



Using the IWGDF Guidelines for Off-Loading the Diabetic Foot

Here are some ways to increase clinical outcomes.

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The International Working Group on the Diabetic Foot (IWGDF) was founded in 1996 as an independent, non-profit foundation established to create awareness of diabetes and to improve the management and prevention of complications associated with the diabetic foot.¹ In 2015, the IWGDF released a guideline with recommendations on “Footwear and Off-loading Interventions to Prevent and Heal Foot Ulcers in Patients with Diabetes.” The guideline when applied is an excellent tool for using evidence-based clinical decision-making instead of intuition or convention, which is the usual approach to decision-making with regard to off-loading. Choosing an appropriate off-loading device at the onset of a diabetic foot ulcer can decrease the chance of developing a chronic wound. This will prevent infections, allowing for early wound closure, and hopefully decreasing the risk of a lower extremity amputation (Figure 1).



Figure 1: Charcot Foot with Cuboid Ulcer

forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes.¹ The commonly accepted “gold standard” for off-loading the diabetic foot is the total con-

transferring weight stress to the lower leg and uniformly distributing pressure over the entire plantar surface of the foot.

The TCC has been shown to significantly reduce ulceration site pressure by as much as 84–92%, and it has been proven to be effective in treating a majority of non-infected, non-ischemic plantar diabetic foot ulcers, with healing rates as high as 72–100%.² Despite the reported benefits of using a TCC in off-loading a diabetic foot, only about 1.7% of diabetic foot ulcer treatment centers use the TCC as the primary off-loading device for the diabetic foot.³ There are several reasons why the TCC is not used as often as it should. Approximately 25% of centers reported that they do not have a skilled healthcare

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TCC

The strongest recommendation from the IWGDF with the highest quality of evidence is to offload with a non-removable, knee-high device with an appropriate foot-device interface to heal a neuropathic plantar

tact cast (TCC), which meets this requirement (Figure 2).² The technique of applying a TCC utilizes a well-molded cast that maintains total contact with the plantar aspect of the foot and the lower leg. The basic concept is to offload the foot by

professional who has training or experience to use the TCC or that there were reimbursement issues associated with using the cast. A slightly larger number of centers (31.6%) attributed avoiding the use of TCC to the

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cost of materials. The most common reasons for not using a TCC were that it took too much time to apply (54.3%) or that the patient refused it or was unable to tolerate the cast (55.3%).³ Other barriers to TCC use include inability for daily assessment of the ulcer, bathing and sleeping difficulties, and the general discomfort of wearing a cast.

Interestingly, none of the reasons listed above were documented contra-indications for using the TCC such as acute soft tissue infections, osteomyelitis, uncontrolled edema, obesity, and/or ischemia.² Why is it that total contact casting, coined the “gold standard”, is used by less than 2% of clinicians who treat diabetic foot ulcers? The term “gold standard” should be reserved for any non-removable device (NRD), something that not only yields good results but has also gained wide acceptance by the medical profession (McGuire J, Sebag J. 2016). Perhaps the most important aspect of a TCC is the “forced compliance” of a non-removable device.²

Based on the recommendations of the IWGDF, a non-removable device (NRD) is the true gold standard for off-loading the diabetic foot wound (McGuire J, Sebag J. 2016). Alternative non-removable devices include the instant total contact cast (iTCC), the Rader football dressing, and the felted foam dressing. The iTCC is simply a removable cast walker (RCW) made non-removable by wrapping it in self-adherent wrap,



Figure 3: Instant total contact cast (iTCC)



Figure 2: Total Contact Cast (TCC)

cast material, or using a cable tie connector to prevent removal by the patient (Figure 3). The iTCC takes less time to apply and remove, in addition to being more cost-effective.⁴ It takes the TCC an average of 33 days to heal an ulcer and the iTCC an average of 41.6 days, although both are deemed statistically equivalent in terms of ulcer healing rates and patient compliance.⁵

Football Dressing

The football dressing developed by Andrew J. Rader, DPM is a bulky non-removable dressing that relies on volume of padding to protect the foot and decrease ambulation, thus reducing plantar pressures (Figure 4a, 4b). The football dressing is easy to apply, requires little training, and is a fraction of the cost of the TCC while maintaining comparable healing rates in the few studies where it was utilized.⁶ The felted foam dressing utilizes a thick adhesive felt pad (1/4 inch) directly applied to the foot (or utilized as a layer in a bandage) with a cut-out around the ulcer to reduce loading pressure. If the felted foam is applied directly to the skin, a barrier such as rubber cement or collodion-based products should be applied to prevent skin irritation from the adhesive.

In one study, 93% of forefoot ulcers treated by the felted foam dressings were healed within 12 weeks (20.9 days) as compared to 92% (31.7 days) of ulcers treated with TCC.⁷ It is recommended that the Rader football and felted-foam dressings be used with a removable cast walker for ambulation in order to comply with the IWGDF guidelines that specify that a knee-high device be used. This way, a portion of the treatment is non-removable (dressings) while allowing the freedom to remove the bulky external cast walker (a knee-high device) for sleeping and resting.

The IWGDF recommends that when a non-removable knee-high device is contra-indicated or not tolerated by the patient, off-loading with a removable knee-high walker with an appropriate foot-device interface should be considered to heal a neuropathic plantar forefoot ulcer in a patient with diabetes.¹ This recom-

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Figure 4a: Football Dressing,



Figure 4b: Football Felted Foam Combination



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mendation is weakly graded with a moderate quality of evidence and is to be considered only when a patient can be expected to be adherent to wearing the device.

A removable cast walker (RCW) is a popular device that is used to offload an ulcer by incorporating a fixed ankle and low-profile rocker sole to prevent forward motion of the leg over the foot during ambulation. This reduces midfoot and forefoot pressures, therefore increasing healing rates. Compared to the average of 33 days of ulcer healing in a TCC or iTCC, an RCW takes about 51.9 days to heal.⁵ Other removable knee-high devices include patellar tendon bearing ankle foot orthoses (AFOs), Charcot restraint orthopedic walkers (CROW), or suspension-style AFOs such as the Zero-G* boot. Shorter supra-malleolar orthoses (SMOs) such as the TORCH (Total contact Orthotic Restraining



Figure 5: TORCH Boot and Custom Molded Shoe

Custom Hybrid) off-loading boot, or the Arizona brace are similar in that they restrict ankle motion but have less capacity to transfer weight to the lower leg (Figure 5).

Patient compliance will always be an issue with removable devices. According to Armstrong, et al. in 2005, it was shown that ulcer heal-

ing rates dropped from 83% (patients who used the TCC) to 52% when patients were able to remove their off-loading devices.⁸ In another study by Armstrong, patients who were monitored by accelerometers only wore their off-loading device for less than 30% of their total daily activity. Even the most compliant patients did not exceed 60% of daily activity.⁹ Anytime a removable device is used, it increases the chances that the patient will ambulate without the device, which will put the wound's healing rate at risk.

When a knee-high device (removable or non-removable) is contraindicated or cannot be tolerated by the patient, the IWGDF recommends off-loading with a forefoot off-loading shoe, cast shoe, or a custom-made temporary shoe.¹ This weakly graded and low quality of evidence recommendation should only be considered when the patient can be expected to be adherent to wearing the shoes. This is an unlikely scenario when you consider the Armstrong data. The elephant in the room is, "What is an appropriate Foot-Device Interface (FDI)?" This unfortunately was not specified in the IWGDF document.

Forefoot off-loading shoes include the Carville healing sandal, depth shoes, Orthowedge® shoes, and commercial wound care shoes, all of which have various approaches to allowing for an FDI. The Carville healing sandal, depth shoes, and surgical shoes can all be modified with the addition of a total contact molded or pixelated insole (Figure 6). Total contact insoles can be quickly manufactured by direct molding using heat moldable materials or cast molding. These insoles use the total contact concept to improve distribution of pressures across the entire plantar surface of the foot. Segmented insoles can also be incorporated into the shoes.

The DARCO PegAssist™ and FORS-15™ off-loading insoles have segments or pixels that can be quickly and easily removed to off-

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Figure 6: Modified Carville Healing Sandal



Figure 6a: FORS 15(TM) Segmented Insole



Figure 6b: FORS 15(TM) with Segments Removed, F

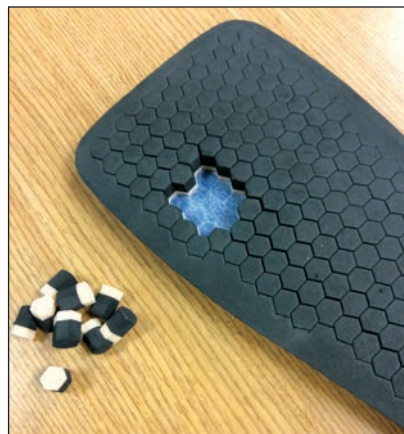


Figure 6c: Darco(TM) Pixelated Innersole



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load selected areas of the foot, especially sites of ulceration. (Figure 6a, 6b, 6c) The issue with these systems is that, although contoured insoles are recommended by IWGDF, they are generally not covered for patients with a single diagnosis of a diabetic foot ulcer or as a transitional device to use after therapy when an NRD has been completed.

Orthowedge™ shoes reduce weight-bearing on the forefoot slightly but increase tension on the Achilles tendon and have a risk of falling that makes them a poor choice for an off-loading device. Commercial wound care shoes such as the DARCO Wound Care Shoe System™ have a rocker sole and a multilayer insole system that allows for heat molding or removal of material from underneath areas of high pressure. Even though shoes have the worst healing data, most clinicians (41.2%) use shoe-based off-loading for diabetics with ulcers compared to only 15.2% who use RCWs which is the knee-high off-loading device of choice.³

In reality, no single off-loading device can function throughout the entire continuum of the treatment. At some point during the management of the wound, the off-loading device must be removed. A decision must be made at that point as to whether the patient can return

to their final off-loading footwear or a transitional device will be required.

The concept of a transitional off-loading was proposed by McGuire in 2006 and 2010.¹⁰ McGuire recommends a step-down approach to off-loading the diabetic foot to heal and prevent recurrence of diabetic wounds. This transitional approach follows the IWGDF guidelines and begins with a knee-high, non-removable device that enforces patient adherence (TCC or iTCC) and is continued until the wound is healed. After closure of the wound, the patient can be transitioned to a removable cast walker to evaluate how the patient performs, with cast breaks for bathing, sleeping, and early ROM exercises. In a truly adherent patient, transition to a shoe-based

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device with an appropriate foot-device interface such as a modified Carville healing sandal, or a surgical shoe with a DARCO PegAssist™ or FORS-15™ off-loading insole can be considered to allow for ambulation with a free ankle.

Shoe-based off-loading systems allow the skin to thicken and mature during the three to four week period after closure of the wound. Rapid transition to standard footwear after the wound closes, regardless of the patient's insistence, may contribute to the wound recurring.¹⁰ The rate of ulcer recurrence in diabetic patients who have a history of previous ulceration is high, with rates of 35–40% over a three-year period, increasing to a rate of 70% over a five-year period.¹¹ If at anytime during the process there is a setback to the patient's ulcer healing progression, the patient should revert to the previous level of off-loading until the wound improves.

Depth shoes that have molded inserts should not be used during this stage since they encourage the patient to use a normal gait and ambulate at a faster pace. Surgical shoes recommended during this stage have a rigid slightly rockered-sole which reduces the speed of a patient's ambulation as well as reducing the tendency to push off the forefoot during gait. Finally, once the wound has remained closed for three to four weeks, the patient can be transitioned to permanent footwear. Recommended devices include depth or custom-molded shoes, with total contact molded insoles and rocker soles to reduce forefoot pressures during propulsion (Figure 7).¹⁰

Diabetic patients with foot ulcers should be regarded as lifelong patients. Routine follow-up care in addition to the use of protective off-loading footwear are essential in preventing recurrence of ulcers. It is essential that patients be advised that continued use of prescribed off-loading therapies is necessary to protect any wound that has healed.¹⁰ They must understand that returning to their former footwear prior to the development

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of their ulcer will likely lead to the ulcer recurring at the same site since the area has already been weakened and is now more likely to ulcerate. At-risk diabetic patients should not walk barefoot, in socks, or thin-soled slippers, whether at home or when outside.¹ Patients should also be counseled to come in immediately should a new pre-ulcer or wound appear.

According to the American Diabetes Association, in 2012, 29.1 million Americans (9.3% of the population) currently suffer from diabetes and about 8.1 million Americans remain undiagnosed. The number of diagnosed Americans does not begin to compare with the 86 million Americans who are “pre-diabetic” and who are at risk at developing diabetes in the near future. In addition, 1.4 million Americans are newly diagnosed



Figure 7: Depth Shoe with Thermoldable Plastazote Innersole

with diabetes every year and this number continues to rise.

With these alarming rates in mind, about 73,000 non-traumatic lower-limb amputations were performed in 2010 in adults 20 years and older with diagnosed diabetes.¹² As much as 25% of the diabetic patient population will develop an ulcer of the foot during his or her lifetime, and one in five of those

will require an amputation.² 61% of the amputations were attributed to neuropathy, 81% to faulty wound healing, and 84% to ulceration as well as 55% to gangrene, 59% to infection, 46% to ischemia, and 81% to initial minor trauma.¹³ Early interventions put in place could drastically decrease the effects of neuropathy and heal ulcers faster to lessen the likelihood of lower limb amputations in diabetics.

Currently, there are no means available to completely ameliorate the effects of neuropathy, so our focus has to be directed to preventing and treating wounds. It is important to diagnose and intervene on diabetic foot wounds as early as possible to prevent the complications that are associated with ulcers.¹⁴ The first four weeks after the onset of a diabetic ulcer are key to optimal healing (similar to the golden hour after the onset of a heart attack when

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early intervention is the key to improved outcomes). Rapid initiation of care will help prevent the development of a chronic wound. Wounds that remain open after the

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first four weeks become difficult-to-heal chronic wounds with less than a 10% chance of healing at 12 weeks.¹⁴

Conclusion

Ultimately, the key to successful reduction of pressure lies more in a patient's compliance and adherence than in the off-loading device itself. A stronger focus on the measurement and improvement of treatment adherence should be placed in future research studies and in clinical practice. The combination of an effective, easy-to-use

off-loading device that will ensure patient adherence with wound healing modalities may possibly form a combination therapy that when treating ulcers will potentially avert lower-limb amputations. **PM**

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