and practice be bridged? One solution is for professional societies to help change the expectations among their members regarding the time that diabetic foot ulcers take to heal. Societies such as the American Podiatric Medical Association and the Society for Vascular Surgery could also formally adopt the international guidelines, which are presently not well-known in the United States. Such a lack of guidelines leads to heterogeneity of treatment that does not benefit the patient. Many providers resist guidelines because they correctly point out that every patient is unique and many additional intrinsic and extrinsic factors, such as technical difficulty, time of application, cost-effectiveness, and reimbursement issues, affect the choice of treatment. We believe that poor off-loading is poor treatment regardless of the constellation of other factors that must be considered. Previous recommendations may have been too general, but recent evidence-based guidelines are specific and support implementation. In addition, in the same way that decubitus ulcers, hip fractures, and six other “reasonably preventable” conditions that occur after admission to the hospital are not reimbursed in the United States by Medicare, the future may bring a similar change in the burden of financial responsibility for what have traditionally been called “nonhealing” neuropathic ulcers.

Many ulcers are, indeed, complicated by factors such as infection and vascular disease, and the same expectations for time to heal cannot be applied to infected neuroischemic wounds. However, off-loading is still important in such complex wounds, perhaps even more so because of the enhanced risk of limb loss in these patients.

An additional barrier to appropriate prescription may be that some practitioners are not trained to specify appropriate footwear interventions and may resist referring patients to qualified specialists. Establishing a good relationship with qualified providers of therapeutic footwear and orthotic interventions is an important component of comprehensive care for the diabetic foot. If a provider does not have such expertise in-house, then locating a qualified individual, perhaps with the help of specialized societies (such as the Pedorthic Footwear Association in the United States [http://www.pedorthics.org]), should be considered.

Another major advance for off-loading the diabetic foot for ulcer prevention and healing would be a requirement that measurable and effective pressure reduction should result from all prescribed interventions and that preferably such pressure reduction be optimal (Fig. 1). Requirements for demonstrated efficacy have recently been introduced in Germany. This will not be possible at every treatment location because of cost, but specialized centers should consider adding the capability for pressure measurement to their prescription approach.

Current clinical practice includes several modalities for healing diabetic foot ulcers that may be effective, although no evidence base for their use exists. We strongly urge clinicians and researchers to prove the effectiveness of these devices to support their use in clinical practice.

Documented pressure reduction is, of course, necessary but not sufficient for healing or preventing foot ulcers. Approaches that force adherence to off-loading in ulcer treatment by the application of some nonremovable device must be given consideration in all cases where there is no contraindication. Considerations for preventing ulcer recurrence are somewhat different although no less important. Ulcer-free survival is poor, and a reduction in the number of ulcer recurrences is a major challenge that needs to be faced. Nonremovable devices cannot be used, and a behavioral intervention combined with footwear that effectively off-loads previously injured regions is required. However, effective strategies to increase adherence have not yet been well established. The provider can increase the chance that the interventions will be used by providing attractive footwear and by accepting the fact that outdoor therapeutic shoes (the typical prescription) are unlikely to be worn at home. The provision of off-loading sandals or slippers may reduce barefoot walking at home, but currently it is likely that the patient will have to bear the cost of the additional footwear. If future studies can show a reduction in repeated ulceration when multiple types of footwear are dispensed, this would be a powerful rationale to petition for change in reimbursement policies. Currently, Medicare allows only one pair of shoes and three pairs of insoles per calendar year, and in Europe, insurance companies generally do not reimburse multiple types of footwear in the same calendar year.

**Summary**

We have presented evidence for the role of off-loading in the prevention and treatment of plantar ulcers in the diabetic foot. We point out that there is a gap between evidence-based guidelines and
current practice, particularly regarding the use of nonremovable off-loading devices to heal uncomplicated neuropathic ulcers. A variety of strategies are proposed to address this gap, notably the adoption and implementation of recently established international guidelines, which are evidence-based and specific, by professional societies in the United States and Europe. Such an approach would improve the current poor expectations for healing of diabetic plantar ulcers.

Financial Disclosure: Dr. Cavanagh holds equity in DIAPedia LLC. He is an inventor on US patents 6,610,897, 6,720,470, and 7,206,718, which elucidate a load-relieving dressing and a method of insole manufacture for off-loading. He has received honoraria from Merck, Eli Lilly, and ConvaTec, and he is the recipient of grants from the National Institutes of Health and NASA.

Conflict of Interest: None reported.

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