The DFU Dilemma: Is the Total Contact Cast a True "Gold Standard"?

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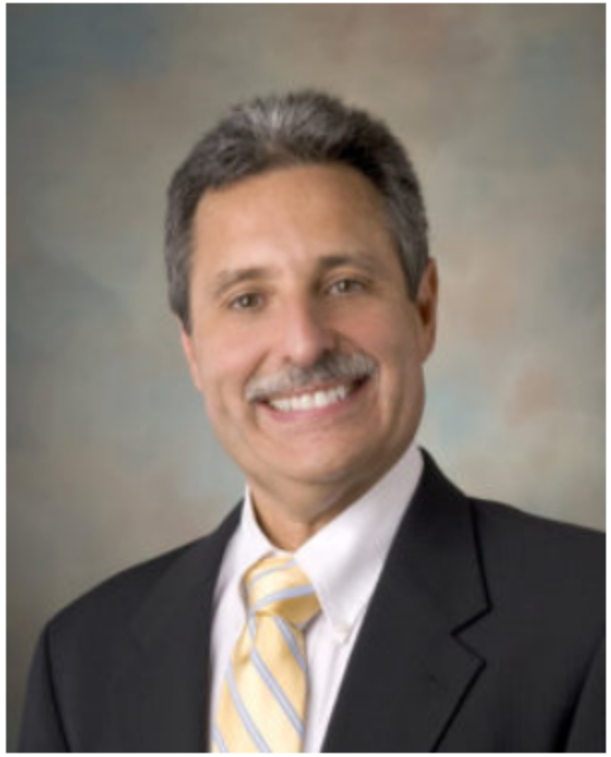

In March 2017, McGuire and Sebag wrote: "Early diagnosis and intervention for diabetic foot wounds is essential for the prevention of complications associated with these ulcers. We are all familiar with the term 'the golden hour' with respect to the first 60 minutes after the onset of a stroke or cardiac arrest. The rapid initiation of aggressive care is the key to positive outcomes for the patient. In this way, the diabetic foot ulcer (DFU) also has a golden hour. The 4-week period following the onset of a diabetic ulcer is a critical time for treatments aimed at preventing the development of a chronic wound, staving off infection, and allowing for early closure of the skin. Wounds that have not achieved 50% closure within the first 4 weeks are destined to become difficult-to-heal chronic wounds. A fundamental component of early intervention and resolution of diabetic foot ulcers is the use of an array of offloading devices that includes everything from total contact casting to depth shoes with molded inserts."[1] However, as they go on to document, there is no consensus among practitioners.

Points for Discussion

1. As healthcare professionals treating lower extremity conditions, we are

witnessing a rapid increase in the incidence of diabetes and a corresponding increase in devastating complications, including diabetic foot ulcers.

2. One of the primary principles of treating the diabetic foot, and DFUs in particular, is offloading of vulnerable tissues. For more than 30 years, the "Gold Standard" approach for offloading DFUs has been the Total Contact Cast (TCC). In fact, TCC is the only offloading approach for DFUs (non-Charcot) for which insurance reimbursement is available. Despite the strong evidence supporting it, the TCC has consistently been grossly underutilized; in fact, it is well documented that fewer than 10% of TCC-eligible patients are treated with this approach.[2]
3. Why is this? Contraindications, non-compliance, time consuming, physician discomfort, inadequate reimbursement, etc.
4. The reality is that the vast majority of patients do not receive any type of device that is clearly designed to offload their wound. In the literature, the percent of patients that are wearing some sort of shoe while being treated for a DFU ranges from 60% to 80%.[3] Many, if not most of these patients, are wearing their standard footwear. Though many patients wear extra-depth shoes with Plastazote® inserts designed to prevent ulcers, extra-depth shoes alone are not adequate for treating active ulcers. Some patients are provided with "post-op" shoes that essentially force them to modify their gate and reduce the force they place on the affected foot. But standard post-op shoes alone are not designed to selectively offload any particular area of the plantar aspect.

In an estimated 10% – 30% of cases, patients are prescribed some sort of CAM boot, wedge shoe, offloading shoe, etc. to aid in offloading, but the data regarding the effectiveness of these approaches is sparse, and none of these are reimbursed by insurance when dispensed to treat a DFU.

What do YOU think?

Are TCCs the "reverse Gold Standard"? What should the Gold Standard be? Join the discussion by sending your comments to editorial@lermagazine.com and we'll print select responses in upcoming issues.

5. So, if the academically accepted "best practice" approach is not accepted by the medical community, is it really the Gold Standard? McGuire and Sebag[1] have proposed that while TCC may be the "preferred approach" for DFU offloading, it cannot be considered the Gold Standard if it is used infrequently. He further proposes that since shoe-based offloading is the most common approach despite being associated with the poorest results, then it should essentially be considered the "Reverse Gold Standard". Therefore, any method that can be broadly adopted, and that is proven superior to the shoe-based approaches that are in common use today, should be carefully looked at as the new Gold Standard.

McGuire goes on to describe a new rationale for employing offloading devices based on 3 key attributes: removability, fixed vs free ankle, and conforming to the foot. And while this is an oversimplification, the premise of his argument in its most basic form is that the deployment of offloading devices should, as much as possible, correspond to the severity of plantar wounds, for example:

- **Severe Wounds:** Devices should be non-removable, fixed ankle, conforming insole
- **Moderate wounds:** Devices may be non-removable, fixed or free ankle, conforming insole
- **Superficial/closed wounds:** Removable, free ankle, conforming insole.

These devices are typically employed sequentially in a transitional manner to heal the wound, mature the skin, and prevent recurrence.

Given the severity of complications often associated with DFUs, including approximately 100,000 lower extremity amputations per year in the United States, there's a need for our industry to come to a consensus on preferred devices for plantar offloading. Patients need offloading options that they will tolerate, and clinicians need to be reimbursed for providing effective and accepted offloading services. While the TCC is highly effective for those who use it, it is clearly not the preferred treatment modality for most patients or physicians, and certainly not an industry "Gold Standard." Since TCC is the only reimbursed offloading therapy for most plantar DFUs, most patients receive no offloading at all. It is time we address this insufficiency of care. Using appropriate and comfortable offloading techniques will increase patient adherence, decrease medical costs associated with wound complications, and provide physicians a better chance to intervene within the 4-week critical period.

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