Integrated negative pressure wound therapy system with volumetric automated fluid instillation in wounds at risk for compromised healing

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ABSTRACT

Nearly all wounds are at risk for compromised healing due to excessive exudation, oedema, contaminants and presence of inflammatory mediators. Compromised wounds have the potential to develop complications, such as infection, which may lead to delayed wound healing, prolonged hospitalisation and more frequent readmissions. It is generally believed that the wound advances from contamination to colonisation when the bacteria on the wound's surface begin to replicate and increase their metabolic activity. Heavy bacterial bioburden increases the metabolic requirements, stimulates a proinflammatory environment and encourages the in-migration of monocytes, macrophages and leukocytes – all of which can negatively impact wound healing. Bacteria also secrete harmful cytokines which can lead to vasoconstriction and decreased blood flow. Thus, controlling or preventing infections is essential for normal wound healing process to occur. While the mainstay of treating wound infection has historically included intravenous, oral and/or topical antimicrobials in addition to frequent gauze dressing changes, a shift towards wound management with advanced modalities, such as negative pressure wound therapy (NPWT), has occurred during the past decade. This review will provide expert opinion and scientific support for the use of NPWT with instillation (NPWTi; V.A.C. Instill® Wound Therapy and V.A.C. VeraFlo™ Therapy, KCI USA, Inc., San Antonio, TX) for the treatment of at-risk and complicated wounds.

Key words: At-risk wounds • Infected wounds • Negative pressure wound therapy with instillation

INTRODUCTION

Negative pressure wound therapy with instillation (NPWTi) differs from standard NPWT systems in that topical solutions are cyclically fed into the foam dressing via an additional set of ingress tubing and held for a user-selected period before removal under negative pressure. Solutions intended for topical use include topical cleansers, antibiotics, antifungals and antiseptics. Alternating topical wound solution instillation with NPWT may assist with wound cleansing, irrigation and removal of infectious material (1–3). Generally, instillation therapy is indicated for wounds, such as acute, traumatic, dehisced, chronic and ulcers (pressure, diabetic and venous), that would benefit from vacuum-assisted drainage and controlled delivery of topical wound

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treatment solutions and suspensions over the wound bed.

More specifically, NPWTi has been reported to have been used in wounds with high levels of exudate and slough content, as well as acute traumatic wounds or wounds acutely debrided due to infected soft tissue (2). The combination therapy has also been reported to be successful in cases of large areas of post-debrided exposed bone and cases of critical bacterial colonisation levels as an alternative to antibiotic-impregnated beads, when appropriate (4).

Until recently, commercially available NPWT-instillation systems (i.e. continuous or gravity-fed) have been cumbersome to set up and limited in their ability to regulate solution volume delivery. The recent introduction of a system that combines NPWT and a new volumetrically controlled NPWTi (NPWT/NPWTi; V.A.C.ULTA™ Therapy, KCI USA, Inc., San Antonio, TX) has simplified and increased the precision of this technique. This instillation technology (V.A.C. VeraFlo™ Therapy; KCI USA, Inc.) uses reticulated open-cell foam dressings that are less hydrophobic and specifically designed for instillation therapy [V.A.C. VeraFlo™ (ROCF-V) and V.A.C. VeraFlo™ Cleanse (ROCF-VC); KCI USA, Inc.]. Although NPWT alone provides adjunctive therapy that helps remove wound fluid and infectious material, NPWTi also includes added benefits, such as controlled, automated wound cleansing through instillation of topical antiseptic or antimicrobial wound solutions over the wound bed. Recent pilot studies using this new NPWT/NPWTi system have shown positive results for the treatment of complex wounds (5,6).

REVIEW OF NPWTi FOR WOUND TREATMENT

A growing number of studies have reported on the effectiveness of NPWTi in various at-risk wound types (2–4,7). A pilot study of five post-surgical diabetic foot wounds treated with NPWTi using a bacitracin-polymyxin B solution showed successful outcomes with complete healing and no amputations, which resulted in early discharges to an outpatient setting. Authors reported that the addition of an instilled solution lowered wound fluid viscosity, facilitating more efficient removal into the canister (4).

Several more recent NPWTi studies have included larger patient groups with infected soft tissue or orthopedic wounds (2,8–10). Gabriel *et al*. (2) published results from 15 patients with complex, infected wounds treated with NPWTi using silver nitrate compared to a retrospective historical Control group treated with moist gauze. NPWTi patients compared to Control patients required significantly fewer days of treatment ($9{\cdot}9 \pm 4{\cdot}3$ versus $36{\cdot}5 \pm 13{\cdot}1$ days, $P < 0{\cdot}001$), cleared clinical infection in a shorter time ($6{\cdot}0 \pm 1{\cdot}5$ versus $25{\cdot}9 \pm 6{\cdot}6$ days, $P < 0{\cdot}001$), achieved wound closure sooner ($13{\cdot}2 \pm 6{\cdot}8$ versus $29{\cdot}6 \pm 6{\cdot}5$ days, $P < 0{\cdot}001$) and had shorter inpatient length of stay ($14{\cdot}7 \pm 9{\cdot}2$ versus $39{\cdot}2 \pm 12{\cdot}1$ days, $P < 0{\cdot}001$). The authors concluded that NPWTi 'may reduce cost and decrease inpatient care requirements for these complex, infected wounds' (2).

Timmers *et al*. (8) also reported on a retrospective, case-control cohort study of patients with osteomyelitis of the pelvis or lower extremity treated with systemic antibiotics and NPWTi with a polyhexanide antiseptic solution or treated with gentamicin polymethylmethacrylate beads and long-term intravenous antibiotics (Control). The rate of infection recurrence was reduced with NPWTi compared to Control [3/30 (10%) versus 55/93 (58·5%), respectively $P < 0{\cdot}0001$]. Mean duration of total hospital stay (36 days with NPWTi versus 73 days with Control; $P < 0{\cdot}0001$) and number of required surgical procedures (two with NPWTi versus five with Control $P < 0{\cdot}0001$) were also significantly less in the NPWTi group. In addition, Schintler *et al*. (9) reported on the successful NPWTi and polyhexanide treatment of 15 patients with complicated skin and soft tissue infection. Therapy duration ranged from 4 to 18 days. Infection was controlled and complete healing was achieved in all patients. The authors concluded that NPWTi may be a viable option for treating challenging, complex wounds at risk for compromised healing (9).

Positive outcomes have also been described in a pilot study of five patients with large infected venous stasis ulcers [multi-drug-resistant *Pseudomonas* ($n = 2$) and methicillin-resistant *Staphylococcus aureus* ($n = 3$)] treated with NPWTi and 12·5% Dakin's solution. After 10 days of NPWTi, quantitative biopsies were negative for bacteria growth. Patients

then received a split-thickness skin graft followed by 4 days of standard NPWT. At 1-month follow up, there was 100% graft take, and all wounds remained healed after 1 year (11). Additional case reports have described successful use of adjunctive NPWTi in infected open abdomen (12) and pyoderma gangrenosum post breast reconstruction (13).

WOUND PREPARATION AND INITIATION CRITERIA

A comprehensive patient and wound assessment should be performed (7). NPWTi should be used in conjunction with appropriate local wound care including irrigation, debridement and systemic antibiotics. Initially, all wounds should be visually assessed for devitalised tissue, and level of contamination and infection can be confirmed by punch-wound biopsy cultures before and after debridement. After confirmation of infection, systemic antibiotic treatment should be administered if signs and symptoms of systemic infection exist and followed by initiation of NPWTi. Appropriate operative debridement should also be performed prior to NPWTi initiation in all wounds and reassessed at each dressing change for initiation of either NPWT or NPWTi. In this way, necrotic tissue, exudate and infectious material are removed from the wound bed, which will assist the wound in progressing through the normal phases of wound healing. Adequate haemostasis should also be achieved before NPWTi is used.

Clinical literature reports that wounds that have benefited from vacuum-assisted drainage and controlled delivery of topical wound treatment solutions include contaminated or stalled wounds, colonised or critically colonised wounds, infected wounds, chronic wounds, high-level exudating wounds and high-risk wounds for amputation (2,7,14).

TREATMENT GOALS/OUTCOMES

The goal of managing any wound is to achieve closure or coverage efficiently while minimising donor site morbidity. Appropriate management should lead to downstaging of reconstruction technique and coverage, whether delayed primary closure, skin graft, skin substitute or vascularised flap.

Goals of NPWTi are helping to clean wounds, clear infection, enhance granulation tissue formation for primary closure or flap/graft coverage, thereby facilitating limb and implant salvage, hospital discharge and reducing complexity of required reconstructive procedures. Soaking the wound with topical solutions can also decrease the viscosity of thick exudates, easing their removal through the foam.

CONTRAINDICATIONS/WARNINGS

Contraindications and warnings for NPWTi include:

- NPWT with or without instillation should not be used in the presence of untreated osteomyelitis, necrotic tissue with eschar present, non-enteric or unexplored fistulas, or malignancy in the wound. NPWT/NPWTi dressings should never be placed in direct contact with exposed blood vessels, anastomotic sites, organs or nerves
- NPWTi dressings should not be used with Octenisept® (Schülke & Mayr GmbH, Norderstedt, Germany), hydrogen peroxide or solutions that are alcohol-based or contain alcohol
- Fluids should not be delivered to the thoracic and abdominal cavity, due to the potential risk to alter core body temperature and the potential for fluid retention within the cavity
- Solutions should not be infused into wounds with unexplored tunnels or unexplored undermining due to the possibility of inadvertently instilling topical wound solutions into adjacent body cavities
- Due to periodic application of negative pressure, NPWTi should not be used on wounds requiring continuous negative pressure, such as over unstable structures, on patients at increased risk of bleeding, or over flaps or grafts
- Some topical wound solutions or suspensions may adversely affect cellular or acellular bioengineered materials
- NPWTi should not be initiated when haemostatic agents have been used in the wound bed

Additional warnings and precautions are provided in the Instructions for Use, which

should always be consulted for complete safety information.

DISCONTINUATION CRITERIA

The wound should be assessed at every dressing change and a decision to continue NPWTi, convert to traditional NPWT, or close the wound should be made during this time. Plans for coverage can be made by consulting the appropriate clinician to evaluate the wound. If hardware and/or bone are still exposed, NPWTi should be continued until there is appropriate granulation coverage. If thick exudate persists and the wound has not improved, additional debridement followed by NPWTi should be considered. Once the wound has improved and the clinician judges that the wound has progressed, conversion to traditional NPWT may be considered. Therapy should be discontinued when the wound is ready for primary closure or coverage with a flap or graft. NPWTi should also be discontinued if any condition of gross infection, sepsis, recurrent infection or untreated osteomyelitis is revealed.

TECHNICAL PEARLS

NPWTi may allow surgeons to perform fewer complex reconstructive procedures for major soft tissue defects and reduce donor site

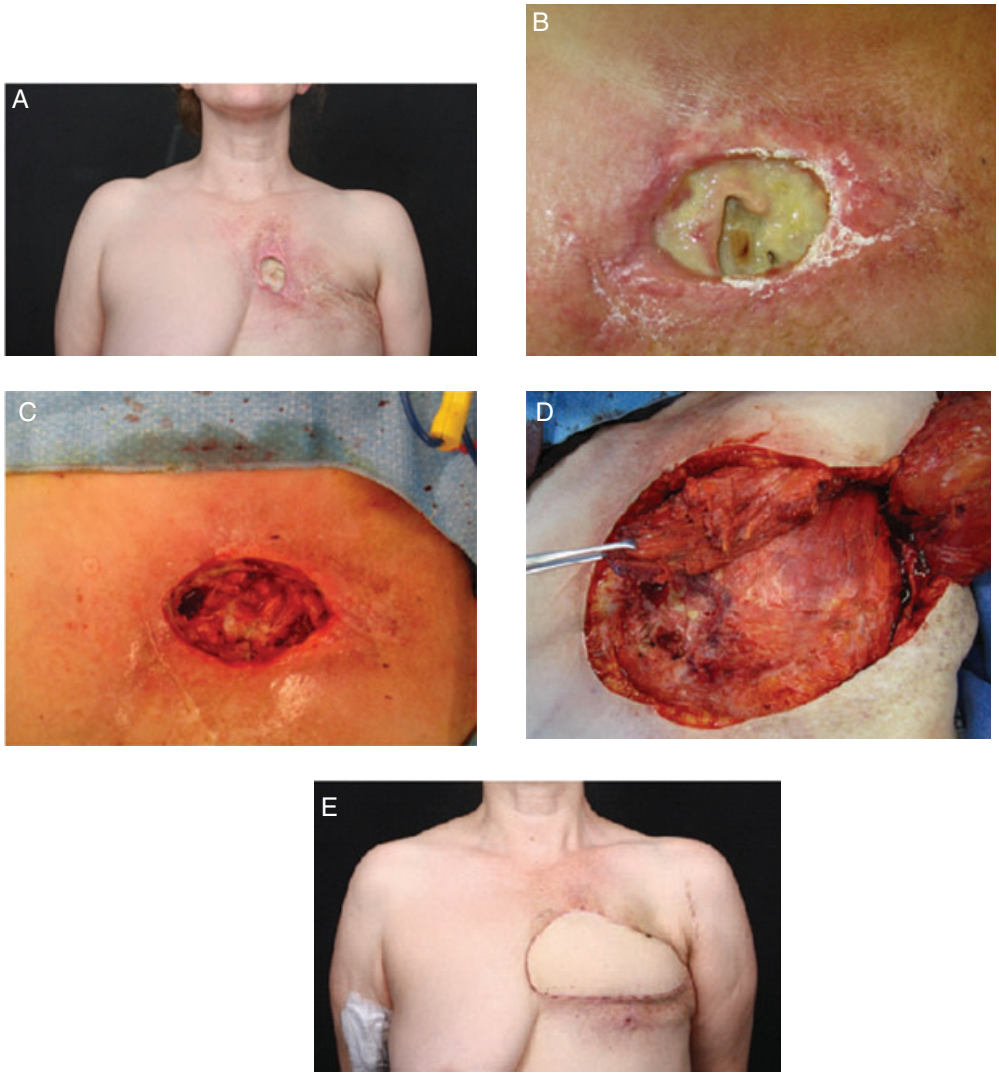

Figure 1. Case study 1: (A) Radiated chest wound. (B) Initial presentation of chest wound. (C) Wound after debridement of rib and cartilage and 4 days of negative pressure wound therapy with instillation (NPWTi/ROCF-V). (D) Excision of radiated skin. (E) Six weeks following chest wall reconstruction with latissimus flap.

morbidity compared to NPWT alone (2,7). Most wounds appear to benefit from at least 1 or 2 days of instillation/irrigation, and use of NPWTi may lead to fewer trips to the operating room for washouts. Wounds can be washed out as frequently as needed at bedside with NPWTi, and improvement is typically seen as long as appropriate aggressive debridement is performed.

An NPWTi cycle includes solution volume, soak time and NPWT time – all of which should be adjusted according to patient wound care needs. The NPWTi device can be set to cleanse the wound as often as necessary to remove debris, and appropriate clinical judgment should be used to assess the frequency needed to achieve this goal. One way to assess optimal frequency and amount of solution delivery is to evaluate the colour and consistency of the exudate and fluid drawn into the canister.

CLINICAL CASES

Case study 1

A 43-year-old female presented with an infected chest wound after radiation. Prior to debridement, the wound was visually assessed for infection. Punch-wound biopsy cultures were positive for bacterial bioburden. Patient received systemic antibiotics and wound was debrided. NPWTi/ROCF-V was initiated, and Prontosan® (B.Braun Medical Inc., Bethlehem,

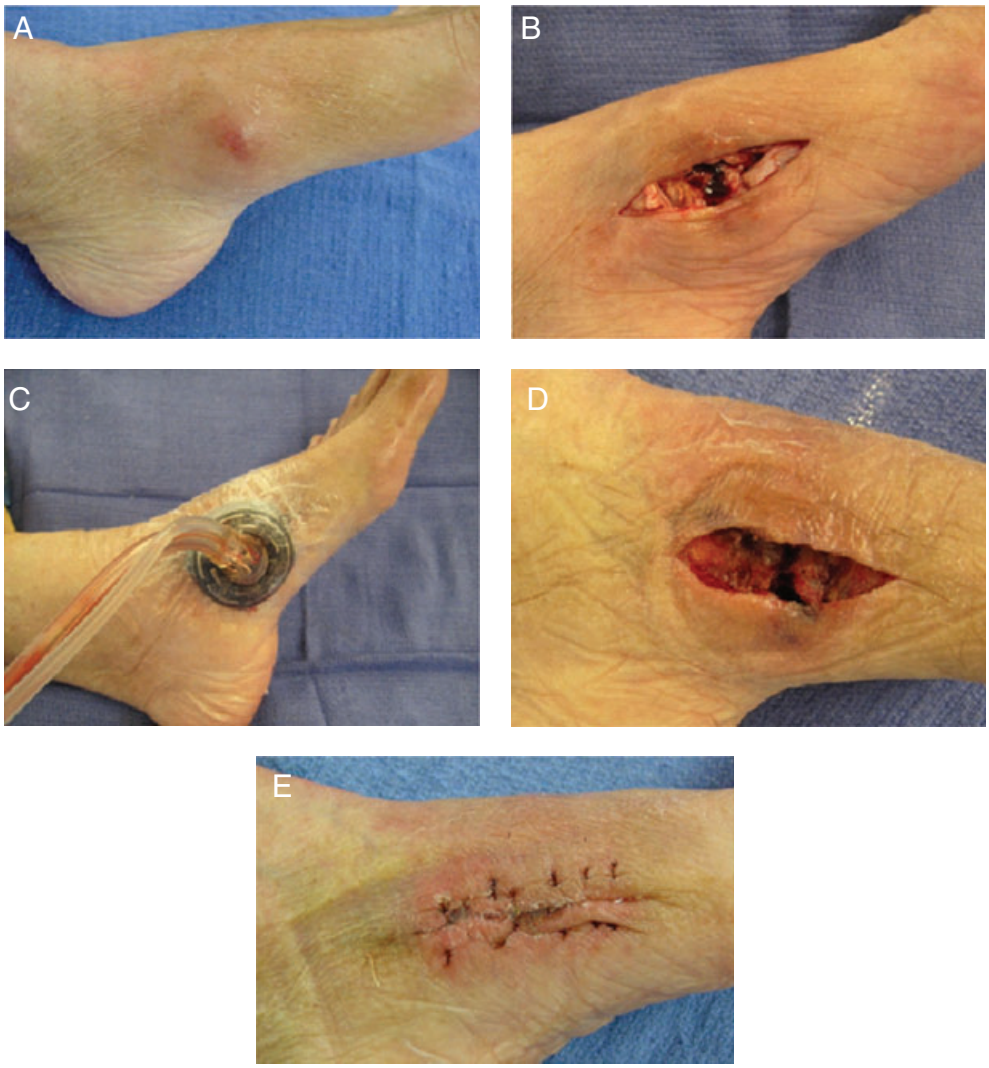

Figure 2. Case study 2: (A) Left foot abscess at presentation. (B) Abscess was drained and the wound debrided. (C) Application of negative pressure wound therapy with instillation (NPWTi/ROCF-V). (D) After 3 days of NPWTi/ROCF-V, wound was ready for primary closure. (E) Two weeks following primary closure.

PA) was instilled until the foam was filled, followed by a soak time of 3 minutes. Instillation was repeated every hour followed by continuous negative pressure at −125 mm Hg for 3 days. No complications occurred during therapy, and granulation tissue was present with negative cultures at the time of coverage with a latissimus flap (Figure 1).

Case study 2

An 86-year-old female diabetic with peripheral vascular disease presented with a left foot abscess. Prior to debridement, the wound was visually assessed for infection. Punch-wound biopsy cultures were positive for bacterial burden. Patient received systemic antibiotics and the wound was debrided. NPWTi/ROCF-V was initiated, and saline was instilled until the foam was filled followed by a soak time of 3 minutes. Instillation was repeated every 2 hours followed by continuous negative pressure at −125 mmHg for 3 days. No complications occurred during therapy, and granulation tissue was present with negative cultures at the time of primary closure (Figure 2).

ECONOMIC VALUE AND FUTURE DIRECTIONS

Costs of wound infection are enormous, both in terms of economics and morbidity. According to the US Centers for Disease Control and Prevention, each year, US hospitals alone experience 1·7 million healthcare-associated infections (HAIs), leading to 99 000 deaths and costing between $37 and $45 billion (15). Although hospitals are making considerable strides in reducing HAIs, the incidence of complicated, at-risk wounds remains on the rise and successful outcomes depend on management that is both aggressive and efficient. Rapid healing and early hospital discharge allow the patient to return more quickly to daily living, reducing costs for hospitals and society. Hence, controlling colonisation of the wound by various means, including NPWTi, is critical for cost control.

Numerous anecdotal studies have shown bioburden reduction and elimination of infection with adjunctive use of NPWTi, and its increased usage will likely continue for the foreseeable future. However, controlled studies that include wide-ranging economic factors associated with hospital costs are needed to prove NPWTi's overall cost effectiveness.

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CONFLICTS OF INTEREST

Dr AG has a Consulting agreement with Kinetic Concepts, Inc. This article is part of an educational supplement funded by Kinetic Concepts, Inc. to provide an overview of the V.A.C.® Therapy family of products for new users in developing markets. Targeted for distribution at the 2012 World Union of Wound Healing Societies (WUWHS) conference, this supplement article presents a brief literature review and clinical experience treating compromised wounds using V.A.C.® Therapy with instillation (i.e. VA.C. Instill® Wound Therapy and V.A.C. VeraFlo™ Therapy).

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