Pressure Mitigation for the Diabetic Foot Ulcer

Off-loading remains an essential method of treating these wounds.

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Introduction

Diabetes mellitus is a serious, lifelong condition associated with multifaceted complications. In the United States alone, over 29 million people, about 9.3% of the population, have diabetes.[1] Persons with diabetes may have up to a 25% lifetime risk of developing diabetic foot ulcerations.[2] Diabetic foot ulceration or DFU can be characterized as neuropathic, ischemic, or neuroischemic.

Approximately 56% of DFUs become infected and foot complications are associated with approximately one quarter of all hospital days for persons with diabetes.[3,4] Twenty percent of patients with infected foot wounds end up with some form of lower extremity amputation. Diabetes-related amputations cost approximately $3 billion per year.[5] The five-year amputation rates are 11%, 25%, and 29% for patients with neuropathic, neuroischemic, and ischemic DFUs, respectively.[6] The 5-year mortality rates are 45%, 18%, and 55% for patients with neuropathic, neuroischemic, and ischemic DFUs, respectively.[6] The five-year mortality rate associated with diabetic patients after a major amputation is worse than that of most cancers, including colorectal cancer, breast cancer, Hodgkin's disease, and prostate cancer.[7] The only cancer with a worse prognosis is lung cancer.

Skin as a Protective Barrier

The skin functions as a protective wall that surrounds and protects the foot from harmful micro-organisms. A DFU constitutes a breach in this barrier. Once a breach occurs, the foot is more susceptible to invasion from harmful bacteria that can cause infection. It stands to reason that the longer an ulcer remains open and untreated, the greater the risk of infection. Studies have shown that wound duration of greater than 30 days is a significant independent risk factor for foot amputations.[8] Therefore it is important to help treat and prevent diabetic foot ulcerations and infections to help prevent amputations.

Foot ulcers are caused by an imbalance between excessive pressure at the plantar aspect of the foot and cycles of repetitive stress resulting from daily ambulation. It does not take much pressure to cause an ulcer, so the skin has a built-in protection system. Harmful pressure or motion against the skin will set off a pain alarm to protect against further injury.

Unfortunately, people with diabetes often develop diabetic peripheral neuropathy with loss of protective sensation. This loss of protective sensation voids the ability to adequately respond to a noxious stimulus, and patients with diabetic neuropathy will not notice the problem until an ulcer has already formed. Foot deformities, limited joint mobility, partial foot amputations, and other structural deformities often predispose diabetic patients with peripheral neuropathy to abnormal weight-bearing, areas of concentrated pressure, and abnormal shear forces that significantly increase their risk of ulceration.[2] Analogous to how one would wear a hole in one's socks, a person with diabetic neuropathy can wear a hole in the bottom of his or her foot.

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When treating a DFU, first ensure that the patient has adequate vascularity and that the wound is free of infection or bacterial colonization. Provision of an ideal wound environment by means of debridement will reduce chronic inflammatory byproducts in a wound.[9,10] Providers should also ensure adequate relief of repetitive pressure. Pressure reduction, commonly known as "off-loading," is most successful

Continued on page 80

Pressure Mitigation *(from page 79)*

when force is spread over a wide area and patient compliance is ensured.[11-13] This article will focus on pressure mitigation for the DFU.

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Pressure Reduction (Off-loading) Modalities

Pressure dispersion, commonly referred to as "off-loading," is most successful when the pressure forces are spread over a wide area.[12] Some commonly described methods to off-load the foot include: bed rest, wheel chair, crutches, half-shoes, depth inlay shoes, removable cast walkers, and total contact casts. Wheelchairs are effective pressure-reduction devices. However, most patients' homes, where much of their daily activities take place, are not designed to accommodate the bulkiness of the wheelchairs, thereby decreasing its effectiveness at pressure mitigation for the DFU.[11]

Although commonly prescribed, crutches and walkers may cause additional pressure to be applied to the contralateral limb, thus putting it at risk for ulceration. Moreover, the majority of patients suffering from diabetic foot wounds may not have the upper body strength, balance, or endurance to use these devices.[11]

The forefoot off-loading shoe or the half-shoe was originally developed to decrease post-operative pressure on the forefoot. The design of the shoe consists of a wedged-sole that ends just proximal to the level of the metatarsal heads to eliminate propulsive gait and dissipate ground-reactive forces on the forefoot.[14] Gait lab analysis has shown half-shoes to be less effective in reducing pressure than the total contact casts and certain types of removable cast walkers.[13]

A recent systematic review assessing the effectiveness of footwear and other removable off-loading devices in the treatment of DFUs found half-shoes to be the second least effective intervention.[15] Half shoes are, however, commonly used in the treatment of diabetic foot ulcerations because they are inexpensive and easy to apply.

Patients are often prescribed therapeutic or depth inlay shoes in the treatment of DFUs. However, therapeutic shoes have not proven to be effective in this role. In a clinical study, 31% of patients randomized to therapeutic shoes healed, versus a 90% healing success rate for patients randomized to total contact casts.[16] Gait lab studies suggest that therapeutic shoes allow much greater pressure in areas of the forefoot.[13] A recent systematic review found currently available therapeutic shoes to be the least effective intervention.[15]

Removable Cast Walkers

Removable cast walkers (RCW), often called walking casts, are devices that limit propulsion by keeping the ankle at 90 degrees and mitigating peak forefoot plantar pressure.[13] Patients can bathe and sleep more comfortably with the RCW, and because they are removable, RCWs can be used for infected wounds and allow for self-inspection of the wound and application of topical therapies. However, the best feature of the RCW is also paradoxically its potential downfall.

The ability to remove the device eliminates the element of "forced compliance" that is the finest attribute of the total contact cast. A study evaluated the activity of patients with DFUs and found that patients wore their prescribed off-loading device for only a small part of their walking activity.[17]

As easy as it was for the clinicians to apply the RCW, it was just as easy for the patients to remove it. The results of several recent meta-analyses demonstrate that non-removable off-loading devices, regardless of the type, prove the most effective pressure mitigation interventions for the healing of DFUs.[15,18-19] It stands to reason that control of this important aspect of care with less easily removable devices may increase the rate of wound healing.[17] This led to the development of the "instant total contact cast."

Instant Total Contact Cast

The instant total contact cast (iTCC) involves simply wrapping an RCW with a single layer of cohesive bandage, Elastoplast, or casting tape, thereby rendering it irremovable.[20] An iTCC may best address the limitations of both a traditional TCC and RCW in that it may enforce compliance and pressure redistribution while allowing for ease of application and examination of the ulcer, when needed. Two studies evaluated the wound-healing efficacy of the iTCC and found no differences in healing rates and the mean healing time between patients who received the TCC versus the iTCC.[21-22]

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Total Contact Cast

Of the numerous off-loading devices, total contact casting (TCC) is

Continued on page 82

Pressure Mitigation *(from page 80)*

considered by many to be the "gold standard" in achieving pressure redistribution. Plaster casting to treat neuropathic foot wounds was first described by Milroy Paul and later popularized in the United States by Dr. Paul Brand at the Hansen's Disease Center in Carville, Louisiana.[23-24] The technique employs a well-molded, minimally padded cast that maintains contact with the entire plantar aspect of the foot and the lower leg. The intimate fit of the cast material to the plantar surface of the foot helps increase the plantar weight-bearing surface area to disperse the plantar pressure from one or two distinct areas to the plantar foot as a whole.[23-24]

The TCC may help reduce inflammatory/reactive components and enhance the repair processes. It may also help reduce or control swelling that can impede healing and it may potentially protect the foot from infection.[25] TCCs have been shown to reduce pressure at the site of ulceration by 84-92%. They are quite efficacious with healing rates, ranging from 72% to 100% over a course of five to seven weeks.[25-28]

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Off-loading Device Utilization

While the healing efficacy for the TCC is well documented with high-level evidence supporting its use, the TCC is paradoxically one of the least-utilized offloading modalities. Data from diabetic foot ulcer management surveys and the U.S. Wound Registry noted that TCCs were used, at most, 2% of the time across the United States.[29-30] One of the reasons for the under-use of the TCC may be that its application is time-consuming and often requires a learning curve.[29] Most centers do not have a physician or cast technician available with adequate training or experience to safely apply a TCC. Improper cast application can cause skin irritation and, in some cases, even ulceration.

Moreover, TCCs do not allow daily assessment of the foot or wound and are therefore often contra-indicated in cases of soft tissue or bone infections. Other patient complaints may include difficulty sleeping comfortably, exacerbated postural instability, as well as bathing difficulties in avoiding getting the cast wet.[29] More clinicians opt to use the RCW[29] that can easily be converted into an iTCC. Studies have shown that the iTCC is equally efficacious as the TCC in healing DFUs, with decreased cost in materials, personnel and time.[30]

Shoe Modification

Shoe modification was one of the most commonly utilized off-loading methods in the United States, 29) and may be commonly implemented because patients are resistant to casts or the extra costs associated with RCWs. Shoe modifications are often less costly than other modalities and are reimbursable, and patients are often more tolerant of the slight modifications made to shoes with which they are most familiar.[29]

Moreover, shoe modifications may be preferred in patients with poor postural stability, since these patients are unable to walk safely in a device that restricts their balance. As with many off-loading modalities, including the RCW and half shoe, studies evaluating outcomes, patient satisfaction, costs, and complications are needed to study this modality completely, compared to other frequently used devices.

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Off-loading and Wound Healing Efficacy

Wound repair is an orchestra of highly integrated cellular and biochemical response to injury.[31] Integrating the field of bio-engineering with advances in our understanding of the complex cellular and biochemical mechanisms of wound healing have led to the development of various advanced wound healing modalities. Despite the plethora of advances made in this area, the results from clinical studies evaluating the efficacy of these advanced wound-healing agents have been less impressive that those associated with the TCC.

By comparison, published healing rates for TCCs are noted to be 80-90%, while only 45-55% for biologic tissues.[32-35] Most studies either offered shoes, sandals, or RCWs to study participants, or allowed individual centers to select the type of pressure relief instead of employing irremovable off-loading. This emphasizes the importance of using advanced wound-healing modalities as adjuvant therapies that work synergistically with standard wound care regimens such as routine debridement, infection control, adequate vascularity to the affected area, and most importantly, pressure mitigation.[38-39]

Without adhering to these important basic principles, the addition of an active adjunctive modality is

Continued on page 84

Pressure Mitigation *(from page 82)*

less likely to result in improved healing rates.

Conclusion

Diabetes mellitus affects hundreds of millions of people. Lower extremity complications in persons with diabetes have become an increasingly significant public health concern in both the developed and developing world. Pedal complications, beginning with peripheral neuropathy, increased focal plantar pressure, and subsequent diabetic foot wounds frequently lead to infection and lower extremity amputation. In order to help diminish the detrimental consequences associated with DFUs, implementation of a common-sense-based treatment approach is essential.

The fundamental basics in the healing of diabetic foot ulcers include adequate perfusion, debridement, infection control, and pressure mitigation. This standard should combine the tried and true approaches to wound healing, along with rational allocation of newer technologies.

Appropriate wound care, adequate debridement, and patient compliance to pressure reduction have been and will continue to be the cornerstones of treatment to potentially avert lower limb amputations. **PM**

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Continued on page 85

Pressure Mitigation *(from page 84)*

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