ORIGINAL ARTICLE



Negative pressure wound therapy with instillation: International consensus guidelines update

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Abstract

The use of negative pressure wound therapy with instillation and dwell time (NPWTi-d) has gained wider adoption and interest due in part to the increasing complexity of wounds and patient conditions. Best practices for the use of NPWTid have shifted in recent years based on a growing body of evidence and expanded worldwide experience with the technology. To better guide the use of NPWTi-d with all dressing and setting configurations, as well as solutions, there is a need to publish updated international consensus guidelines, which were last produced over 6 years ago. An international, multidisciplinary expert panel of clinicians was convened on 22 to 23 February 2019, to assist in developing current recommendations for best practices of the use of NPWTi-d. Principal aims of the meeting were to update recommendations based on panel members' experience and published results regarding topics such as appropriate application settings, topical wound solution selection, and wound and patient characteristics for the use of NPWTi-d with various dressing types. The final consensus recommendations were derived based on greater than 80% agreement among the panellists. The guidelines in this publication represent further refinement of the recommended parameters originally established for the use of NPWTi-d. The authors thank Karen Beach and Ricardo Martinez for their assistance with manuscript preparation.

KEYWORDS

NPWTi, topical wound solution, wound bioburden, wound cleansing, V.A.C. Veraflo therapy

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1 | INTRODUCTION

Although standard negative pressure wound therapy (NPWT) has been used to successfully manage both acute and chronic wounds since 1997, the benefits of regular wound cleansing between dressing changes have become more apparent in recent years to address healing impediments. Thus, instillation of a topical solution with removal via alternating negative pressure cycles is an important evolution of the NPWT concept. During negative pressure wound therapy with instillation and dwell time (NPWTi-d), a topical wound solution is instilled and allowed to dwell in the wound at set intervals to facilitate regular wound cleansing and wound bed preparation to help promote wound healing in certain complex wounds.

Best practices for the use of NPWTi-d have shifted in recent years based on a growing body of evidence and expanded worldwide experience with the technology. Although NPWTi-d was initially largely used as a last-resort therapy, it is increasingly being used to influence the wound-healing process by combining the mechanisms of action of standard NPWT (eg, draw wound edges together, promote perfusion and granulation tissue formation, remove exudate, reduce oedema) with the benefits of cyclic cleansing that dilutes and solubilises wound debris. In addition, a new NPWTi-d dressing with through holes is available to help expand the use of this therapy in wounds that contain devitalised tissue or in patients who are not candidates to undergo immediate surgical debridement.²

To better guide the use of NPWTi-d with all instillation dressing configurations, there is a need to publish updated international consensus guidelines, which were last produced over 6 years ago. While numerous studies regarding successful use of NPWTi-d have been published during the past 5 years, only a few of the studies provide comparative data. Although expert opinion is low-level evidence, it can provide valuable guidance until further comparative studies are available.

Principal aims of these guidelines are to update recommendations, based on panel members' experience and published results, regarding appropriate application settings, topical wound solution selection, and wound and patient characteristics for use of NPWTi-d (V.A.C. VERAFLO Therapy, KCI, an Acelity Company, San Antonio, Texas) with various reticulated opencell foam (ROCF) dressing types (ROCF-V, V.A.C. VERAFLO Dressing and ROCF-CC, V.A.C. VERAFLO CLEANSE CHOICE Dressing, KCI, an Acelity Company).

2 | METHODS

2.1 | Advisory panel meeting

Panel members were selected by the sponsor based on publication experience on the topic of NPWTi-d and level of

Key Messages

- updated recommendations have been developed from an international, multidisciplinary expert advisory panel meeting that was recently convened to discuss best practices for the use of negative pressure wound therapy with instillation and dwell time
- these consensus recommendations, based on panel members' experience and published results, are meant to help guide selection of application settings, topical wound solutions, and wound and patient characteristics for use of negative pressure wound therapy and instillation with various reticulated open-cell foam dressing types
- normal saline was recommended as the first choice of instilled topical solution with negative pressure wound therapy, with instillation for most wounds, vs topical antiseptic solutions, which were previously used more often as first-line instilled topical solutions
- reticulated open-cell foam dressings with through holes were recommended over standard reticulated open-cell foam dressings (without through holes) in wounds that contain areas of devitalised tissue

clinical experience with the therapy. An attempt was made to include attendees from a range of specialties and geographical areas to capture diverse practice patterns for discussion. Eleven physicians, a registered nurse, and a nurse practitioner attended the advisory panel meeting. Panel members were selected from North America, Europe, and Asia and included specialties of general surgery, plastic surgery, nursing, wound care, and podiatric surgery.

Prior to the face-to-face meeting, panel members were provided with the agenda for the meeting and topics for discussion. The multidisciplinary advisory panel meeting took place on 22 to 23 February 2019 in Charlotte, North Carolina, United States. The sessions were directed by a moderator (author P.K.) and organised into the following topics: (a) review of technology and mechanisms of action, (b) literature review of clinical use, (c) discussion and development of consensus statements, and (d) attendee presentations of clinical experience and case studies. The meeting was recorded for follow up.

2.2 | Literature search and dissemination of studies

A literature search was performed using PubMed, the Cochrane Library, OVID, EMBASE, ScienceDirect, and

alternative resources. The following terms were used for the literature search: ("Lavage" or "instill" or "instillation" or "irrigated" or "irrigation" or "topical solution" or "topical wound solution" or "topic solution") and ("NPWT" or "vacuum assisted closure" or "VAC" or "vacuum sealing" or "drainage" or "NPWTi" or "NPWTi-d") and ("VERAFLO" or "VERAFLOW" or "Veraflo dressing" or "Veraflo cleanse dressing" or "Veraflo cleanse choice dressing" or "Ulta"). Registered studies from ClinicalTrials.gov were reviewed using the same search criteria for completed and terminated studies to determine publication bias. References from identified publications and abstracts were also reviewed. The literature search yielded 67 relevant articles, which were copied and provided to panel members upon arrival at the meeting.

2.3 | Post-meeting follow up

A list of 109 consensus statements was drafted after the meeting by the co-moderator and sent in the format of a survey (SurveyMonkey, San Mateo, California) to all advisory panel members for review and response. Panel members were asked to mark agreement or disagreement for each statement and were instructed to send any additional comments via e-mail. Blank responses were not counted.

The survey results were tallied and summarised in a standardised report provided by the survey software company. Final consensus guidelines were then drafted based on the survey results. Edits were collected from all panel members and were incorporated by the medical writer into the final submitted document. All content in this manuscript was agreed on by all authors.

2.4 | Consensus agreement

A modified Delphi method⁴ was used to yield consensus for each of the statements below. For this panel, consensus was considered to have been achieved when there was at least 80% agreement to the statement. Each statement that received at least 80% agreement, or agreement from at least 11 of 13 survey participants, was included in the final consensus statements. The results of the survey are organised in Tables 1 to 10, with the first column representing each statement proposed in the survey. The second column reports the tally and percentage of "yes/no" responses, and the third column indicates whether the guideline statement achieved consensus.

3 | RESULTS

3.1 | Overview

The consensus statements that achieved greater than 80% agreement by the members of the expert panel are outlined

below. Other statements reached a high degree of agreement but did not meet the threshold for inclusion in the consensus statement. Exclusion of these statements in the final consensus statement does not necessarily mean that the contents of these statements are ill advised, and therefore, all statements are included in the supporting tables.

Consensus Statement 1: In conjunction with appropriate wound care, such as debridement and systemic antibiotics, NPWTi-d may be used as an adjunct therapy in the following acute, chronic, and/or infected wound types: (a) traumatic wounds; (b) surgical, including dehisced, wounds; (c) diabetic wounds; (d) venous leg ulcers; (e) pressure injuries/ulcers; (f) wounds with exposed intact bone; (g) wounds with treated, underlying osteomyelitis; (h) infected or contaminated wounds in the presence of orthopaedic fixation hardware; (i) full-thickness burns after excision; (j) wounds resulting from evacuation of a haematoma and when haemostasis is achieved; and (k) wounds that are a bridge between staged/delayed amputation (Table 1).

NPWTi-d should be targeted within the framework of a clearly defined treatment plan and timetable. Holistic wound care treatment begins with thorough patient and wound assessments for underlying intrinsic and extrinsic factors. Fundamental principles of wound treatment application include appropriate antibiotic therapy, debridement, wound bed preparation, and local wound care. NPWTi-d does not replace debridement or appropriate surgical care. Alternative treatment options should be taken into consideration if the predefined treatment plan and timetable are not attainable.

NPWTi-d aids in automatic cleansing of the wound surface and solubilising devitalised tissue for removal.⁵ It can assist with early, aggressive removal of exudate and be used to lessen bacterial load.⁶ According to panel members, the therapy can be particularly beneficial in wounds that contain several small debris particles, in wounds with loss of wound bed integrity in order to prepare the wound bed prior to a split-thickness skin graft (STSG) or full-thickness skin graft, in diabetic wounds, and in cases where granulation tissue formation is needed.

Successful use of NPWTi-d has been reported in treating a wide variety of complicated wounds including diabetic foot wounds,⁷ extremity and trunk wounds,⁸ pressure ulcers,⁹ venous leg ulcers,¹⁰ sternal wounds,¹¹ breast wounds,¹² abdominal wounds with intact synthetic mesh,¹³ necrotising fasciitis after debridement,¹⁴ and infected wounds requiring operative debridement.¹⁵

Consensus Statement 2: Compatible solutions that may be used with NPWTi-d with ROCF-V or ROCF-CC dressings include: (a) normal saline, (b) hypochlorous acid solution, (c) sodium hypochlorite solution (dilute Dakin's solution 0.125% or quarter strength), (d) acetic acid solution (0.25% to 1.0%), and (e) polyhexamethylene biguanide (0.1%) + betaine (0.1%) (Table 2).

TABLE 1 General use statements and survey results

| Consensus statement | Yes | No | Consensus |
|---|--------------|------------|-----------|
| NPWTi-d is an appropriate adjunctive therapy for traumatic wounds | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for surgical, including dehisced, wounds | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for diabetic wounds | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for venous leg ulcers | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for pressure injuries/ulcers | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for wounds with exposed intact bone | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for wounds with treated, underlying osteomyelitis | 12/13 (92%) | 1/13 (8%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for infected or contaminated wounds in the presence of orthopedic fixation hardware | 11/13 (85%) | 2/13 (15%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for full-thickness burns after excision | 12/12 (100%) | 0/12 (0%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for wounds with exposed synthetic mesh over an intact abdominal wall | 10/13 (77%) | 3/13 (23%) | No |
| NPWTi-d is an appropriate adjunctive therapy for a wound created from hematoma evacuation when hemostasis has been achieved | 12/13 (92%) | 1/13 (8%) | Yes |
| NPWTi-d is an appropriate adjunctive therapy for wounds that are a bridge between staged/ delayed amputation | 12/13 (92%) | 1/13 (8%) | Yes |

Instillation of topical wound solutions should be performed using appropriate clinical practices and only with solutions compatible with NPWTi-d foam dressings and disposable components. All recommended solutions in this consensus statement are compatible with NPWTi-d foam dressings and disposable components. Lactated Ringer's solution is also compatible with NPWTi-d dressings and has been recommended in other guidelines as an appropriate instillation solution. ¹⁶

Use of topical antiseptics for wound cleansing is on the upsurge. According to Kramer et al, an infected or critically colonised wound should be treated antiseptically in addition to the appropriate administration of systemic antibiotic therapy. Similarly, the primary purpose of the original concept of NPWTi-d was to provide a mechanism whereby topical antiseptic wound solutions could be regularly delivered to the wound bed during NPWT while the dressing and therapy remained in place. 18

Use of saline for instillation was not recommended by 5 of 11 panel members in the original International

Consensus Guidelines published in 2013.³ Shortly thereafter, a published randomized controlled trial demonstrated that instillation of normal saline achieved comparative outcomes as with other antiseptic solutions, including polyhexamethylene biguanide (0.1%) + betaine (0.1%).¹⁹ Other case series have also been published showing successful outcomes with saline.^{7,8,20} Based on these studies and the experience of the panel members, results of this consensus panel support a shift toward use of saline as the preferred topical wound instillation solution with NPWTi-d for the majority of wounds.

Although many of the panel members stated that they only used saline as the instilled topical wound solution for NPWTi-d, some panel members recommended a topical antiseptic solution as the first choice for instillation in certain cases, such as presence of acute infection or high levels of bacteria colonisation. The choice of topical antiseptic solution may be based on tolerability, spectrum of activity, availability, and/or cost, and all topical wound solutions

TABLE 2 Instillation solution statements and survey results

| Consensus statement | Yes | No | Consensus |
|---|--------------|------------|-----------|
| An appropriate solution is normal saline | 12/12 (100%) | 0/12 (0%) | Yes |
| An appropriate solution is hypochlorous acid solution (examples: Vashe, Puracyn, NeutroPhase) | 10/11 (91%) | 1/11 (9%) | Yes |
| An appropriate solution is oxidized water/quarter strength sodium hypochlorite/quarter strength hypochlorous acid/sodium chloride solution (examples: Dermacyn, Microcyn) | 7/11 (64%) | 4/11 (36%) | No |
| An appropriate solution is sodium hypochlorite solution (Dakin's solution 0.125%) | 10/12 (83%) | 2/12 (17%) | Yes |
| An appropriate solution is silver nitrate (0.5%) | 5/10 (50%) | 5/10 (50%) | No |
| An appropriate solution is acetic acid solution (0.25% to 1.0%) | 11/13 (85%) | 2/13 (15%) | Yes |
| An appropriate solution is sulfur-based solution (sulfonamide) | 4/10 (40%) | 6/10 (60%) | No |
| An appropriate solution is polyhexamethylene biguanide (0.1%) + betaine (0.1%) | 12/13 (92%) | 1/13 (8%) | Yes |
| An appropriate solution is topical 2.0% lidocaine HCl diluted to 0.1% | 7/12 (58%) | 5/12 (42%) | No |

should be used in line with the solution manufacturerrecommended dwell times and concentrations for effectiveness.

Based on published literature²¹⁻²⁴ and clinical experience, several panel members recommended use of an antiseptic solution, vs saline, as a preferred solution for instillation with NPWT when treating wounds with orthopaedic fixation hardware.

Several panel members recommended an antiseptic solution, such as hypochlorous acid solution or sodium hypochlorite solution, as the initial topical solution for wounds with clinical signs of infection, followed by saline instillation after 24 to 48 hours, based on their own experiences. With this method, the wound benefits from the antiseptic effects of the solution but without the potential cytotoxic effects of some antiseptic solutions with longer-term use. This should be in conjunction with appropriate systemic antibiotic therapy, and the switch to saline is made based on ongoing patient and wound assessments. Further research may be needed to confirm the recommendation.

Based on previously published recommendations in Germany,¹⁶ these advisory panel members also agreed that 0.04% polyhexanide solution should not be instilled directly on cartilage unless it has been strongly diluted (0.005%) to prevent damage to the cartilage. Several studies^{17,25,26} and panel members support use of acetic acid solution, diluted to 0.25%, to ensure dressing compatibility, with NPWTi-d as an available and inexpensive therapy combination that is well tolerated with no reported resistance.

Solutions that are compatible with NPWTi-d dressings and disposables but did not achieve consensus for use with NPWTi-d include silver nitrate, polyhexanide 0.04% solution (Lavasept, B. Braun Medical, Hessen, Germany), oxidised water/quarter-strength sodium hypochlorite/quarter-strength hypochlorous acid/sodium chloride solution (eg, Dermacyn & Microcyn [Dyamed Biotech, Kuala Lumpur, Malaysia]), sulphur-based solutions, and 2% topical lidocaine diluted to 0.1%.

It is possible that the ongoing cleansing effects from the presence of an instilled topical wound solution may have a greater influence on NPWTi-d outcomes vs the solution type itself in various wounds. Bioburden reduction achieved with antiseptic solutions can also have various effects on wound healing depending on the host, wound type, or solution type. Panel members recommended against instillation of topical antibiotics because of the potential development of local resistance and contact sensitisation. Much more research is needed to understand the effects of each of the solutions on specific wound types.

Consensus Statement 3: NPWTi-d is not recommended: (a) in wounds with presence of exposed, unprotected organs and vessels; (b) in wounds with presence of undrained abscess(es); (c) over split-thickness skin grafts; (d) over dermal substitutes; and (e) in acutely ischaemic wounds (Table 3).

In addition to the cautions and contraindications listed in the manufacturer guidelines, panel members outlined certain wound types and characteristics that they do not recommend

TABLE 3 Uses for NPWTi-d that are not recommended: statements and survey results

| Consensus statement | Yes | No | Consensus |
|---|--------------|------------|-----------|
| NPWTi-d IS NOT recommended in wounds with presence of exposed, unprotected organs and vessels | 12/13 (92%) | 1/13 (8%) | Yes |
| NPWTi-d IS NOT recommended in wounds with presence of undrained abscess(es) | 11/13 (85%) | 2/13 (15%) | Yes |
| NPWTi-d IS NOT recommended over split- thickness skin grafts | 12/12 (100%) | 0/12 (0%) | Yes |
| NPWTi-d IS NOT recommended over dermal substitutes | 12/12 (100%) | 0/12 (0%) | Yes |
| NPWTi-d IS NOT recommended in acutely ischemic wounds | 11/12 (92%) | 1/12 (8%) | Yes |

for use with NPWTi-d. Complete drainage of any abscesses should be ensured before NPWTi-d application. A computed tomography scan or other imaging modality may be necessary to delineate areas of undrained abscesses and to confirm full drainage.

Unlike standard NPWT, NPWTi-d should not be used as a bolster dressing. Use of NPWTi-d over skin grafts or dermal substitutes is not recommended because the instilled solution may cause the STSG or dermal substitute to float off the surface.

Panel members stressed the importance of maintaining an intact seal for therapy effectiveness. Application of a hydrocolloid barrier ring around the wound was recommended to help fixate the dressing in challenging anatomical locations. Use of the therapy was not recommended in cases where a seal cannot be maintained under any circumstance.

Most panel members did not recommend use of NPWTi-d for acutely ischaemic wounds because of underlying causes that need to be addressed before NPWTi-d can be effective. The focus should be on treating the ischaemia, and

TABLE 4 Precautions for use: statements and survey results

| TABLE 4 Precautions for use: statements and survey results | | | |
|---|--------------|------------|-----------|
| Consensus statement | Yes | No | Consensus |
| NPWTi-d may be used with caution in wounds that contain appropriately protected vessels or organs | 11/13 (85%) | 2/13 (15%) | Yes |
| NPWTi-d may be used with caution in wounds that contain appropriately protected tendons, ligaments and nerves | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d may be used with caution in wounds with explored tunnels | 12/13 (92%) | 1/13 (8%) | Yes |
| NPWTi-d may be used with caution in wounds with explored areas of undermining | 13/13 (100%) | 0/13 (0%) | Yes |

Abbreviation: NPWTi-d, negative pressure wound therapy with instillation and dwell time.

if NPWTi-d is used for these wounds, lower pressures could be used based on clinician preference.

Consensus Statement 4: NPWTi-d may be used with caution in: (a) wounds that contain appropriately protected vessels or organs; (b) wounds that contain appropriately protected tendons, ligaments, and nerves; (c) wounds with explored tunnels, and (d) wounds with explored areas of undermining (Table 4).

Advisory panel members added that caution should be taken in the event of any changes to the surrounding skin, such as maceration, eczema, or atrophic skin. In these situations, there is a risk that the dressing cannot be adhered tightly or that the surrounding skin may deteriorate under the drape or may tear upon drape removal.

With bleeding wounds, there is a potential risk that blood could be removed, putting the patient at risk. In patients with an increased risk of bleeding or patients taking anticoagulants, there is a risk of bleeding under negative pressure. According to manufacturer's guidelines, patients at risk of bleeding complications should be treated and monitored in a care setting deemed appropriate by the treating physician. If active bleeding develops suddenly or in large amounts during NPWTi-d, measures should be taken to stop bleeding and seek immediate medical assistance.

TABLE 5 NPWTi-d with ROCF-V or ROCF-CC discontinuation of use: statements and survey results

| Consensus | | | |
|---|--------------|--------------|-----------|
| statement | Yes | No | Consensus |
| NPWTi-d may be discontinued when clinical goals are met | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d may be discontinued when wound is deemed ready for surgical closure or coverage | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d may be discontinued when wound is clinically stable for standard NPWT or other advanced therapy to be applied | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d should be discontinued when wound has decompensated | 11/13 (85%) | 2/13 (15%) | Yes |
| NPWTi-d should be used indefinitely | 0/13 (0%) | 13/13 (100%) | No |

Some panel members did not recommend use in cases of patients with hidradenitis suppurativa or calciphylaxis, but other panel members reported successful use of NPWTi-d in the presence of both of these conditions, similar to a small case series described in the literature.²⁷⁻²⁹

Consensus Statement 5: NPWTi-d, regardless of dressing, may be discontinued when (a) clinical goals are met, (b) wound is deemed ready for surgical closure or coverage, (c) wound is clinically stable for standard NPWT or other advanced therapy to be applied, or (d) wound has decompensated (Table 5).

All panel members agreed that NPWTi-d should not be used indefinitely but that judging when to discontinue NPWTi-d is not always clear, especially for new users of the therapy. Discontinuation of the therapy can be based on many factors, including achievement of clinical goals for the therapy, patient discharge orders, and patient noncompliance. Panel members acknowledged that

TABLE 6 NPWTi-d with ROCF-V use: statements and survey results

| CSUILS | | | |
|--|--------------|------------|-----------|
| Consensus statement | Yes | No | Consensus |
| NPWTi-d may be considered for use in adequately cleansed and debrided wounds | 13/13 (100%) | 0/13 (0%) | Yes |
| NPWTi-d may be considered for use in clean wounds | 12/13 (92%) | 1/13 (8%) | Yes |
| NPWTi-d may be considered for use in contaminated wounds | 12/13 (100%) | 1/13 (8%) | Yes |
| NPWTi-d may be considered for use in wounds with heavy bioburden | 11/13 (85%) | 2/13 (15%) | Yes |
| NPWTi-d may be considered for use in acutely infected wounds | 8/12 (67%) | 4/12 (33%) | No |
| NPWTi-d may be considered for use in chronically infected wounds | 11/13 (85%) | 2/13 (15%) | Yes |
| NPWTi-d may be considered for use in wounds that are difficult to granulate | 13/13 (100%) | 0/13 (0%) | Yes |

Abbreviation: NPWTi-d, negative pressure wound therapy with instillation and dwell time.

administrative pressures can encourage step-down therapy because of cost containment concerns. Rigorous cost analyses to determine the total comparative cost of NPWTi-d are lacking. Small comparative studies have shown a reduction in the number of operating room visits, length of hospital stay, and time to final surgical closure with use of NPWTi-d, 8,10,15 which could positively impact total cost of care.

Clinical goals of therapy can include preparation for reconstructive surgery, stabilisation of the wound bed, successful wound bed decontamination, restoration of wound bed integrity, or stimulation of granulation tissue. Goals of therapy should be reassessed at each dressing change, and device and dressings can be adjusted as needed. Panel members suggested discontinuation of the therapy within 7 days if the wound is not progressing, even after therapy adjustments are made.

TABLE 7 NPWT setting statements for ROCF-V and ROCF-CC dressing use and survey results

| Consensus statements | Yes | No | Consensus |
|--|--------------|-------------|-----------|
| NPWT time settings for ROCF-V | | | |
| An appropriate NPWT time is 30 min | 7/13 (54%) | 6/13 (46%) | No |
| An appropriate NPWT time is 1.0 h | 10/13 (77%) | 3/13 (23%) | No |
| An appropriate NPWT time is 2.0 h | 12/13 (92%) | 1/13 (8%) | Yes |
| An appropriate NPWT time is 2.5 h | 13/13 (100%) | 0/13 (0%) | Yes |
| An appropriate NPWT time is 3.0 h | 12/13 (92%) | 1/13 (8%) | Yes |
| An appropriate NPWT time is 3.5 h | 10/13 (77%) | 3/13 (23%) | No |
| An appropriate NPWT time is 4.0 h | 5/13 (46%) | 8/13 (62%) | No |
| NPWT time settings for ROCF-CC | | | |
| An appropriate NPWT time is 15 min | 3/12 (25%) | 9/12 (75%) | No |
| An appropriate NPWT time is 30 min | 6/11 (55%) | 5/11 (45) | No |
| An appropriate NPWT time is 1.0 hour | 9/12 (75%) | 3/12 (25%) | No |
| An appropriate NPWT time is 2.0 h | 11/12 (92%) | 1/12 (8%) | Yes |
| An appropriate NPWT time is 2.5 h | 10/12 (83%) | 2/12 (17%) | Yes |
| An appropriate NPWT time is 3.0 h | 8/12 (67%) | 4/12 (33%) | No |
| An appropriate NPWT time is 3.5 h | 8/12 (67%) | 4/12 (33%) | No |
| An appropriate NPWT time is 4.0 h | 3/12 (25%) | 9/12 (75%) | No |
| NPWT pressure settings for ROCF-V | | | |
| An appropriate NPWT pressure setting is -75 mmHg | 7/13 (54%) | 6/13 (46%) | No |
| An appropriate NPWT pressure setting is -100 mmHg | 9/13 (69%) | 4/13 (31%) | No |
| An appropriate NPWT pressure setting is -125 mmHg | 13/13 (100%) | 0/13 (0%) | Yes |
| An appropriate NPWT pressure setting is -150 mmHg | 9/13 (69%) | 4/13 (31%) | No |
| An appropriate NPWT pressure setting is -175 mmHg | 2/12 (17%) | 10/12 (83%) | No |
| NPWT pressure settings for ROCF-CC | | | |
| An appropriate NPWT pressure setting is -75 mmHg | 6/12 (50%) | 6/12 (50%) | No |
| An appropriate NPWT pressure setting is -100 mmHg | 7/12 (58%) | 5/12 (42%) | No |
| An appropriate NPWT pressure setting is -125 mmHg | 13/13 (100%) | 0/13 (0%) | Yes |
| An appropriate NPWT pressure setting is -150 mmHg | 7/13 (54%) | 6/13 (46%) | No |
| An appropriate NPWT pressure setting is -175 mmHg | 2/12 (17%) | 10/12 (83%) | No |

Abbreviations: NPWT, negative pressure wound therapy; ROCF, reticulated open-cell foam.

In the United States, use of NPWTi-d is allowed in acute care, long-term care facilities, and skilled nursing facilities but is not approved for use in the home setting. Therefore, discharge from any care setting to home for patients using NPWTi-d means that NPWTi-d is

automatically discontinued. In some countries in Europe, such as France, NPWTi-d is allowed in the home care setting with professional patient care. Panel members agreed that, even if a patient is scheduled for home care discharge, short-term cleansing intervals with NPWTi-d up

TABLE 8 NPWTi-d with ROCF-V or ROCF-CC instillation settings: statements and survey results

| settings: statements and su | settings: statements and survey results | | | | |
|---|---|-------------|-----------|--|--|
| Consensus statement | Yes | No | Consensus | | |
| NPWTi-d dwell settings for ROCF- V | | | | | |
| An appropriate dwell time is ≤1 min | 1/13 (8%) | 12/13 (92%) | No | | |
| An appropriate dwell time is 2 min | 4/12 (33%) | 8/12 (67%) | No | | |
| An appropriate dwell time is 5 min | 7/13 (54%) | 6/13 (46%) | No | | |
| An appropriate dwell time is 10 min | 11/13 (85%) | 2/13 (15%) | Yes | | |
| An appropriate dwell time is 15 min | 10/13 (77%) | 3/13 (23%) | No | | |
| An appropriate dwell time is 20 min | 10/13 (77%) | 3/13 (23%) | No | | |
| An appropriate dwell time is 30 min | 5/12 (42%) | 7/12 (58%) | No | | |
| NPWTi-d dwell settings for ROCF- CC | | | | | |
| An appropriate dwell time is ≤1 min | 1/13 (8%) | 12/13 (92%) | No | | |
| An appropriate dwell time is 2 min | 4/12 (33%) | 8/12 (67%) | No | | |
| An appropriate dwell time is 5 min | 9/13 (69%) | 4/13 (31%) | No | | |
| An appropriate dwell time is 10 min | 12/13 (92%) | 1/13 (8%) | Yes | | |
| An appropriate dwell time is 15 min | 10/13 (77%) | 3/13 (23%) | No | | |
| An appropriate dwell time is 20 min | 9/13 (69%) | 4/13 (31%) | No | | |
| An appropriate dwell time is 30 min | 3/12 (25%) | 9/12 (75%) | No | | |

Abbreviations: NPWTi-d, negative pressure wound therapy with instillation and dwell time; ROCF, reticulated open-cell foam.

to 24 hours can benefit the wound environment before discharge.

Consensus Statement 6: In conjunction with appropriate wound care, such as debridement and systemic antibiotics, NPWTi-d with ROCF-V may be considered for use in wounds with the following characteristics: (a) adequately cleansed and debrided wounds, (b) clean wounds, (c) contaminated wounds, (d) wounds with heavy bioburden, (e) chronically infected wounds, and (f) wounds that are difficult to granulate (Table 6).

Along with proper wound care, the addition of NPWTi-d, which allows topical wound solutions to dwell in the wound bed during NPWT, has been shown in studies to help facilitate the removal of wound debris and exudate when compared with NPWT alone. 6.8,15 In cases of chronically infected wounds, it is important to rule out underlying chronic osteomyelitis, which requires surgical management and systemic antibiotic treatment prior to NPWTi-d intervention.

Consensus was not achieved for the use of NPWTi-d in acutely infected wounds, largely because there was concern among panel members that NPWTi-d cannot be the primary treatment to address underlying acute, systemic infection. Culture-specific systemic antibiotics in conjunction with excisional debridement and decompression should be first-line treatment, followed by NPWTi-d when appropriate.

Consensus Statement 7: An appropriate negative pressure time phase is 2.0 to 3.0 hours with ROCF-V dressing and 2.0 to 2.5 hours with ROCF-CC dressing (Table 7).

In general, NPWTi-d with ROCF-CC vs ROCF-V is recommended for wounds with areas of devitalised tissue. Panel members agreed that slightly shorter time phases of negative pressure may be more useful with ROCF-CC dressing use in wounds with a more fibrinous base. More frequent cycles of cleansing may also aid in the removal of debris and exudate. In anatomic locations where there is increased potential for leaks, clinicians may want to consider less frequent cycles to minimise risk of leaks. These recommendations are based on panel opinion, clinician strategy, and device design. Further comparative studies are necessary to determine more definitive negative pressure times.

Consensus Statement 8: The recommended negative pressure setting for NPWTi-d with ROCF-V and ROCF-CC dressing is – 125 mmHg (Table 7).

The recommended setting of negative pressure has not varied from the original consensus guidelines,³ even with the introduction of the ROCF-CC dressing. There was strong agreement among consensus panel members that a negative pressure setting of -125 mmHg should be used for NPWTid treatment of wounds with few exceptions. This supports the vast majority of published studies that have demonstrated positive results with a negative pressure setting of -125 mmHg.

TABLE 9 NPWTi-d with ROCF-CC: statements and survey results

| Consensus statement | Yes | No | Consensus |
|--|--------------|------------|-----------|
| ROCF-CC can be considered in wounds that contain ≤10% surface area coverage w/ clean, healthy and viable tissue | 10/13 (77%) | 3/13 (23%) | No |
| ROCF-CC can be considered in wounds that contain ≤20% surface area coverage w/ clean, healthy and viable tissue | 9/13 (69%) | 4/13 (31%) | No |
| ROCF-CC can be considered in wounds that contain ≤40% surface area coverage w/ clean, healthy and viable tissue | 12/13 (92%) | 1/13 (15%) | Yes |
| ROCF-CC can be considered in wounds that contain ≤60% surface area coverage w/ clean, healthy and viable tissue | 10/13 (77%) | 3/13 (23%) | No |
| ROCF-CC can be considered in wounds that contain thick exudate that may be difficult to remove with standard NPWT or NPWTi-d with standard ROCF-V dressing | 12/13 (92%) | 1/13 (8%) | Yes |
| ROCF-CC can be considered in contaminated wounds | 13/13 (100%) | 0/13 (0%) | Yes |
| ROCF-CC can be considered in wounds with heavy bioburden | 11/13 (85%) | 2/13 (15%) | Yes |
| ROCF-CC can be considered in acutely infected wounds in conjunction with appropriate wound care such as debridement and systemic antibiotics | 13/13 (100%) | 0/13 (0%) | Yes |
| ROCF-CC can be considered in chronically infected wounds in conjunction with appropriate wound care such as debridement and systemic antibiotics | 12/13 (92%) | 1/13 (8%) | Yes |
| ROCF-CC can be considered in wounds with inadequate sharp debridement | 9/13 (69%) | 4/13 (31%) | No |
| ROCF-CC can be considered in wounds that could benefit from wound cleansing when there is a delay in sharp debridement | 13/13 (100%) | 0/13 (0%) | Yes |
| ROCF-CC can be considered for wound cleansing in patients who are not candidates for sharp debridement | 13/13 (100%) | 0/13 (0%) | Yes |

Abbreviations: NPWTi-d, negative pressure wound therapy with instillation and dwell time; ROCF, reticulated open-cell foam.

Consensus Statement 9: An appropriate instillation solution dwell time for both NPWTi-d with ROCF-V dressing and ROCF-CC dressing is 10 minutes (Table 8).

The instilled solution should be allowed to dwell in the wound so that it has adequate time to cleanse the wound. 30 When using an antiseptic solution, the manufacturer's recommendations should be considered before setting the dwell time. In general, panel members recommended considering shorter dwell times in wounds that are challenging to seal and longer dwell times in wounds with areas of fibrinous tissue. In wound locations whereby gravity could cause excess solution to pool around the wound edge, ambulation and

fluid volume should be limited during instillation to help maintain integrity of the seal. In addition, some topical wound solutions may benefit from longer instillation times, although 10 minutes can normally be used.

Consensus Statement 10: NPWTi-d with ROCF-CC dressing can be considered: (a) in wounds with 20% to 40% surface area coverage with clean, healthy, and viable tissue; (b) in wound beds that contain thick exudate that may be difficult to remove with standard NPWT or NPWTi-d with standard ROCF-V dressing; (c) in contaminated wounds; (d) in wounds with heavy bioburden; (e) in acutely infected wounds in conjunction with appropriate wound care such as

TABLE 10 NPWTi-d with reticulated open-cell foam-CC not recommended for use: statements and survey results

| Consensus statement | Yes | No | Consensus |
|--|--------------|------------|-----------|
| ROCF-CC IS NOT recommended in wounds that contain approximately 100% surface area coverage w/ dry intact eschar | 10/11 (91%) | 1/11 (9%) | Yes |
| ROCF-CC IS NOT recommended in wounds with presence of exposed, unprotected organs and vessels | 11/11 (100%) | 0/11 (0%) | Yes |
| ROCF-CC IS NOT recommended in wounds with presence of undrained abscess(es) | 10/11 (91%) | 1/11 (9%) | Yes |
| ROCF-CC IS NOT recommended in wounds that measure less than 3 × 3 cm in size | 5/11 (45%) | 6/11 (55%) | No |
| ROCF-CC IS NOT recommended in wounds that measure less than 2 × 2 cm in size. | 8/11 (73%) | 3/11 (27%) | No |
| ROCF-CC IS NOT recommended in wounds that measure less than 1 × 1 cm in size | 12/12 (100%) | 0/12 (0%) | Yes |
| ROCF-CC IS NOT recommended over split- thickness skin grafts | 12/12 (100%) | 0/12 (0%) | Yes |
| ROCF-CC IS NOT recommended over dermal grafts (eg, autograft, allograft, xenograft, synthetic) | 10/10 (100%) | 0/10 (0%) | Yes |
| ROCF-CC IS NOT recommended in acutely ischemic wounds | 10/11 (91%) | 1/11 (9%) | Yes |

debridement and systemic antibiotics; (f) in chronically infected wounds in conjunction with appropriate wound care such as debridement and systemic antibiotics; (g) in wounds that could benefit from wound cleansing when there is a delay in sharp debridement; and (h) for wound cleansing in patients who are not candidates for sharp debridement (Table 9).

Understanding the wound environment that may be best suited for ROCF-CC vs standard ROCF-V dressing can aid in dressing selection. The through holes of the ROCF-CC dressings allow easier removal of wound debris and thick exudate compared with standard ROCF-V dressing,² and therefore, ROCF-CC dressings are recommended in wounds that contain areas of devitalised tissue.

NPWTi-d can provide a gentle way of cleansing large acute wounds such as necrotising fasciitis. NPWTi-d with ROCF-CC can serve as a beneficial temporising therapy in patients who are awaiting debridement. However, several panel members cautioned about the use of NPWTi-d with ROCF-CC dressing in lieu of accepted surgical practices and stressed that the therapy should not replace or unnecessarily delay a surgical debridement. Prior to initiation of NPWTi-d in all cases of wound management, including cases of inadequate debridement with major necrosis, it is important to understand the dynamics of any underlying disease and how it affects progression of the wound. ¹⁶

Consensus Statement 11: NPWTi-d with ROCF-CC dressing is not recommended: (a) in wounds that contain approximately 100% surface area coverage w/dry intact eschar; (b) in wounds with presence of exposed, unprotected organs and vessels; (c) in wounds with presence of undrained abscess(es); (d) in wounds that measure less than 1×1 cm in size; (e) over split-thickness skin grafts; (f) over dermal grafts (eg, autograft, allograft, xenograft, synthetic); or (g) in acutely ischaemic wounds (Table 10).

Although NPWTi-d with the ROCF-CC dressing may aid in removal of areas of devitalised tissue, it was agreed by panel members that the effectiveness of the therapy would be limited in wounds covered with eschar before debridement. Because of the through holes in the ROCF-CC dressing, as well as the space needed for sufficient fixation of the tracking pad, the dressing is generally not beneficial in small wounds measuring less than 1×1 cm in wound area. On a non-routine basis, some panel members suggested that it can be a successful adjunctive therapy over infected or contaminated wounds that contain dermal substitutes.

4 | DISCUSSION

The guidelines presented in this consensus document provide a general framework for use of NPWTi-d. Based on published evidence and clinical experience, these usage recommendations were developed by a consensus panel composed of experts on this topic to update consensus guidelines published in 2013.³

Use of NPWTi-d was recommended by panel members for a wide variety of wound types and conditions that may benefit from daily periodic wound cleansing while the dressing remains in place. In general, ROCF-CC dressings with through holes were recommended over standard ROCF-V dressings (without through holes) in wounds that contain areas of devitalised tissue. Although the two dressings are suited for different wound environments, panel members recommended similar NPWTi-d device settings for each of the dressings. Panel members recommended instillation of saline with a dwell time of 10 minutes and a negative pressure time phase of 2.0 to 3.0 hours with ROCF-V dressing and 2.0 to 2.5 hours with ROCF-CC dressing at –125 mmHg for most wounds. In the past 5 years, there has been a shift to normal saline as the first choice of instilled topical solution for most wounds vs topical antiseptic solutions, which were previously used more often as first-line instilled topical solutions.³

There are obvious limitations to using a consensus panel to develop recommendations, including the relatively small number of panel members, bias in panel member selection, group member influences on the collective opinion, and potentially incomplete presentation of the group response. In addition, a modified Delphi method was used to develop consensus as opposed to a rigorous consensus-building process, such as the standard Delphi method. However, peer-reviewed publications were used whenever available to support the consensus statements. The guidelines in this publication represent further refinement of the recommended parameters originally established for the use of NPWTi-d in 2013.³

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