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

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WOUNDS 2012;24(6):152–159

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Abstract: A total contact cast (TCC) is considered the gold standard for healing diabetic foot ulcers (DFU). Numerous studies have demonstrated the excellent healing success of a TCC; however, its adoption in routine clinical use does not match its success rate. This lack of implementation is due to several factors: Medicare's payment structure, lack of clinical training, and a variety of patient factors. These factors have reduced clinicians' use of TCC to approximately 25% of DFU. The aim of this review was to analyze and demonstrate common scenarios for outpatient wound centers where a TCC may be beneficial to both patients and hospital systems, and to expand its usage to more closely reflect its healing success rate.

The rising incidence and prevalence of diabetes in the United States has resulted in a synonymous escalation of nonhealing diabetic foot ulcers (DFU).[1] Patients with these foot ulcers have flooded urgent care centers, primary care offices, podiatric services, inpatient wards, emergency rooms, and ultimately, wound care centers. Such occurrences have resulted in a boom of advance modalities to help heal these ulcers and prevent amputations. These modalities include bioengineered skin substitutes, platelet derived growth factors, negative pressure therapy, hyperbaric oxygen, advanced wound dressings, ultrasonic debridement tools, "superbug" busting antibiotics, and stem cell therapy.[2–4]

The challenges in healing DFU have fostered the use of advanced modalities. Concerns with diminishing reimbursement in procedural services, by both providers and hospital systems struggling to fight disease and maintain financial viability, have promulgated the use of such expensive modalities.[5] Studies supporting the healing potential of advanced modalities over standard saline moistened dressings have further created a tailspin of doctrine termed "standard of care" that advanced (as well as expensive) modalities are preferable to treat DFU that have failed to heal.

Furthermore, studies touting DFU healing rates with various modalities have used variable offloading tools that do not provide consistent optimal pressure relief. Ideal offloading is obtained through minimal pressure on the diabetic ulcer. To date, a rigid total contact cast (TCC) has demonstrated the

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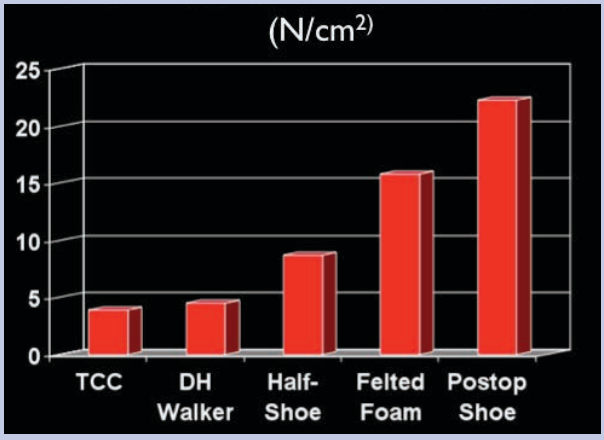

Figure 1. Peak plantar pressures on first metatarsal head.

lowest peak plantar pressure on an ambulatory patient (Figure 1).[6]

A 2005 nationwide (United States) survey of 895 private practices treating DFU indicated that shoe modifications were used in 41.2% of cases for offloading, despite the lack of evidence supporting its use.[7] Total contact casting was utilized in more than 40% of clinics; however, only 1.7% of the centers used the TCC as treatment for the majority of DFU in their care (Figure 2).[7] If the TCC were used as standardized pressure relief in various clinical trials, then further validity could be given to the efficacy of bioengineered dressings, regenerative matrices, negative pressure therapies, and other advanced modalities.

Traditional DFU healing protocols include risk factor modification, offloading, debridement, and a protective dressing. A common failure in this pathway is the offloading method. 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).[8]

Numerous published studies and clinical workshops over the last few decades have demonstrated the superiority of a TCC system in healing DFU.[9–13] Peer-reviewed studies have shown average healing of 80%–90% within 6 weeks for DFU.[10,14] The healing success of the TCC is reduced in the author's 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] Such products may also pose similar exclusions as a TCC for meeting application criteria.

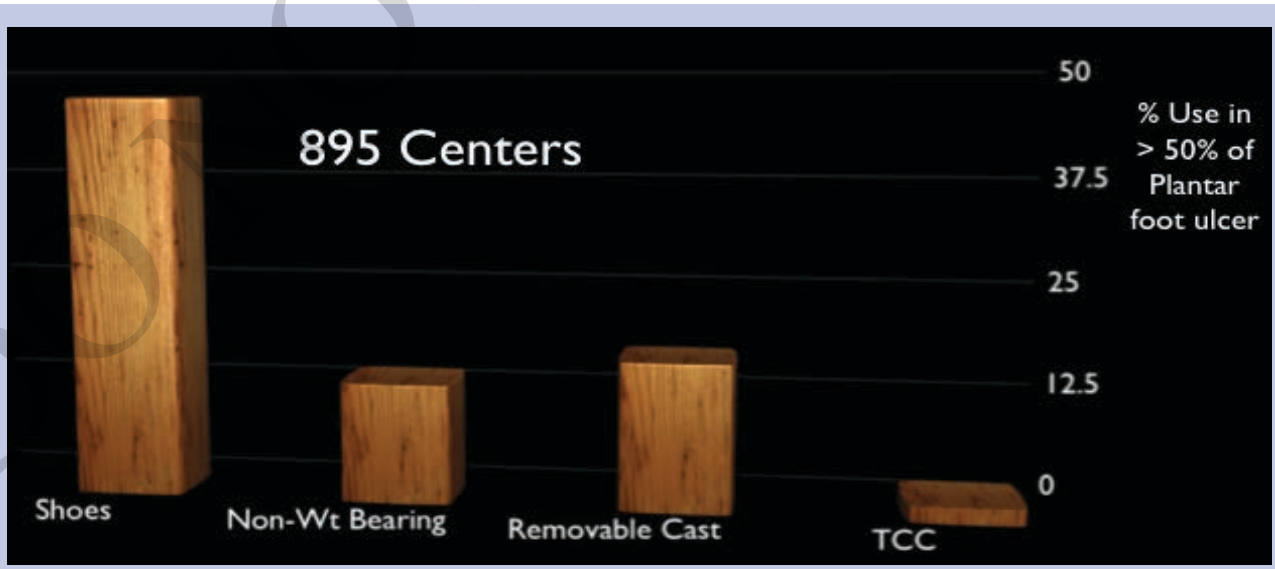

Figure 2. Offloading modalities.

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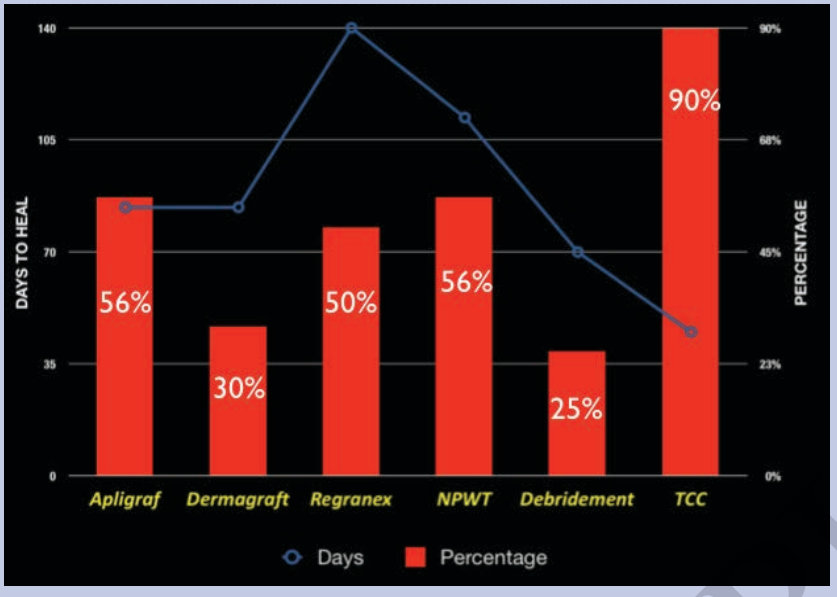

Figure 3. Diabetic foot ulcer healing rates of various modalities.

A meta analysis-derived parabolic healing velocity curve also substantiates the healing rate using a traditional casting system versus sharp debridement and bioengineered products.[16] 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.[17] Such denials have created significant contro-

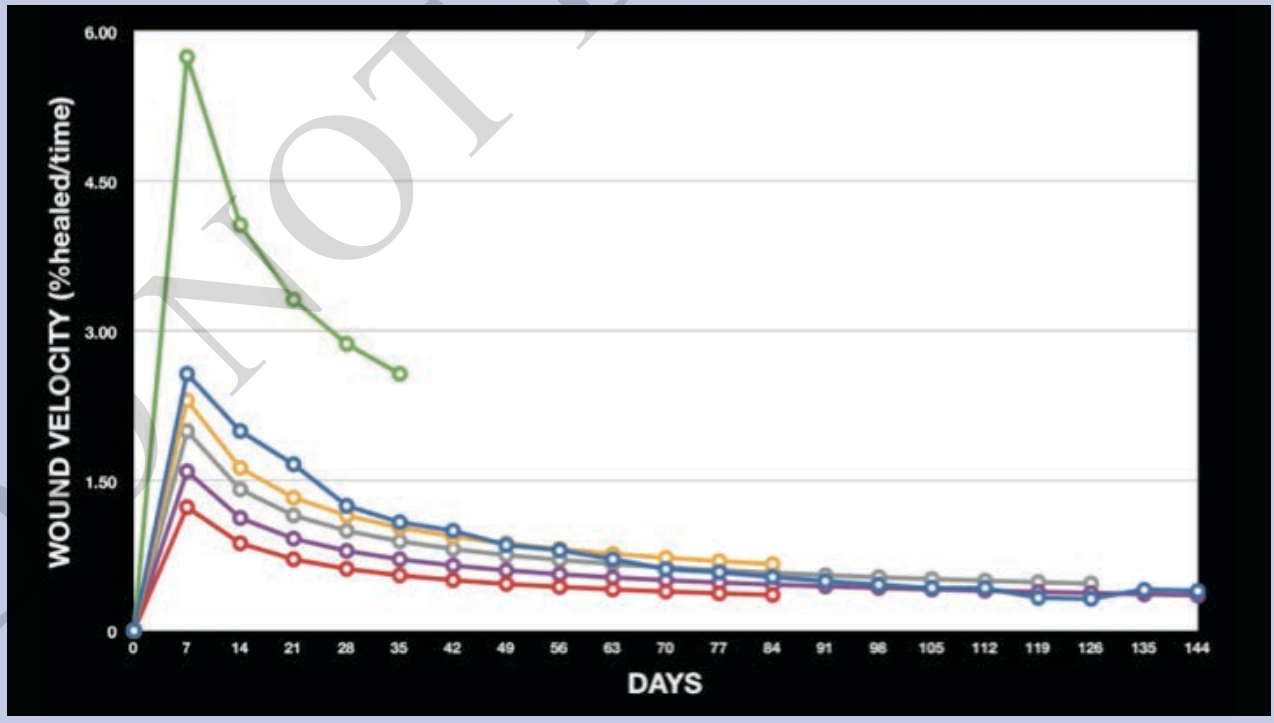

Figure 4. Healing velocity for various modalities.

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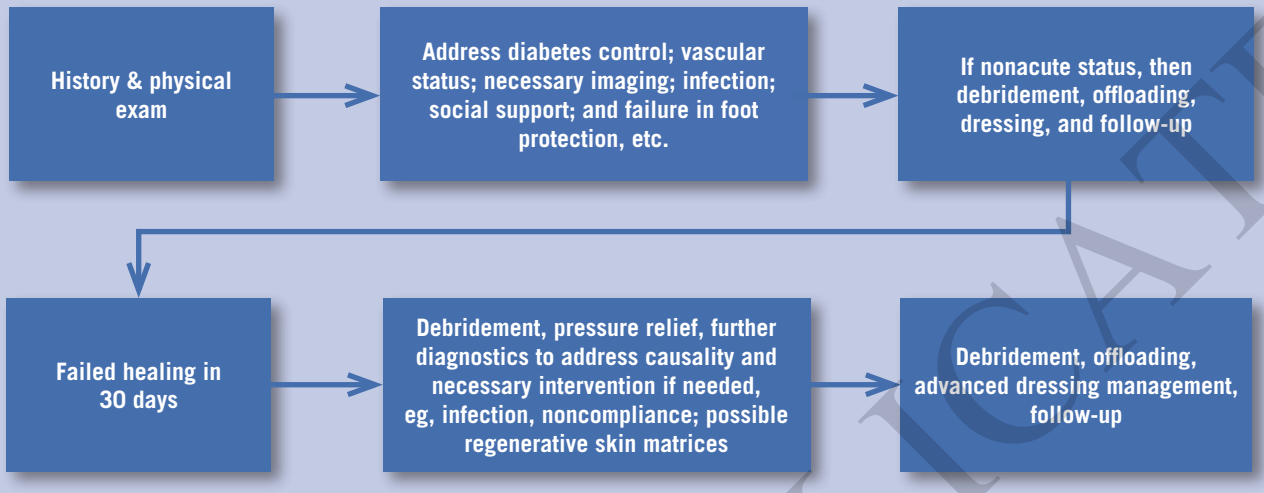

Figure 5. Managing a diabetic foot ulcer at a wound center.

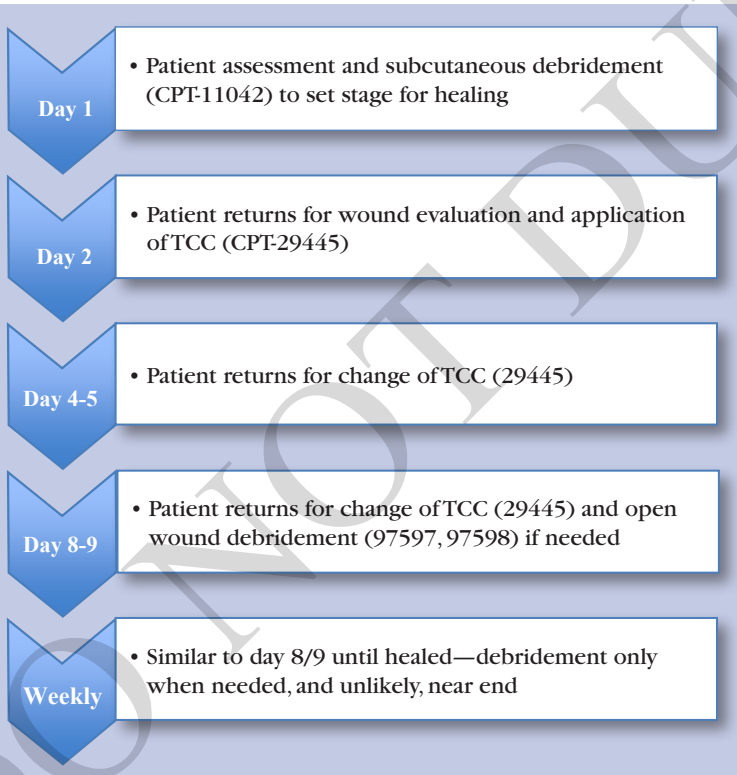

Figure 6. Current recommended pathway for optimal offloading and TCC application.

versy 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.[18]

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 author's 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

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Table 1. Fee schedules for hospital and physician.

CPT	Hospital Fee Schedule	Physician Fee Schedule
11042: Excisional debridement	188	46
97597: Selective debridement	103	23
29445: Cast application	175	105
99204: Level 4 (new patient)	128	124
99213: Follow-up evaluation	75	48
99212: Follow-up evaluation	75	24
15271: Apligraf/Dermagraft/Oasis	230	88
99183/C1300: Hyperbaric oxygen (HBO)	400	100

Keypoints

- 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 the author's 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]

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. The prototype clinic was based on this author's experience and a retrospective review of 25 wound centers.

Model clinic profile. Based on electronic medical records of wound centers, along with program directors' experience and literature review[11]:

- Hospital based outpatient wound center: 1300 new patient visits/year
- Percent of patients with diabetes and a foot ulcer(s): 30%
- Percent healed within 12 weeks without using a cast: 56%
- Percent that require > 12 weeks and < 1 year of wound care: 44%

Outline of unhealed ulcers beyond 12 weeks:

- 40% of patient visits require debridement/skin products
- 50% of patient visits require e/m (consultation)
- 5% of patient visits require hyperbaric oxygen (Wagner 3 or greater)
- Average of 25% of patients will require bioengineered skin substitute after 30 days of failed healing. TCC not included in these patients.

Healing Rate Model[10–14]:

1. 90% of DFU heal within 6 weeks of TCC (best case)
2. 56% of patients without TCC heal in 12 weeks (best case)

Current (2012) national average Medicare reimbursement rates were used to apply fee schedules for various points in the treatment for diabetic ulcers (Table 1).

Data Analysis

Two comparison models were created to determine cost associated healing models.

Based on known healing parameters, as cited above, a comparison of treating DFU with and without the use of a TCC was computed (Table 2). Additionally, the quantity of biologic skin products needed, without TCC, for healing foot ulcers was based on prior published data.[19,20]

Results

The physician reimbursement model indicates a steeper reimbursement capture rate and a higher aggregate reimbursement using the TCC in the first 7 weeks of ulcer management (Figure 7). The TCC graph is terminated at 7 weeks because of the 80%–90% probability of healing Wagner 1 and 2 ulcers versus < 56% probability with non-cast healing modalities.[11,15] Although a clinician may be incentivized to maximize revenue by prolonging healing, this approach will compromise patient care and reduce

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Table 2. Comparison of treating diabetic foot ulcers with and without the use of a TCC.

	No. patients		
Total new patients	1300		
Diabetic (30%)	390		
No TCC Scenario		**Hospital Revenue**	**Physician Revenue**
Healed in 12 wks (56%)	218	$487,906	$156,538
Not healed (treatment up to 1 yr [44%])	172	$1,032,860	$334,920
Total Revenue (No TCC + HBO)		$1,520,766	$491,459
Avg. Revenue/Patient		$3,899	$1,260
TCC Scenario			
Not TCC candidate (75%)	293	$1,140,575	$368,594
Not healed with TCC (2.5%)	10	$68,348	$10,084
Healed with TCC in 6 weeks (22.5%)	88	$86,960	$90,734
Additional Patient Visit Potential	88		
Avg. Revenue/Patient		$3,323	$1,204
Total patients seen/year	478		
Additional revenue from additional patients		$291,574	$105,618
Total Revenue With TCC Use + HBO		$1,587,456	$575,029
TCC Opportunity		**$66,690**	**$83,570**

Keypoints

- A 1-year prospective financial and clinic volume was extrapolated, and accounted for time frame intervention and prediction modeling based on the scenarios outlined for the model clinic (Table 2).
- The sample model of a typical wound center's volume and case management pathway for healing DFU presented in this study, strongly suggests using all available evidence based methods to safely heal these ulcers. The TCC can play a complementary role to the tools available for limb salvage.

turnover volume, resulting in reduced capacity to see new patients.

Hospital systems and program managers often are held hostage to budget restrictions and quarterly revenue capture. Since hospitals are not affected by global payment periods with bioengineered skin substitutes, they may fare better than physicians when noncast approaches are used for more than 7 weeks. This incongruence among hospital reimbursement, physician plan of care, and optimal patient outcomes, can lead to disastrous consequences. However, as with the physician, the hospital system will have a steeper and higher aggregate revenue capture in the first 7 weeks using the TCC versus alternative methods (Figure 8).

The use of TCC versus alternative offloading methods analysis, along with the wound center model used in this review, was examined further. A 1-year prospective financial and clinic volume was extrapolated, and accounted for time frame intervention and prediction modeling based on the scenarios outlined for the model clinic (Table 2).

In the scenario where alternatives to TCC are used for

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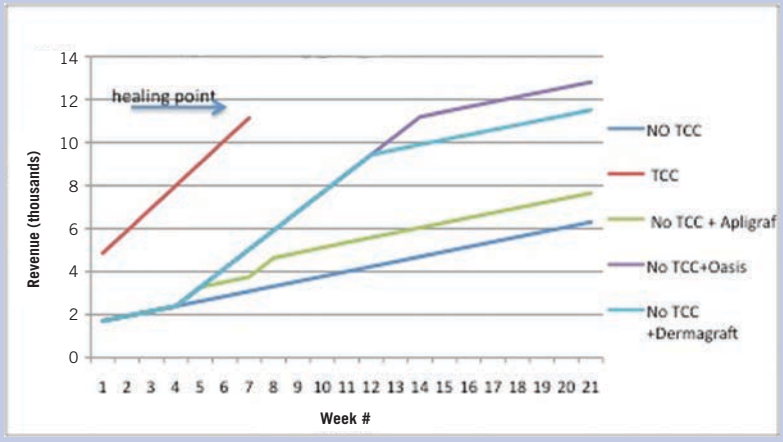

Figure 7. Aggregate physician revenue.

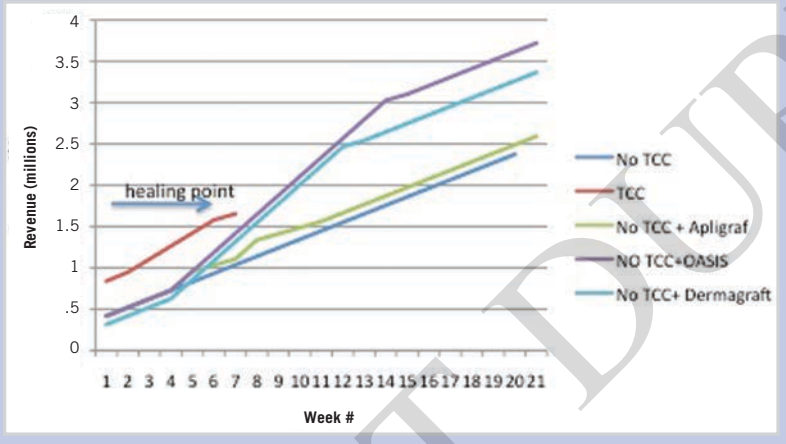

Figure 8. Aggregate hospital revenue.

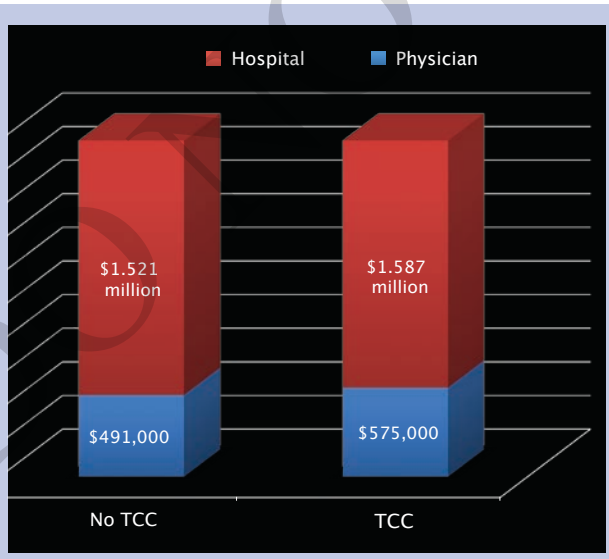

Figure 9. Total annual revenue.

offloading, approximately 218 DFU are healed in less than 12 weeks in a clinic averaging 1300 new patient visits per year. Approximately 172 patients are expected to take beyond 12 weeks and were followed in the treatment model for up to 1 year. Total expected clinic revenue is approximately $1.52 million and physician revenue of $491,000 when alternative pressure relieving methods are combined with debridement, office visits, bioengineered skin, and hyperbaric oxygen. These methods were incorporated to exhibit a best-case scenario for the clinician and hospital without using the TCC.

The second scenario shows an outpatient wound center using the TCC method of offloading on only 25% of DFU. The 75% of DFU not receiving the TCC were treated similarly to the non-TCC model above. Ten percent of those patients with a TCC (10% x 25% = 2.5%) may not heal in the average 6-week intervention. Consequently, 22.5% of patients with DFU are able to use the TCC and heal in an average of 6 weeks. A minimum of 88 patients are expected to heal in an average of 6 weeks using the TCC in this model, which allows the clinic to see at least 88 additional new patients per year versus the non-TCC scenario. The resultant total revenue using TCC is $1.59 million for the hospital and $575,000 for the physician by utilizing TCC for only 25% of DFU. The net financial gain is nearly $66,690 for the hospital and $83,570 for the physician when this minimal TCC model is deployed (Figure 9). Opportunity exists to expand use of TCC on many more patients, thereby further increasing revenues. More importantly, by healing this group of patients quickly using TCC, there is an invaluable benefit to the patients' quality of life, and the clinic and physician's reputation. Healing this group of patients eliminates the chance of further hospitalizations and amputations as a result of these wounds, saving the health care system immeasurable amounts of additional outlays.

Conclusion

Healing DFU presents many challenges. In order to sustain a wound center's ability to heal the growing population of patients with these wounds, there will be

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an increasing need to heal these wounds effectively and expeditiously. The sample model of a typical wound center's volume and case management pathway for healing DFU presented in this study, strongly suggests using all available evidence based methods to safely heal these ulcers. The TCC can play a complementary role to the tools available for limb salvage. Adding TCC for just 4 additional patients (based on 88 pts/year) per day provides a tremendous opportunity to improve quality of care and sustain a clinic's financial viability in a challenging economic environment. A need also exists to improve opportunities where more patients are able to qualify for TCC through improved cast technology, clinician training, patient support, and wound center administration awareness. As an evidence-based gold standard, TCC should be considered for every foot wound and ruled out, and not used only as a last resort.

Acknowledgment

Disclosure: Dr. Shah is a paid consultant for MedEfficiency, Inc.

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