# Use of negative pressure wound therapy to help facilitate limb preservation

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**ABSTRACT**

Because of changes in demography, non-communicable diseases cause more deaths worldwide than infectious disease for the first time in history. One of the most prevalent of these maladies is diabetes mellitus, which resulted in 4·6 million deaths in 2011. There will be approximately 552 million people with diabetes worldwide by 2030. For these patients, one of the most common severe complications will be a foot wound. Patients with diabetes have at least a 25% lifetime risk of developing a foot ulcer. Many of these infections go on to amputation. Those patients have a 50% mortality rate in the 5 years following the initial amputation. Indeed, these problems are costly as well. In 2010, spending on diabetes was estimated to account for 11·6% of the total health care expenditure in the world. This review merges scientific evidence with expert experience to show the role of negative pressure wound therapy using reticulated open cell foam (V.A.C.® Therapy, KCI USA, Inc., San Antonio, TX) in limb preservation.

**Key words:** Diabetic foot ulcer • Limb preservation • Negative pressure wound therapy • Venous leg ulcer

## DIABETIC FOOT ULCERS

Diabetic foot ulcers (DFUs) are a challenging problem for clinicians (1–9). In the presence of neuropathy and the associated absence of pain, foot ulceration can be subjected unknowingly to repetitive pressure and shear on the sole of the foot (7,10). The patient may be entirely unaware of the initial ulceration or its progression that occurs during daily walking. Redistribution of shear and pressure forces is a key aspect in the treatment approach to ulceration and surgical wounds in persons with diabetes. Unless these stresses are attenuated, healing wounds, already viscoelastically compromised by diabetes itself, are literally torn open by continued stress. This exposes the damaged integument which increases the risk for amputation – particularly when combined with peripheral arterial disease. One could liken this pathway to a stairway, where each factor on the step above contributes negatively to the aetiologic foundation below (Figure 1) (11).

To redistribute plantar pressure and unload ulcerative forces off of diabetic foot wounds, the gold standard method is the total contact cast (TCC) (12–14). In addition to redistributing pressure, it reduces the activity level of the patient, and because the TCC cannot be removed, it protects the foot from repetitive injury and bacterial contamination (15). In two randomised clinical trials TCCs, reapplied on a weekly basis, produced generally higher healing rates compared to other off-loading modalities (13,16). In addition, the proportion of patients in TCCs with healed wounds is better than those reported from clinical trials of wound healing with skin substitutes, electrical stimulation or other pressure reduction approaches. Critical downsides to the TCC technique are that it is time consuming, often not well tolerated by patients (especially the

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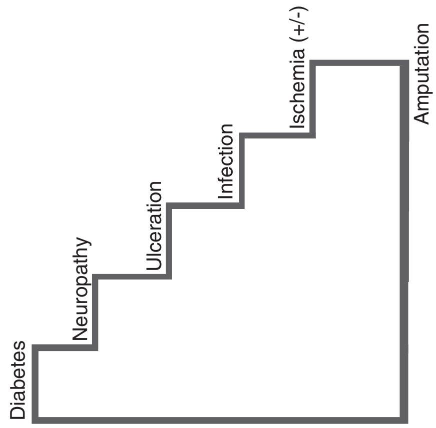


**Figure 1.** The stairway to amputation [Adapted from Ref 11].

frail and elderly), and a technically challenging application that requires expertise and special supplies.

Several off-the-shelf commercially available devices, which simulate the TCC in pressure reduction are termed 'removable cast walkers' (RCWs) (17). They are circumferential and attach (typically by Velcro) to the leg and extend from the foot to an area distal to the knee similar to a standard cast. Previous gait laboratory studies have suggested that certain RCWs offload the foot to a degree equivalent to that of TCCs (17).

## MERGING EFFECTIVE PRESSURE OFFLOADING WITH NEGATIVE PRESSURE WOUND THERAPY (NPWT)

If RCWs reduce pressure to a degree equivalent to TCCs, why are they less effective in healing wounds? The answer may lie in the fact that these devices are (by their very name) *removable*. In a project conducted by our group using computerised activity monitoring systems, only 28% of the total activity undertaken by patients with diabetic foot wounds was conducted while wearing the RCW (18). It would stand to reason, therefore, that no advanced wound healing modality, such as NPWT, could stand up to this sort of repetitive stress or live up to its therapeutic potential. Therefore, we have proposed a simple solution: render the RCW *irremovable* by wrapping it with a cohesive bandage or a single layer of plaster of Paris. This has been termed an 'instant total contact cast' (iTCC) (19).

Negative pressure wound therapy using reticulated open-cell foam (NPWT/ROCF; V.A.C.® Therapy, KCI USA, Inc., San Antonio, TX) has become an increasingly used adjunct in treating the complex diabetic foot wound. This modality has been shown to both improve wound healing and reduce the risk for amputation (20–22). A multicentre randomised controlled trial (RCT) by Blume *et al*. (22) compared NPWT/ROCF with advanced moist wound therapy (AMWT) for the treatment of patients with DFUs. Within the 112-day active treatment phase, a significantly greater number of DFUs closed with NPWT/ROCF compared to AMWT [73/169 (43·2%) versus 48/166 (28·9%), respectively; $P = 0{\cdot}007$]. DFUs treated with NPWT/ROCF also had decreased time to closure, as indicated by the Kaplan–Meier median estimate for 100% ulcer closure [96 days (95% CI 75·0–114·0)] for NPWT versus not determinable for AMWT; $P = 0{\cdot}001$). More importantly, there was a significant reduction in secondary amputations with NPWT/ROCF as compared to AMWT [7/169 (4·1%) versus 17/166 (10·2%), respectively; $P = 0{\cdot}035$].

Newly available ultra-lightweight, disposable, single-patient use NPWT (SP-NPWT) devices (V.A.C.Via™ Therapy System, KCI USA, Inc.) allow patients to take care of activities of daily living and still achieve the benefits of NPWT. However, walking unprotected on the NPWT hose/foam apparatus introduces potential risk for complications in a profoundly neuropathic foot. Therefore, current investigators have incorporated a bridging technique (See 'Technical Pearls' below) to safely and effectively combine use of NPWT/ROCF with iTCC.

## THE ROLE OF NPWT IN LIMB PRESERVATION

NPWT/ROCF has also become an important adjunctive technique in limb preservation, because this integrated wound care system has been shown to reduce incidence of infected DFUs, diabetic foot wounds and venous leg ulcers (VLUs), as well as subsequent lower extremity amputations (20,23–25). An overarching goal of diabetic foot care and limb preservation is to move the patient as quickly, comfortably and safely as possible from an acute to a post-acute setting. Resource utilisation data from the first large-scale randomised trial of NPWT reported approximately 89% of total days of therapy were delivered whilst outpatient (26). This growing demand for outpatient usage has prompted industry to create smaller devices better geared towards portability, quiet operation and long battery life. This 'bridge-to-home' is seen as an important attribute of NPWT for years to come.

## INITIATION CRITERIA AND WOUND BED PREPARATION

Initially, a thorough patient and wound assessment is important to determine treatment plans incorporating NPWT/ROCF with appropriate offloading techniques and good wound care practice (e.g. debridement and antibiotics) (27,28). Other medical assessments include vascular and wound bed assessments to determine the optimal treatment plan for DFUs or VLUs. Debridement, infection and exudate management, and wound margin assessments should also be performed before initiation of NPWT/ROCF.

Managing the wound environment of a DFU is essential for proper wound healing. Several studies have shown successful use of NPWT/ROCF in preparing the wound bed for closure by promoting granulation tissue formation and decreasing the wound size (20,22,29–31).

## TREATMENT GOALS

The main treatment goals for managing a DFU or VLU are to reduce the complexity and size of the ulcer. To that end, we prefer a 'vertical' and 'horizontal' wound healing strategy. The 'vertical' strategy involves filling in defects and covering vital structures with NPWT. The 'horizontal' philosophy involves skin grafting, assisting secondary healing through bioengineered tissue or other substances, and aggressive offloading. The ability of NPWT/ROCF to manage the wound environment and promote perfusion and granulation tissue formation allows for reduction of ulcer size and wound bed preparation for closure (32). This is crucial for preventing infections and amputations (33).

## CONTRAINDICATIONS

Although there are no specific contraindications of NPWT/ROCF for DFUs or VLUs, those that would generally apply include malignancy in the wound, untreated osteomyelitis, and necrotic tissue with eschar present. Also, foam dressings should not come in direct contact with exposed vessels or organs. All contraindications and warnings can be found in the clinical guidelines (34).

## TECHNICAL PEARLS: USE OF NPWT/ROCF WITH THE ITCC AND OTHER OFFLOADING MODALITIES ON PLANTAR WOUNDS

Using a technique known as 'bridging,' described by Greer and co-workers (35), the foam remains on the plantar wound but the tubing and interface, which could potentially cause tissue injury and necrosis to the dorsum or side of the foot, are remote. Separated with a bridge of foam, the tubing and pressure-sensing pad are moved to the dorsum of the foot or even more proximally up the anterior aspect of the removable cast boot or out the end of the device. This entire construct can then be wrapped in a cohesive bandage, allowing the patient to walk in a protected fashion with the device in place whilst ensuring adherence to pressure offloading (36). Dressings may be changed every other day (or three times per week). An available bridge dressing (V.A.C.® GranuFoam™ Bridge Dressing, KCI USA, Inc.) that allows concomitant use of NPWT with offloading devices or compression products is ideally suited for this type of technique in many cases.

A gait laboratory study performed by Armstrong and colleagues (36) evaluated the effect of bridging compared with standard offloading without applied NPWT in ten patients. While there was an increase (statistically significant) in plantar pressure [22 kPa (9·9%),

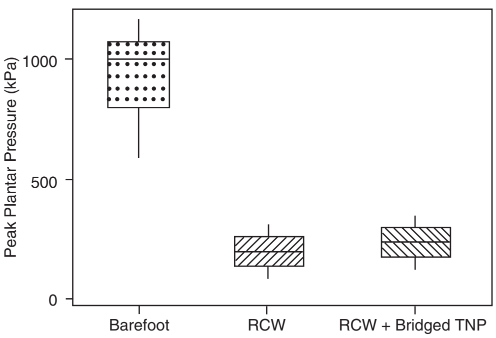


**Figure 2.** Plantar pressure in bridged topical negative pressure device [Adapted from Ref. 36] [RCW, removable cast walker; Bridged TNP, topical negative pressure (i.e. NPWT) device applied plantarly with foam dressing bridged to dorsum of foot.].

Figure 2] with NPWT applied, the authors concluded that this increase in pressure does not add undue stress to the plantar aspect of the foot and still allows for the benefits of NPWT and sufficient offloading.

## CLINICAL CASES

### Case study 1

This 59-year-old patient shows the use of NPWT/ROCF on a typical wound following emergency debridement for a deep-space diabetic foot infection. Initial wound shows progression from 24 hours following intraoperative debridement to 4 weeks following bridged NPWT with RCW protection to 3 more weeks in a TCC followed by healing after 9 weeks. Dressings were changed every other day (Figure 3).

### Case study 2

This 39-year-old diabetic male presented with a septic right foot. Plantar wound was debrided followed by NPWT/ROCF. The bridging technique was used to prepare the wound for skin grafting. Dressings were changed every other day (Figure 4).

### Case study 3

Treatment of this 60-year-old male patient illustrates the use of a portable, SP-NPWT (V.A.C.Via™ Therapy, KCI USA, Inc.) and a bridge dressing on a partial calcanectomy debridement with 4 weeks of outpatient therapy. Dressings were changed every other day (Figure 5).

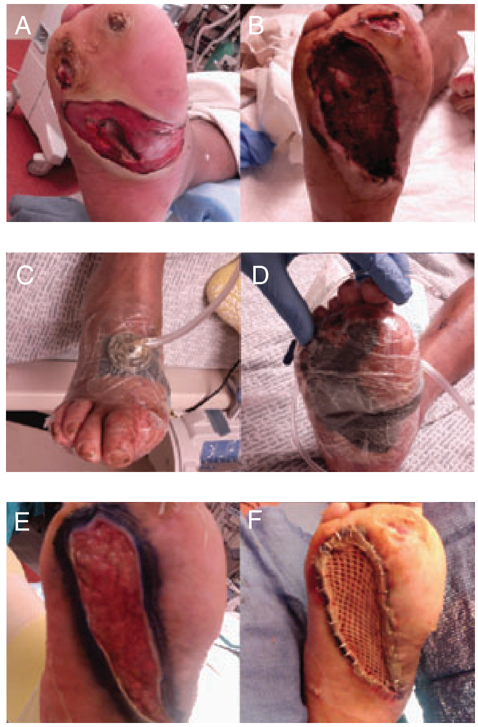


**Figure 4.** Case study 2: (A) Initial presentation of a plantar wound. (B) Debridement of wound. (C) Application of negative pressure wound therapy using reticulated open cell foam (NPWT/ROCF). (D) Bridging technique. (E) Granulation tissue formation after 3 weeks of NPWT/ROCF. (F) Application of split-thickness skin graft.

## FUTURE DIRECTIONS AND ECONOMIC VALUE

There is enhanced optimism with these difficult DFU cases. By merging established and effective treatment modalities and bringing them to the amputation prevention team, the toll of


**Figure 3.** Case study 1: (A) Initial wound presentation following intraoperative debridement. (B) After 4 weeks of bridged negative pressure wound therapy using reticulated open cell foam. (C) Three weeks of total contact cast. (D) Wound healed after 9 weeks.

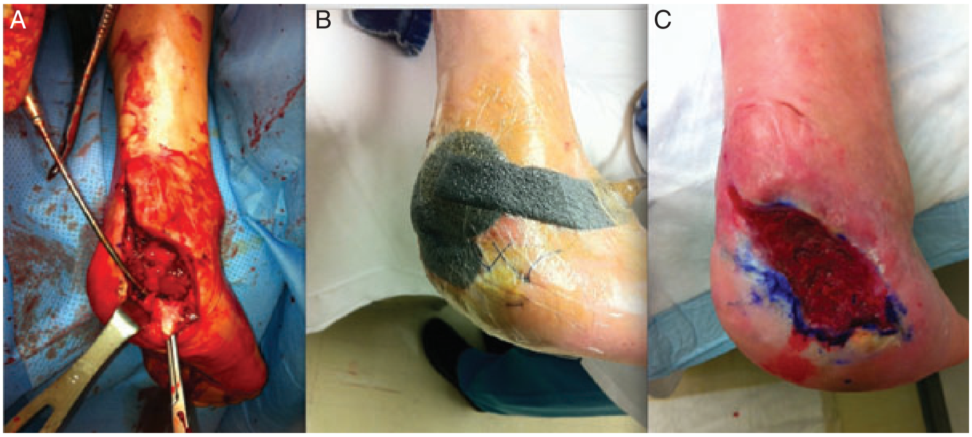


**Figure 5.** Case study 3: (A) Debridement of a partial calcanectomy. (B) Application of single-patient use negative pressure wound therapy using the bridging technique for 4 weeks. (C) Wound after 4 weeks of therapy.

diabetic foot ulceration can be further reduced. This has tremendous implications from an economical standpoint because the annual costs of DFUs and lower extremity amputations alone are estimated at $18·9 billion and $11·7 billion, respectively (2007 US dollars) (5). A multidisciplinary approach is vital for successful limb preservation (23); teams of doctors and nurses, in almost any permutation, help in reducing the risk for amputation (37–42). Merging clinicians with interest in managing the structural components and specific aspects of lower extremity wound healing with those specialised in open and endovascular intervention appears to yield natural clinical outcomes. This is particularly true when this 'toe and flow' (11,43) concept is surrounded by excellent general and specialist medical care for the patient with diabetes.

Wound care costs are substantial for the health care system, and cost-effectiveness studies are necessary in selecting therapies that maximise clinical outcomes with budget limitations. For example, Apelqvist *et al*. evaluated economic costs for the treatment of diabetic foot wounds using NPWT/ROCF and standard moist wound therapy based on clinical outcomes from an RCT by Armstrong and Lavery and found that the average total cost to achieve healing was lower using NPWT/ROCF (20,26). Other studies have also showed the cost effectiveness of NPWT/ROCF for the treatment of acute and chronic wounds (24,32,33,44,45). Further works in this area should focus on comparative effectiveness between technologies measuring not only time to healing and cost but also quality of life using standard and portable form factors.

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## CONFLICTS OF INTEREST

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