Offloading Foot Wounds in People with Diabetes

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Abstract: Up to 25% of people with diabetes will develop a foot ulcer at some point during their lifetime, and 1 in 5 will require an amputation. In 2006, more than 65,700 lower-limb amputations were performed in the United States alone in people with diabetes, and the 5-year mortality rate following an amputation is worse than for most malignancies. Along with an interdisciplinary team approach to diabetic limb salvage, “toe and flow,” a vertical and horizontal approach to wound healing, is changing the way these patients are cared for. The vertical strategy for wound healing refers to covering important structures and filling defects with negative pressure wound therapy, while the horizontal strategy utilizes skin grafting, bioengineered skin substitutes, and aggressive offloading. The gold standard for offloading foot wounds in people with diabetes is total contact casting, however, recent studies have shown that the modality is seldom used in the current clinical setting. Other offloading devices include removable cast walkers, half shoes, healing sandals, and, more recently, lightweight, rapidly custom-built braces. Offloading of the diabetic foot is often overlooked as a critical part of wound healing, but past experience guides the authors to the conclusion that it is often not what one puts on the wound, but rather what is taken off that primarily affects healing in many of these patients.

Key words: diabetic foot ulcer, offloading, total contact casting, review

In general, foot ulcers in people with diabetes result from repetitive moderate stress encountered by the insensate foot during ambulation. Without the ability to adequately respond to noxious stimuli, patients with neuropathy may sustain a breach of the skin, the way sensate persons wear holes in their stockings. As there are no current means available to completely ameliorate the effects of neuropathy, the present tenet for treating and preventing wounds focuses on the redistribution of pressure.

Although many types of offloading devices are currently utilized, only a small number of case series exist which describe the frequency and rate of wound healing associated with these modalities. This review details the most commonly used modalities for offloading the diabetic foot, as well as evidence supporting their continued use.
Total contact casting. Total contact casting (TCC) is considered by most diabetic foot specialists to be the gold standard offloading modality. 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. The technique, which employs a well-molded, minimally padded cast, maintains contact with the entire plantar aspect of the foot and lower leg. Total contact casting has been shown to reduce pressure at the site of ulceration by 84%–92%, and there is a large body of work that supports the clinical efficacy of TCC. Furthermore, TCC has proven to be effective in treating a majority of noninfected, nonischemic plantar diabetic foot wounds, with healing rates ranging from 72%–100%.

Averaged throughout gait, peak plantar pressures are highest in the forefoot, while they tend to be less significant in the rearfoot and medial arch. Shaw et al and Armstrong and Stacpoole-Shea noted that, in TCC, a large proportion of the pressure reduction that occurs in the forefoot is transmitted to the cast wall or rearfoot, resulting in decreased forefoot pressure. This supports the postulate of several authors who have suggested that TCC is effective because it permits walking by uniformly distributing pressures.

Figure 1. Postural instability in ulcer treatment modalities. The total contact cast, when applied with a walking heel, may cause significantly more postural instability than one applied without a heel. Casts applied without heels have comparable stability profiles with many other common offloading modalities.

Figure 2. Mean peak pressure (N/cm²) for ulcers under the metatarsal heads among various removable cast walkers. Manufacturers of the products compared include DH Walker (Centec Orthopaedics, Camarillo, Calif) also licensed under the name Easy Step Pressure Relief Walker (Kendall Orthopedics, Mansfield, Mass); Aircast Walker (Aircast, Summit, NJ); 3D Walker (DeRoyal Orthopedic, Powell, TN); CAM Walker (Darco International, Inc., Huntington, WV).
over the entire plantar surface of the foot.\textsuperscript{3,5,7,12-14}

Besides its capacity to offload, TCC serves to protect the foot from infection and helps control edema.\textsuperscript{15} Perhaps the most important attribute of TCC may be its ability to ensure appropriate patient adherence. In other words, because the device is not easily removed, the patient has no option other than to comply with the regimen prescribed by the clinician.

Despite all of the reported benefits of TCC in offloading the diabetic foot, there are a number of potential negative attributes that may limit its use. First, most centers do not have a skilled health care professional or cast technician available with adequate training or experience in TCC, and improper cast application can irritate the skin, potentially leading to frank ulceration. Furthermore, TCC does not allow patients, family members, or health care providers to assess the foot or wound on a daily basis. In many cases, TCC makes sleeping and bathing difficult for patients, and certain casting designs may exacerbate postural instability.\textsuperscript{16}

Total contact casting is generally contraindicated in cases involving concomitant soft tissue infection, osteomyelitis, and/or ischemia.\textsuperscript{17} It may not be appropriate in the treatment of heel ulcers, due to the excessive pressure transmitted to the posterior foot.\textsuperscript{11} It has also been reported that the cost of materials and lack of reimbursement associated with TCC are important factors in determining the frequency of its use by the treating physician.\textsuperscript{18}

In 2008, Wu et al\textsuperscript{18} conducted a diabetic foot management survey, and found that among 895 centers involved in the active treatment of diabetic foot ulcers, only 1.7% used TCC for the majority of diabetic foot ulcer treatment. In Europe, the situation is just as concerning. In a 2008 prospective cohort study, termed the “Eurodiale Study,” Prompers et al\textsuperscript{19} investigated strategies for diabetic foot management in 14 centers, throughout 10 European nations, and found that among the subgroup of patients with neuropathic plantar forefoot or midfoot ulcers, TCC was prescribed for offloading in only 18% of cases.

In response to the growing concern over the lack of use of TCC, Fife et al\textsuperscript{20} reported the average cost of treatments with TCC was in fact about half as much, per patient, as the cost of treatments in which TCC was not used. However, with respect to reimbursement, the authors noted that for every TCC application, a treatment facility loses $18, whereas the application of a living-skin equivalent typically results in a profit of $422.

\textbf{Removable cast walkers and the “instant” total contact cast.} The removable cast walker (RCW) offers several potential advantages over traditional TCC. Removable walkers are, as their name implies, easily removed for self-inspection of the wound and application of topical therapies that require frequent administration. Patients can bathe and sleep more comfortably when wearing these devices, and, because they are removable, RCWs can be used with infected wounds.

Data from gait laboratory studies suggest that the amount of pressure reduction in certain RCWs may be equivalent to TCC.\textsuperscript{4} Figures 2 and 3 illustrate mean peak pressure for ulcers beneath the metatarsal heads using various offloading techniques. In 2 randomized controlled trials comparing the proportion of healed ulcers.
ulcers treated with TCC versus other readily available and popular devices (eg, RCWs, half shoes, and therapeutic depth inlay shoes), it was shown that TCC healed a higher proportion of wounds compared to other modalities. The results of a recent study published by Faglia and colleagues suggest that RCWs could be as effective as TCC in the treatment of plantar neuropathic diabetic foot ulcers, with respect to reduction of ulcer size and total healing rate.

Despite the fact that RCWs have been shown to offload pressure about as well as TCC, optimal healing may not occur in situations whereby patients do not wear the devices as often as prescribed. Moreover, the opportunity for patients to remove the walker eliminates the element of “forced adherence,” and excessive walking without the device can have serious consequences in terms of wound healing. Thus, the potential for non-compliance represents an inherent flaw in the offloading capabilities of RCWs.

In 2003, Armstrong et al evaluated the activity of patients with diabetic foot ulcers and their adherence to their offloading regime. The study, using accelerometers worn on the patients’ waist and hidden in the RCW, suggested that patients wore their offloading device for less than 30% of their total daily activity.

More recently, an emphasis has been placed upon improving the design of removable walkers, which could result in better patient compliance. A 2012 study by Crews et al, comparing 3 different heights of RCWs, demonstrated similar offloading capacity between a knee-high walker and ankle-high walker. Figure 4 shows data from lower profile removable cast walkers/sandals based on percentage pressure reduction compared with the full-length device.

Understanding that TCC is technically difficult and time consuming, and that patient compliance plays a key role in wound healing, Armstrong et al described a modified cast walker, which is less easily removed. This concept, termed instant total contact cast (iTCC), involves wrapping an RCW with either a layer of cohesive bandage or plaster/fiberglass (Figure 5), thereby making it more difficult for patients to remove. Thus, the iTCC affords adequate offloading and provides the added benefit of “forced compliance” to the prescribed course of pressure reduction.

Two recent randomized controlled trials support the above-mentioned postulate. In the first study, subjects given iTCC appeared to heal as readily at 12 weeks as patients undergoing standard TCC therapy (80% iTCC vs 74% TCC). A second study performed in parallel...
with this project compared the iTCC with a standard RCW and suggested that substantial differences exist in healing at 12 weeks between the irremovable and removable devices (83% vs 52%).

In 2007, Piaggesi and colleagues described an "off-the-shelf" instant contact casting device, which is made irremovable by applying a plastic lace. The lace can only be removed by a specific tool. The authors found no difference in healing rate, healing time, and number of adverse events between their device and TCC.

Scotchcast boot. The Scotchcast boot is an alternative plaster of Paris cast, developed when fiberglass materials were introduced. As a substitute for plaster of Paris, Scotchcast is much lighter with high integral strength. The basic functions of the cast are to reduce the pressure on the lesion, maintain patient mobility, and protect the remaining foot.

The Scotchcast boot is a well-padded cast cut away by the ankle and made either removable or nonremovable by cutting away the cast over the dorsum of the foot. A closure is made, consisting of padding and tape with fabric hook-and-loop fastener straps. Windows are cut over the ulcers as needed, and a removable heel cap of fiberglass is added for large heel ulcers. The boot is worn with a cast sandal to increase patient mobility, keeping the patient ambulatory while protecting the ulcer from any pressure.

Once the ulcer has healed, the patient can gradually start increasing the wear time of normal protective footwear while decreasing the wear time of the Scotchcast boot. The patient usually keeps the boot and the sandal, as this can be worn if an ulcer recurs.

The main advantage of this type of cast is that it is removable, and allows regular inspection and redressing of the wound. However, as discussed previously, the potential for non-adherence can have dire consequences, and an alternative cast for the noncompliant patient would be the nonremovable version of the Scotchcast boot.

Although the Scotchcast boot has been used successfully for more than a decade in several United Kingdom clinics, predominantly in the treatment of neuropathic and sometimes neuroischemic ulcers, no comparisons of healing rates between this type of cast and more standard casts, such as the TCC, exist. Preliminary data demonstrate healing rates ranging from 61% to 88% with a mean healing time of between 10 and 13 weeks. As with other modalities, a comparison study is warranted to investigate the efficacy of this cast against other currently used methods of offloading.

Half shoes. Originally designed to decrease pressure on the forefoot postoperatively, the half shoe has become quite popular for treating foot wounds in people with diabetes. These devices are inexpensive and easy to apply. Chantelau and coworkers retrospectively evaluated 22 patients who received the half shoe compared with 26 who received "routine wound care" and crutch-assisted gait. The results from this study suggest that more patients healed faster when using the half shoe (70 days vs 118 days), and developed fewer serious infections requiring hospitalization than those receiving standard therapy (4% vs 41%). In a gait laboratory study comparing half shoes to TCC and RCWs, half shoes were found to be much less effective at reducing pressure. Further studies evaluating outcomes, patient satisfaction, costs, and complications associated with the use of half shoes are needed.

Healing sandals. Applying a rigid rocker to the sole of a specially designed sandal may limit dorsiflexion of the metatarsophalangeal joints, thereby limiting plantar progression of the metatarsal heads during propulsion in gait. In addition, the molded nature of a healing sandal provides a greater distribution of metatarsal head...
pressures which may provide for a shorter pressure-time integral. The device is lightweight, stable, and reusable. It does, however, require a significant amount of time and experience to produce the rigid-sole rocker design and other modifications. Most facilities do not have the time or expertise to modify these devices. Finally, these devices do not work as well as many other modalities that take less effort to produce. Recently, a device known as the MABAL shoe has been introduced, which integrates the qualities of the healing sandal and RCWs. It is removable, and may provide more contact with the foot than does a standard healing sandal. In a study by Hissink et al this device showed a similar time to healing when compared to studies of TCC. However, this potentially promising device also has many of the downfalls of TCC and the healing sandal, in that special expertise for its fabrication and application is required.

Felted foam. Felted foam is another frequently used offloading technique fashioned by fixing a bilayered felt foam pad over the plantar aspect of the foot with an aperture corresponding to the ulcer site. There is always a concern when applying an aperture around a wound that “the edge effect” will increase shear and vertical forces at the wound’s periphery. This approach is frequently used at some diabetes centers with anecdotal reports of success, but to date, there are no controlled studies describing outcomes associated with this padding technique.

In 1997, Fleischli et al conducted a study comparing the offloading ability of TCC, half shoes, RCWs, rigid postoperative shoes, and felted foam accommodative dressings, and found that TCC and certain RCWs achieved the best reduction of plantar pressures at the site of neuropathic ulcerations. The half shoe finished a distant third, followed by the felted foam dressing and surgical shoe.

Crutches, walkers, and wheelchairs. It would stand to reason that completely offloading a foot with crutches, walkers, or wheelchairs would be very effective in promoting healing in the diabetic wound. However, the vast majority of patients for whom these devices are prescribed do not have the upper body strength, endurance, or will power to use these devices when they do not perceive any limitation in function in their ulcerated limb. Additionally, it should be noted that some of these devices can, in fact, place the contralateral limb at risk for ulceration by increasing pressure to the unaffected side. In the case of wheelchairs, it is prudent to understand that most patients’ domiciles are not designed for wheelchair access; thus, reducing their utility in the place where they may potentially be most active—at home.

Therapeutic footwear (depth inlay shoes). Many patients are prescribed therapeutic shoes in an effort to assist in pressure reduction and wound healing. However, these devices have not proven to be effective in this role. Gait laboratory studies suggest that therapeutic shoes allow up to 900% more pressure in areas of the forefoot compared to TCC and some RCWs. Furthermore, even the most optimistic studies using shoes as a primary offloading mechanism suggest that half of noninfected, nonischemic, superficial wounds—University of Texas Wound Classification System Grade 1A—will heal at 12 weeks. Therefore, the true value of therapeutic shoes and insoles might lie in the prevention of ulceration, rather than in offloading an active ulceration.

T-brace. The Toad Anti-Gravity (TAG) foot brace (Toad Medical Corporation, Washoe Valley, NV) is a novel device, specifically engineered for patients with diabetic foot ulcers and other lower extremity conditions requiring limited- or non-weight bearing. The brace functions by suspending a person’s weight by the calf and maintaining ground contact with a posterior carbon fiber strut connected to a rocker sole. This removable device is lightweight and easy to apply, and appears to offload the mid- and rearfoot well. The T-brace features a silicone suction-type liner which maintains suspension of the leg without causing a tourniquet effect. The suspension height of the foot is adjustable. Further studies will be required to confirm the utility of the T-brace and other, similar devices.

Conclusion

It is important to understand that while the recent history of treatment of wounds in general—and wounds in people with diabetes specifically—has been marked by some exciting advances on the high-technology front, it is in fact the low-technology systematic aspects of care that must assume priority. Wound care professionals often say, “It’s not what one puts on a wound that heals it, but what one takes off.” Appropriate wound care, debridement, and pressure reduction have and will continue to be the cornerstones of treatment. The key to successful pressure reduction possibly lies more in patient adherence than in the prescribed offloading devices. Individuals with dia-
betes who have lost the “gift of pain” may not always adhere to the offloading regimen. Combining an effective, easy-to-use offloading device that ensures patient compliance with advanced wound healing modalities may form a formidable team in healing ulcers and potentially averting lower-limb amputations.

References

25. Armstrong DG, Short B, Espensen EH, Abu-Rumman


