EXPERT OPINION

Advances and alternatives in diabetic ulcer offloading

Figure 1. Diabetic foot ulcer

KEY MESSAGES

1. Effective offloading of high pressure areas of the foot is a key treatment principle for diabetic foot ulcers.
2. Diabetic foot ulcers are best offloaded with knee-high devices such as total contact cast or walker.
3. Healing of the ulcer occurs most effectively when these devices are non-removable.
4. It is important to consider both the offloading properties of a device and the patient's experience with the device.
5. Consider "transitional offloading" when moving a patient from cast or walker to custom-molded shoes.

Diabetic foot ulcers pose life-threatening risks to patients with diabetes. Offloading of high pressure areas of the foot is key to successful treatment. We review various methods here.

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Diabetes is a chronic condition that affects nearly 10% of the US population, with individuals of American Indian/Alaskan Native, non-Hispanic black, and Hispanic heritage known to be at greater risk than Caucasians.[1] A common complication seen in diabetes is damage of peripheral nerves (diabetic neuropathy), which can subsequently lead to muscle weakness and loss of pain sensation. The etiology of plantar foot ulcers is multifactorial: An insensate foot, combined with increased plantar pressure from structural foot deformities, acute or repetitive trauma, or poor fitting shoes, can progress to the development of plantar foot ulcers.[2,3]

A plantar foot ulcer is a wound penetrating through the dermis (full-thickness lesion) at the plantar side of the foot. In people with diabetes, these are known as diabetic foot ulcers (DFUs). The lifetime risk of developing a foot ulcer in the diabetic population is between 15% and 25%.[4-6] The International Working Group on the Diabetic Foot reports that, annually 9.1–26.1 million individuals with diabetes will develop a foot ulcer annually.[7] Treatment for DFUs is estimated to be one-third the total cost of diabetes care: in 2012, that totaled an estimated $176 billion in US healthcare expenses.[8] Despite the significant costs directed toward treating these ulcers, about 20% of patients have unhealed ulcers at 1 year.[9] Of the patients with healed DFUs, there is a 40% recurrence rate within 1 year. [7]

The presence of these ulcers can lead to further complications including osteomyelitis and soft tissue infections. Infections of foot ulcers delay wound healing,[2,10] increase a person's risk for amputation of the foot or leg,[2] and increase the risk of mortality.[11] Within the US diabetic population, the major predictive factor of amputations of the lower leg is the development of a foot ulcer. Indeed, roughly 85% of amputations in this population are preceded by a DFU.[2] Post-amputation, the 5-year mortality rate in this group is approximately 45% for those with foot ulcers.[2] Compared to diabetic patients without foot ulcers, diabetic patients who develop a foot ulcer have a 2.5-fold increased risk of death from complications related to diabetes.[11]

Diabetic foot ulcers are a significant complication for geriatric patients with diabetes. A recent health care services and outcomes study reported a mean age of 67 ± 16 years for its 2.5 million diabetic foot ulcer cases and 67 ± 16 years for its 4.2 million diabetic foot infection cases.[12] The economic implications of treating geriatric diabetic foot ulcers is also not insignificant.

Medicare reimbursements in the United States for beneficiaries with diabetic foot ulcers are roughly 3 times higher for health care services compared to diabetic patients without a prevalent diabetic foot ulcer.[13]

Current treatment paradigm

The core principles for treating DFUs were originally put forward by Frederick Treves (1853-1923) and included: *sharp debridement, wound offloading*, and *diabetic foot education*.[14] These principles have been expanded since then and now include: *wound care with surgical debridement, wound offloading, dressings that promote a moist wound environment, vascular assessment, infection management, and glycemic control.*[8,15-17] Each of these components in the multiplex treatment of DFUs is individually important and strongly recommended; the component with the highest level of supporting evidence is wound offloading.[18]

Although the total contact cast (TCC) has long been considered the gold standard for offloading the diabetic foot, few practitioners use this modality daily.[19,20,21] The majority of studies of the TCC have demonstrated healing rates as high as 90% at 12 weeks.[22,23] Despite these data, the majority of practitioners treating DFUs use one of several alternative devices to try and accomplish the same results. These include the removable cast walker (RCW), the irremovable cast walker (iRCW) or instant total contact cast (iTCC), the modified Carville healing sandal, the felted foam technique, the football dressing, commercial offloading shoes, and depth footwear. There has been much research dedicated to improving offloading of diabetic feet in recent years. This review will cover recent advances in offloading.

Offloading the diabetic foot

When a person steps on the ground, the ground exerts a force on the body known as the ground reactive force. This ground reactive force can be split into two components: the horizontal component (also called shear stress) and the vertical component. The shear stresses and, less significantly, the vertical pressures are key contributory factors in the formation of DFUs and their poor healing potential.[24] Plantar shear stresses are higher in people with diabetic neuropathy when compared to non-neuropathic counterparts.[25] It has also been shown that diabetic patients with a history of foot ulcerations have significantly more plantar shear stress than diabetic patients with no history of ulceration.[24] Current accepted treatment modalities for offloading DFUs include TCCs, RCWs, and iRCWs.

Total contact cast (TCC)

A TCC can be applied using plaster or fiberglass materials.[26] Generally, the cast is prepared using casting tape that has been molded to keep contact with the bottom of the foot and lower leg.[26] In the TCC, the foot is suspended by the load-bearing capacity of the walls of the TCC, which contributes mechanically to the pressure reduction and redistribution properties of the TCC.[27] Direct measurements inside the walls of the TCC have shown that the TCC wall bears 23-34% of the plantar load.[28] This reduces the forces applied over the ulcer area.[29-31] Studies have shown that casting controls localized swelling[30,32] and acts as a barrier to infection.[33] Furthermore, given that each cast is custom made to an individual's unique foot and lower leg architecture, they can be useful in cases when premade cast walkers do not fit adequately.[31]

Figure 2. Classic TCC

TCCs are irremovable, which presents several obvious drawbacks. For instance, TCCs do not allow for daily inspection of the ulcer. TCCs are also contraindicated in patients with severe peripheral arterial disease,[30] untreated osteomyelitis or soft tissue infections, ulcers on the contralateral limb, and in patients with poor balance. TCCs should only be used if the diabetic patient has ankle pressures ≥ 80 mm Hg, a toe pressure ≥ 74 mm Hg, an ankle-brachial index ≥ 0.55, or a toe-brachial index ≥ 0.55. TCCs also markedly interfere with a patient's daily activities including sleeping, bathing and operating motor vehicles. If improperly applied, a TCC can lead to further ulcers and irritation, therefore

Table 1: Available Total Contact Casting Systems

Casting System	Description
TCC-EZ™	Roll-on Fiberglas to make application easier Less benefit in heavier or more mobile patients Higher cost
TrueKast™	Built-in saw for easy removal Conversely, the saw may decrease compliance
BSN Cutimed™	Traditional Fiberglas TCC with BSN cast tape
M-Medical™	Traditional Fiberglas TCC with padded protection to prevent iatrogenic lesions
3M-Soft Cast™	Knitted Fiberglas material impregnated with a water-activated resin

they should only be applied by a qualified healthcare professional.[26] To minimize complications related to the cast, traditional TCC made from plaster of paris or other rigid cast material require weekly applications, which is labor and cost intensive.[4,10] As a result, the inherent irremovable nature of the TCC obligates the patient to be compliant with treatment, which leads to improved patient outcomes.[26]

Figure 3. TCC System with Cast Shoe

Many of the advances in TCC have come from developing new systems which can increase efficiency and decrease application time. The application time and difficulty in applying the cast itself have traditionally been barriers to utilizing TCC in clinical setting. Several casting systems are now available which can ease the usage of the TCC (Table 1).

Rader football dressings

The Rader football dressing was introduced in 2008[35] and its use has been increasing as more data has become available. The dressing can be used for patients in whom a TCC is contraindicated or when a cast walker cannot be obtained due to insurance limitations or other circumstances.[35] The football dressing uses several layers of cast padding, secured with woven gauze roll bandage, additional padding, additional gauze and a layer of self-adherent wrap to finish the dressing and keep it in place. One can substitute a ¾-inch polyurethane foam layer against the foot or add a felted foam component to the dressing to augment its cushioning effect.

Figure 4. Rader Football Dressing

Removable and irremovable cast walkers

Removable cast walkers reduce pressures on the forefoot by having a rocker sole and keeping the ankle at 90-degrees.[10] Unlike TCC, RCWs allow for daily inspections of the ulcer and dressing changes, and since they are easily removed, they can be used for infected DFUs.[26] RCWs also have less interference in a patient's daily activities such as bathing and sleeping.[33] RCWs have the benefit of greater forefoot offloading when compared to TCCs (forefoot being the most frequent site of diabetic ulceration).[36] Nevertheless, since these cast walkers are easily removed, they decrease patient adherence and decrease the rate of ulcer healing.[26] Adherence of cast walkers can be increased by making them irremovable. This is done by securing them in place with plaster, fiberglass, cohesive bandage, or a cable or ziptie. Like TCCs, cast walkers, both removable and irremovable, are contraindicated in patients with severe peripheral artery disease and poor balance.[37] Because they are pre-fabricated and not custom-made, they may not be suitable for all patients, particularly those with lower extremity deformities, wider feet or very short legs.[26] There are several other viable alternatives to TCCs in patients that may have contraindications. Table 2[38-47] lists alternatives to total contact casting. See Snyder and Lanier[37] for an evaluation of these methods and their application to offloading DFUs.

Figure 5. Removable Cast Walker with Memory Foam Insert

Insoles to improve healing

Total contact insoles improve pressure distribution and increase the effectiveness of offloading devices being used. Unfortunately, many insoles are not adjustable or custom-molded to either the foot (heat molded) or a positive cast of the patient. The typical multi-laminate insole dispensed today is rarely molded because of time and financial constraints. Medicare's Therapeutic Shoe Bill clearly states that the insole must be molded prior to insertion into a depth shoe. Most patients end up dynamically molding the insole over time, a technique clearly discouraged by the shoe bill itself. Custom-molded insoles have been demonstrated to be superior to non-custom insoles in decreasing pressures under the metatarsal heads.[48] Pixellated insoles designed to allow for easy removal of pressure from ulcerated areas have been shown to reduce pressure by as much as 46% in one small study.[49]

Total contact molding increases insole contact area, spreading pressure out across the entire surface of the foot. Multi-laminate insoles have the potential to be molded or conform over time, but do not have an inherent ability to offload. Without contouring, they are sophisticated cushioning devices at best. Some commercial offloading devices have insoles with removable hexagonal, square, or diamond shaped plugs to selectively offload specific areas of the foot. The plug insole system utilized by the Bonapeda Fors-15™ multi-density insole, in the Ossur™ Active Offloading Walker (formerly the DH Walker), the Darco Peg Assist™ system, and the Donjoy MaxTrax™ Diabetic Walking Boot are examples of such insole systems.

Figure 6. Depth Shoe with Heat Molded Innersole

Thin soles that are not thick enough to fill the arch of the

Table 2: Summary of Alternatives to Total Contact Casting for Diabetic Foot Ulcers

Device	Description
Below-Knee Cast	• Similar efficacy between TCC and standard casting[38] • Open-toe design may cause injury in neuropathic patients • Heavy padding may lead to excess movement inside cast
Charcot Restraint Orthotic Walker (CROW)	• Allows for daily ulcer inspection and edema control • Can be cumbersome for frail patients • Rapidly loses the probe-to-bone feature • Can be very expensive
Prefabricated Walker	• Healing rate of 85% within 13 weeks when made irremovable and 55% if removable[39] • May be equivalent or superior to TCC in decreasing plantar pressures[40,41] when made irremovable • Ulcerations should be padded and monitored closely
Prefabricated Pneumatic Walking Brace (PPWB)	• Prefabricated walker with inflatable air cells for improved fit • May reduce some shearing
IPOS™ Shoe (Integrated Prosthetic and Orthotic System)	• Half-shoe designed with 10 degrees of dorsiflexion and heel elevated 4cm to prohibit forefoot contact • Requires patient compliance with gait • Requires an ability to dorsiflex the ankle • Can be tripping hazard
Orthowedge™	• May be effective in offloading great toe ulcerations[42] • Tripping hazard • Requires an ability to dorsiflex the ankle
Modified Healing Sandal	• Dual-density total contact orthotic made of Plastazote in a surgical shoe • Healing rate of 74% within 13 weeks[43]
Reverse IPOS™ Heel Relief Shoe	• Shoe design that is open in the back to offload the heel • Requires an ability to toe walk • May create difficulty in balance and gait instability
L'Nard™ Splint/Multiboot	• Suspension of the heel to eliminate pressure • Adjustable toe post to relieve forefoot pressure • Rotator bar positioned to the side, controls hip and leg rotation
Ankle Foot Orthoses	• Made of molded thermoplastic material • Dorsiflexion restriction device requires a rocker sole
Patella Tendon Bearing Brace (PTB)	• Custom brace transfers weight of the foot to the patella • Reduces pressure to prevent/treat distal ulcerations[44] • Loses effectiveness if edema subsides • Can be very expensive
Toad™ Anti-Gravity (TAG) Foot Brace	• Body weight is suspended by the calf and ground contact is maintained by a posterior carbon fiber strut connected to a rocker sole • Reduced effectiveness if edema subsides • Results from a halted randomized controlled trial demonstrated reductions in peak plantar pressures between 67.3% to 89.4%[45]
MABA™ L Shoe/Scotch Boot	• Removable Fiberglas cast and shoe combination • Healing comparable to other methods[46]
Felt and Foam Total Contact Padding	• Anatomically designed to offload an ulcer when applied to the plantar skin or incorporated in a dressing • 93% healing in 12 weeks compared to 92% with TCC[47]
Motus™ Smart Boot	• Developed by Sensoria Health and Optima; uses sensors and other technologies to improve offloading • Has built-in compliance tracking system • Limited data on effectiveness • Expensive

foot may be able to cushion areas on the plantar surface but cannot transfer forces away from high-pressure areas effectively unless they are coupled with a rocker soled shoe. In our experience, the Bonapeda™, MaxTrax™, and Donjoy™ devices have sufficient depth of the foam material to allow for total contact auto-conformation of the insoles. We have found that the depth of the Darco™ and Ossur™ devices are adequate for many flat feet with low arches but lack the additional depth necessary to fill the average- or high-arched foot. An alternative to this is the Bledsoe™ Boot which uses a thick Memory Foam™ insole that auto-conforms to the plantar sole with pressure.

Figure 7. Pixellated Innersole

The removable feature of the prefabricated walker gives clinicians the ability to remove and reapply the devices for ulcer debridement and application of advanced wound-healing products. Patients can also remove them for dressing changes and wound care at home. Any time a device is removable, however, it increases the probability that the patient will walk without it. Most patients "cheat" and remove the devices to ambulate, placing their wound healing at risk.[7] To avoid this problem in our clinic, we have employed a system of securing the walker with simple inexpensive plastic cable ties to ensure patient compliance.

There is also a growing trend toward clinical usage of sensory-enhanced insoles. These insoles can monitor patient activity levels, track patient fitness and gait velocity. These devices can also monitor plantar pressures and could be beneficial in creating an environment where a patient has increased self-management. Some examples of these insoles include the Feetme™ smart inner insole, a device that connects to a phone app and collects real time data related to gait. Surrosense Rx™ is another smart insole marketed for diabetic patients. More research is needed in the usefulness of these new devices; however, current findings suggest that they may decrease the recurrence of foot ulcers.[50]

Clinical evidence

There is strong clinical evidence that offloading DFUs is a necessary component in wound healing.[16-18] Of the different offloading methods, TCC and irremovable cast walkers are regarded as the most effective in achieving healing of DFUs. This is supported by a recent systematic review of 19 interventional studies with 1605 patients with DFUs.[51] The authors found that using TCCs as an offloading method improved wound healing when compared with RCWs, therapeutic shoes, and conventional wound care. In the same study, no advantage was found for iRCWs over TCCs. Despite TCCs being more effective in offloading diabetic foot ulcers, few practitioners use this modality daily. Indeed, less than 2% of US foot clinics use TCC.[52] RCWs are far more commonly used.[40,41]

See Improving Patient Experience and Adherence[53-57] on page 38.

Transitional healing

Although there are few studies demonstrating a reduction of force in areas of high pressure on the foot using the depth shoe or healing sandal, the RCW, iTCC, and TCC are irrefutably superior in their ability to produce consistently reproducible results when healing wounds.[58] A "transitional approach," first discussed by this author in 2010,[59,60] represents a logical approach to applying each of the devices based on their demonstrated ability to offload the foot and heal open wounds. Table 3 outlines the transitional approach to diabetic foot offloading.

Knee-high devices that force compliance and restrict forward motion of the ankle should be employed as a first line treatment when the wound is open.[8] Once the wound is closed, the patient can transition to a shoe-based total contact device such as the modified surgical shoe with an insert, or a commercial offloading shoe with a similar total contact-molded insole to protect and mature the skin for the first 3 to 4 weeks after wound closure. Rapid return to standard footwear is fraught with problems and may account for a large portion of the recurrences noted in the literature associated with diabetic foot wounds.

After the wound has closed and the epithelium thickened to be able to withstand the shear and pressure forces produced during ambulation, the patient can transition to the final or permanent offloading device such as a depth or custom molded shoe. Even when completely healed, the foot should be protected with a heat or cast-molded, in-shoe, total contact foot orthotic designed to offload areas of high pressure and never return to the type of footwear used when they developed the wound. In the neuropathic foot, the risk of ulceration is higher in these high-pressure areas.[61] The addition of a rocker sole to the shoe

Table 3: Transitional Approach to Diabetic Foot Offloading

Wound State	Ulcer Healing Stage	Appropriate Offloading Device
Open Wound	Inflammatory and Proliferative Phases	TCC, iTCC, RCW
Closed Wound	Maturation Phase: <4 weeks	Modified surgical shoe; commercial offloading shoe
	Maturation Phase: >4 weeks or when epithelium can withstand shear forces	Depth or custom-molded shoe with protective orthosis and rocker sole

further reduces midfoot and forefoot pressures, decreasing the likelihood of wound recurrence.[62]

Conclusion

Diabetic foot ulcerations are a major cause of morbidity and hospitalization. They are a significant predictive factor of infection, amputation, and mortality. Therefore, treating DFUs and improving patient outcomes deserves serious focus by clinicians. The primary method of treating diabetic foot ulcers is offloading. Of the offloading methods currently in use, knee-high casts that are irremovable, such as TCCs and iRCWs, have been associated with improved wound healing. Total contact casts are of benefit in patients with lower extremity deformities which require custom molded casts. Before applying casts, it is necessary to consider certain contraindications such as depth of ulcers, presence of infection, and peripheral artery disease. It is also important to consider the patient's experience with the casting device, including how the device will impact their gait and ways of improving patient adherence if the device is removable. Addressing limb-length discrepancies (congenital and iatrogenic), improving patient education, and, more controversially, daily monitoring, are all strategies to consider when attempting to improve patient adherence with offloading devices.

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IMPROVING PATIENT EXPERIENCE AND ADHERENCE

To improve patient experience and adherence when wearing offloading devices, the clinician treating the diabetic foot ulcer should consider several key issues: patient comfort and gait, patient education, and methods of monitoring patient adherence levels. Electronic monitoring has the potential to improve adherence and reinforce a patient's ownership of the healing process.

Comfort and Gait

Patient adherences is a significant challenge in offloading DFUs. Better offloading adherence is predictive of greater DFU healing at 6-week follow-up visits.[52] A common means of forcing patient compliance is making a cast irremovable. However, making a cast irremovable and forcing patient compliance does not address the underlying reasons why a patient was non-adherent. A significant predictive factor of patient offloading adherence and delayed DFU healing is self-reported level of postural instability.[53] As such, overcoming the challenge of adherence is inseparably linked to improving the gait and comfort of the patient wearing the offloading device. Crews and Candela[54] found that when a contralateral limb lift is used in ankle-high removable cast walkers, there is an increase in patient comfort and gait.

Patient Education

Another key component in addressing patient adherence is education about the efficacy of the device being used. Educating the patient on the importance and expected efficacy of the offloading device, especially in the case of removable cast walkers, may be important predictors of adherence. Studies have shown that patients are more likely to wear diabetic footwear to prevent secondary diabetic foot ulcers when there is a perceived value of the footwear itself.[55,56] It is not unreasonable to predict that educating the patient more completely on the value of their offloading device when treating a present diabetic foot ulceration will have similar benefits of increased adherence. A more thorough discussion of patient education was written by Pal.[57]

Monitoring Patient Adherence

Monitoring patient adherence has generally been confined to research. There is no widespread objective measure of daily adherence utilized in foot clinics. Much of the determination of adherence has been subjective evaluation. There is a well-established positive association between adherence and ulcer healing. Therefore, there is a great need for technology which can monitor patient adherence throughout the day. Incorporating such a monitoring system into the standard care of DFUs could have significant benefits to patient outcomes.[58] However, whether using such technology is ethical and fiscally responsible is still a matter of debate.

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