



Debunking Common Barriers Cited for Avoiding TCC Use

We are great at putting things on DFUs.
Why are we so bad
at taking the most critical thing off?

BY ANTHONY TICKNER, DPM

Diabetic foot ulceration (DFU) is currently the leading cause of diabetes-related hospitalization and non-traumatic lower extremity amputation. Excessive pressure is reported to contribute to delay in healing of up to 94% of these ulcerations.¹ This, in conjunction with the high mortality rate reported following amputation, should emphasize the necessity of off-loading.² Dr. Paul Brand introduced the total contact cast (TCC) to the U.S. in the 1960s, initially for treatment of leprosy-related neuropathic ulcerations.³ Its use gradually transitioned to treatment of DFUs with several randomized controlled trials, systematic reviews, meta-analyses, and a Cochrane review demonstrating a statistically significant increase in healing rates and reduction in healing times compared to other off-loading modalities.⁴⁻¹³ While this has resulted in the TCC being touted as the “gold standard” in off-loading, post-operative shoes and removable cast walkers are the most common off-loading modalities employed.¹⁴⁻¹⁶ Difficulty in training staff in proper application and removal of TCCs, disruption of clinic flow, the potential for iatrogenic complications, patient inability to tolerate the device, and contra-indication of use in patients with isch-

emia or Wagner Grade 3 DFUs are the most common barriers to use cited.^{4,6,7-9,13,17}

Ready-to-use TCC kits have been developed to assist in minimizing barriers related to staff training, disruption of clinic flow, and the potential for iatrogenic complications by simplifying appli-

scheduled clinic appointment to be seen.²⁰ The majority of iatrogenic complications are minor and reversible with resolution occurring within less than two weeks if identified and treated early.¹⁸⁻²⁰ Ready-to-use TCC kits with easy application and removal procedures and close patient follow-up and repetitive edu-

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cation and removal techniques and the process of ordering necessary supplies. Healing rates with these devices are comparable to those reported with conventional TCC use.¹⁸ Amputation secondary to iatrogenic complications sustained with conventional TCC have been reported.^{19,20} However, use of a ready-to-use prefabricated roll-on TCC kit reported no amputations occurring secondary to iatrogenic complications sustained with its use.¹⁸

Patient compliance is also an important consideration. Fourteen percent of iatrogenic complications have been reported to occur secondary to patients getting their cast wet and waiting until their next

cation on when to be seen earlier should mitigate the barriers of staff training, clinic flow disruption, and the concern for iatrogenic complications with TCC use.

Patient Intolerance of TCCs?

While patient intolerance of TCC use is a commonly mentioned barrier, there is no objective evidence to support this claim.^{4,5,8,14,18,21,22} Two studies that reported on patient satisfaction with treatment, not TCC use specifically, found rates to be equivalent between TCC and therapeutic shoes, and lower for conventional TCC compared to an “off-the-shelf instant” TCC.^{4,8} Only one

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study has reported specifically on patient tolerance of a ready-to-use type TCC.¹⁸ Tolerance of device use until wound resolution resulted in significantly shorter healing times. Even in some patients who refused continued applications, the short time of use either assisted in expediting or achieved wound resolution. No one wants to be in a cast. Explanation of its benefits for patients and their support network in expediting wound resolution and reducing the risk for infection and amputation may increase patient tolerance of TCC use.

The majority of TCC studies involve treatment of small, superficial, non-infected, nonischemic plantar forefoot ulcerations.^{10,11,23-31} This, however, is not the typical DFU presenting for treatment. In the clinical practice, guidelines for management of the diabetic foot put forth by the Society for Vascular Surgery, the American Podiatric Medical Association and the Society for Vascular Medicine, at least 65% of DFUs are complicated by peripheral arterial disease (PAD).³² A five-year retrospective re-

sent palpable pedal pulses), and 12% with severe PAD (ABI < 0.5).³⁴ Thirty-two percent of patients had a falsely elevated ankle-brachial index (ABI), making diagnosis of PAD severity difficult. The prevalence of PAD was found to increase

(90% at 1.4 months vs 32% at 2.2 months).²⁵ The five-year retrospective review of TCC use in which 44% of patients had PAD reported an overall healing rate of 76% at a mean of 33 days.²¹ The presence of PAD did not hinder healing of

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with age > 70 and the presence of disabling co-morbidities. Validation of the IDSA DFI Severity Classification found that 82% of DFUs are mildly to moderately infected at presentation.³³

TCC and Wagner Grade 3

While TCC use is contra-indicated for the treatment of Wagner Grade 3 DFUs and ischemia, it has been performed with successful results.^{17,18,21,24-26,29} Dr. Brand himself reported that “Only a small percent-

any plantar first metatarsal head ulceration or contribute to the development of superficial iatrogenic ulceration.

PAD

PAD was included in a prospective, non-randomized trial comparing the use of a windowed TCC to an off-loading shoe.¹⁷ The TCC group had an increased healing rate and a decreased time to healing compared to the off-loading shoe group (81%, 2.3 ± 1.2 months vs. 70%, 4.5 ± 4.4 months, respectively) despite having significantly more patients with ulcerations of longer duration, greater width and depth; and mid-foot location.

Patient age and TCC use were the only two variables found to have a statistically significant positive prognostic factor for healing. A three-year retrospective review on the use of a prefabricated roll-on TCC also reported comparable healing rates to conventional TCC use despite having treated subjects with larger ulcerations, mid- and rear-foot ulcerations, Wagner Grade 3 DFUs, and ulcerations complicated by mild to moderate PAD.²⁴ The primary reasons reported to result in an increased time to healing were: refusal of continued TCC use, an HbA1c ≥ 8%, active or former tobacco use, and non-forefoot ulcer location. A recent retrospective and systematic review on TCC use in patients with PAD suggests that TCC use in patients with an ankle pres-

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view of prospectively collected data on TCC use in all patients presenting to a single facility for treatment found that 44% had PAD defined as no signs of CLI and one or more of the following: absent palpable pedal pulses, presence of intermittent claudication, an ABI < 0.9, a toe brachial index < 0.6, and a TCOM between 30 and 60mmHg.²¹

The Eurodiale study, a one year retrospective review of all patients presenting with a DFU to one of 14 diabetic foot centers in ten European countries found that 61% of patients had PAD; 49% with moderate PAD (ABI < 0.9 or ab-

age of diabetic patients have vascular compromise to such an extent as to prevent a plantar foot ulcer from healing after the pressure of walking has been relieved.” He reported not having seen ischemia in patients with diabetes severe enough to prevent TCC use during 17 years of practice.³⁴ A prospective, controlled clinical trial which included patients with PAD (ABI between 0.5 and 0.99) compared TCC use to daily dressing changes for ulceration treatment. A significant increase in healing rate and decreased time to healing occurred for those subjects treated with TCC use

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sure ≥ 80 mmHG, a toe pressure ≥ 74 mmHG, an ABI ≥ 0.55 , or a TBI ≥ 0.55 may be a viable treatment option for pressure-related neuropathic ulcerations. Once again, prolonged healing times and amputation were

Shibuya N. The impact of foot ulceration and amputation on mortality in diabetic patients. I: From ulceration to death, a systematic review. *Int Wound J*. 2016 Oct;13(5):892-903.

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²⁴ Mueller MJ, Diamond JE, Sina-
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Effective off-loading is one of the most important factors in achieving rapid resolution of pressure-related DFUs.

found to occur if TCC use was discontinued. Wounds in patients with mild to moderate PAD in which TCC treatment was utilized have not been reported to worsen, only fail to decrease in size. Repeat vascular evaluation is recommended should this occur.³⁵

Effective Off-Loading

Effective off-loading is one of the most important factors in achieving rapid resolution of pressure-related DFUs. Although the TCC is the reported "gold standard" in off-loading, its use remains nominal. Provider performance of individual patient risk and benefit assessment in those with mild to moderate PAD and/or infection, utilization of ready-to-use TCC kits, the ability to perform weekly and more urgent follow-up as needed, and performance of repetitive patient education on cast safety and maintenance should mitigate the common barriers cited for not using the most optimal off-loading modality for pressure-related neuropathic ulcerations. **PM**

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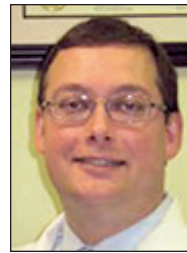
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Dr. Tickner is a double board certified wound care surgeon. In addition to being a highly sought-after international wound care consultant, he is also the medical director of limb salvage and amputation prevention services at

Associated Foot Specialists in Hudson, MA. He also serves on the board of directors for both the Association of the Advancement of Wound Care (AAWC) as well as the Massachusetts Foot & Ankle Society.