Clinical and Economic Benefits of Healing Diabetic Foot Ulcers With a Rigid Total Contact Cast

Shishir Shah, DO

Sub-optimal offloading results in delayed healing and thus directs the clinician into considering more advanced, and oftentimes expensive, modalities. Current US health care guidelines are vague in ensuring that optimal offloading is provided to patients prior to failed healing. Healing failure, or wounds that have failed with "conservative" care after 30 days, are then considered appropriate for receiving care with advanced modalities. Biomedical companies have further marketed this intersection between stalled healing and product qualification use. As a result, there has been an unprecedented rise in the cost of healing wounds without a reciprocal return on investment. A recent study reported that the cost of healing a wound using TCC was half the cost of treating a wound without using TCC ($11,946 vs. $22,494).

Numerous published studies and clinical workshops over the last few decades have demonstrated the superiority of a TCC system in healing DFU. Peer-reviewed studies have shown average healing of 80%–90% within 6 weeks for DFU. The healing success of the TCC is reduced in practice to approximately 25% of DFU due to lack of reimbursement, noncompliance, active infection, high grade ulceration, and mobility/fall risk limitations. Advanced modalities, such as skin substitutes or growth factors, have, at best, demonstrated a 56% healing rate within 12 weeks (Figure 3). Such products may also pose similar exclusions as a TCC for meeting application criteria.

A meta analysis-derived parabolic healing velocity curve also substantiates the healing rate using a traditional casting system versus sharp debridement and bioengineered products. The wound velocity of the TCC shows a steep rate of change in healing in the first few weeks compared to other modalities (Figure 4). This rate of change is equivalent to rapid acceleration and shorter healing times with the TCC. An endpoint of 35 days, or 5 weeks, was established due to the nearly 90% probability of wound closure. Based on these alarming differences, it would seem that a TCC would be a first line of defense in healing DFU. The bottom line is that DFU heal faster with a TCC.

Although a vast number of clinicians have employed the TCC in their practices, there are several factors that discourage the industry from uniformly adopting the TCC. One key factor stems from clinics and physicians concerned with payment bundling. Claim denials are often a result of using debridement codes or skin substitute codes (eg, Apligraf, Dermagraft, Oasis) along with TCC application. This is in direct conflict with the American Medical Association’s position that TCC is a separate and distinct procedure. Such denials have created significant controversy between providing the gold standard for offloading and receiving reimbursement for patient care.

A smaller portion of insufficient use is due to lack of trained clinicians who are able to apply a TCC.

The aforementioned phenomenon has piqued this author’s interest in thoroughly analyzing the protocol/pathway driven model for healing DFU, and how it relates to facilities’ and clinicians’ financial motivations in choosing a particular route for healing DFU.

Healing Pathway

The approach for managing a DFU at a wound center is shown in Figure 5. Pressure relieving options in an ambulatory patient include: diabetic shoes, modified pressure relieving shoes, foam/felt footwear, Charcot Rigid Orthotic Walkers (CROW) boots, modified removable casts, cam walkers, and TCC.

Figure 6 shows the current recommended pathway for optimal offloading and the application of TCC.
In the past, approximately 25% of all patients with diabetes qualified for a TCC at initial presentation to the clinic, as indicated in this model. The clinics viewed qualified candidates as patients with a DFU who: 1) are not infected; 2) have adequate arterial flow; 3) do not have significant edema or pain; 4) have gait stability; 5) have no automobile driving issues, or any patient safety hazards/compliance issues; 6) have Wagner 1 or 2 ulcers. It should be noted that the majority of DFU patients referred to this clinic present with poor vascular status and/or infections. Patients with adequate vascular status and no infection make likely candidates for TCC; for many practices, as high as 80% of DFU patients would be good candidates for TCC.

Additional patients can be reconsidered for TCC after other interventions have been completed, such as infection control or vascular surgery. The TCC will reduce edema, so those patients can be casted, with the first cast change in 2–3 days to maintain adequate fitting. To address stability, a cane or walker could be added, which allows these patients to be casted. Finally, the patient needs to enlist family, friends, and community resources to help them through the treatment process, and to maximize their ability to heal. It is much easier to enlist help for a few weeks, rather than decades after losing a limb.

**Methods**

Based on this clinical pathway (Figure 6) and reimbursements, a clinic model was developed.

**Reduction in Peak Plantar Pressures**

![Graph showing reduction in peak plantar pressures](image)
Percentage of Centers Utilizing TCC

Figure 2. Offloading modalities.

Time to Closure

Figure 3. Diabetic foot ulcer healing rates of various modalities.
Velocity of Healing Times

Figure 4. Healing velocity for various modalities.

Healing Pathway

Figure 5. Managing a diabetic foot ulcer at a wound center.
**Key Points**

- To date, a rigid total contact cast (TCC) has demonstrated the lowest peak plantar pressure on an ambulatory patient (Figure 1).\(^6\)
- The healing success of the TCC is reduced in practice to approximately 25% of DFU due to lack of reimbursement, noncompliance, active infection, high grade ulceration, and mobility/fall risk limitations. Advanced modalities, such as skin substitutes or growth factors, have, at best, demonstrated a 56% healing rate within 12 weeks (Figure 3).\(^9,14,15\)

---

**Clinical Pathways and Reimbursement**

- **Day 1**
  - Patient assessment and subcutaneous debridement (CPT-11042) to set stage for healing

- **Day 2**
  - Patient returns for wound evaluation and application of TCC (CPT-29445)

- **Day 4-5**
  - Patient returns for change of TCC (29445)

- **Day 8-9**
  - Patient returns for change of TCC (29445) and open wound debridement (97597, 97598) if needed

- **Weekly**
  - Similar to day 8/9 until healed—debridement only when needed, and unlikely, near end

*Figure 6.* Current recommended pathway for optimal offloading and TCC application.