



# POSITION DOCUMENT



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# Topical negative pressure in wound management

*CJ Moffatt*

The challenges of effective wound management are becoming increasingly complex. This EWMA position document on topical negative pressure (TNP) therapy is a welcome resource to aid healthcare professionals in managing situations that require more than conventional, conservative management. This important development in wound care is being shown in a growing number of randomised controlled trials, as well as case studies, to produce dramatic improvements in clinical outcomes. It can impact on healing rates, hospitalisations and, in the case of mediastinitis and the open abdomen, mortality. Evidence is particularly strong for managing trauma, especially open fractures, with TNP therapy.

It should be noted that the majority of clinical trials of TNP therapy have used the vacuum assisted closure (V.A.C.<sup>®</sup> Therapy\*) system, and it is therefore this specific device that is described throughout this document. The VAC system incorporates a polyurethane or polyvinyl alcohol foam dressing that maintains porosity under suction and equalises the pressure applied across the wound bed. There are alternative methods of applying TNP to a wound surface, for example one that uses gauze as its contact layer. However, evidence supporting this system is largely limited to case studies<sup>1</sup>.

The benefits and successes of TNP therapy are well reviewed in the literature. This position document outlines these reviews and indicates areas where TNP therapy should be used with caution or avoided completely, and shows the need for accurate wound assessment and a precise application technique. It reviews the pathophysiological effects of TNP and presents a European perspective on the practical issues of successfully integrating TNP therapy into clinical practice.

Gustafsson, Sjögren and Ingemansson introduce this position document by outlining the theory and background to the development of TNP therapy and describing the key components of the VAC system. They then discuss the mechanisms by which TNP therapy promotes wound healing. These include increasing local blood flow, reducing oedema and stimulating the formation of granulation tissue.

Despite the clear-cut clinical benefits to using TNP therapy, its perceived expense compared with alternative dressings is sometimes an obstacle to its use, particularly outside of hospital settings. In the second paper, Trueman puts forward an economic case for the intervention. By factoring in cost savings due to faster healing, reduced nurse time and shorter hospital stays, it can be suggested that the higher acquisition costs of VAC dressings can be offset. Additional ongoing research should help rectify some of the limitations of existing data and bolster the economic argument.

In the third paper, Vowden, Téot and Vowden suggest that a generic strategy can be used across all wound types to integrate this technology into practice. They put forward general patient and wound specific issues and use the concept of wound bed preparation to present a straightforward approach to identifying when it is appropriate to use TNP therapy. Building on this, they describe how to incorporate the intervention into an overall management strategy, with particular emphasis on the importance of defining treatment objectives and clinical endpoints.

While Vowden *et al* suggest a generic therapeutic strategy that can be applied to all wound types, it is vital that clinicians appreciate that application techniques will be different depending on the type of wound being treated. In the final paper, Wild illustrates this point using the management of the open abdomen as an example. His illustrated guide, for example, demonstrates that by using a special abdominal VAC dressing, intestinal adhesions – a serious complication of this wound type – can be avoided.

It is acknowledged that many questions remain to be answered about TNP therapy. However, TNP therapy is nonetheless a major breakthrough in wound management with the potential to dramatically improve survival and reduce the risk of complications. It is our responsibility as clinicians to ensure that we have the knowledge and practical skills to enable all appropriate patients to benefit maximally from its use both in the hospital and community setting.

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# Understanding topical negative pressure therapy

R Gustafsson<sup>1</sup>, J Sjögren<sup>2</sup>, R Ingemansson<sup>3</sup>

## INTRODUCTION

Surgery and other advanced technical interventions are increasingly being carried out on the elderly, compromised patient population and this trend looks set to continue. As a result, healthcare professionals are now more likely to encounter wounds that are difficult to manage with complex healing problems. The recent introduction of a technology that uses topical negative pressure (TNP) via a polyurethane (PU) or polyvinyl alcohol (PVA) foam dressing to enhance wound healing is therefore particularly welcome, and its use has seen a paradigm shift in the management of many different wound types. This paper describes the physiological effects and considers the mechanisms of action of TNP therapy using this system.

## HISTORY OF TNP THERAPY

Negative pressure is a term used to describe a pressure that is below normal atmospheric pressure. At room temperature and at sea level a defined volume of air contains molecules moving in random directions. These moving molecules exert a force that is equal to the normal atmospheric pressure of 760mmHg. Negative pressure can be achieved by transferring gas molecules away from the area of interest (eg wound site) with, for example, a suction pump.

The clinical application of negative pressure dates back thousands of years. It was first used as an adjunct to acupuncture techniques in Chinese medicine after it was noted to cause hyperaemia<sup>1</sup>. Later, in 1841, Junod adopted the method using warmed glass cups applied to the patient's skin to "stimulate the circulation". As the air cooled, a subatmospheric pressure was created within the glass cups, which caused the hyperaemia<sup>1</sup>.

Numerous versions of TNP therapy have since been reported<sup>1</sup>. In 1993, Fleischmann *et al* applied TNP to wounds via a foam dressing for an extended period to promote granulation and healing in 15 patients with open fractures<sup>2</sup>. They noted an efficient cleaning of the wound with no bone infection (although one patient sustained a soft tissue infection). In their early studies, negative pressure within the wound was achieved with an unsophisticated wall suction apparatus or surgical vacuum bottles. These were associated with practical problems in terms of the delivery, control and maintenance of negative pressure levels.

Pioneer investigators, Morykwas and Argenta, set up a series of animal studies using TNP therapy with a PU foam dressing acting as an interface between the wound surface and the vacuum source<sup>3</sup>. This foam was a crucial element, and prompted the development by Kinetic Concepts Inc of a commercial system (the vacuum assisted closure [VAC] system) (Figure 1, Table 1). The regular structure of large open pores (400–600µm) within the PU foam dressing used as part of the system allows equal distribution of pressure across the entire wound surface. The foam also reduces in volume under pressure, resulting in cell stretch, wound contraction and removal of fluid (Figure 2).

More recently, competitors have developed variations of this system, but these do not use the PU foam.

## KEY POINTS

1. The recent introduction of topical negative pressure (TNP) therapy has created new possibilities for the management of many different wound types.
2. Several mechanisms occur as a result of TNP that support healing. These include stimulation of blood flow, granulation tissue and angiogenesis.
3. In addition, the negative pressure within the pores of the polyurethane or polyvinyl alcohol foam dressing used contracts the wound and draws the wound edges closer together.
4. By understanding these mechanisms clinicians can consider whether it is appropriate to use this intervention.

## PATHOPHYSIOLOGICAL EFFECTS

At a basic level the VAC system provides a sophisticated, sterile, closed dressing with properties allowing a moist healing environment. Various mechanisms have also been confirmed that support healing. These include:

- increases local blood flow
- reduces oedema
- stimulates formation of granulation tissue
- stimulates cell proliferation
- removes soluble healing inhibitors from the wound
- reduces bacterial load
- draws the wound edges closer together.

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Figure 1 | **The VAC therapy system**

Table 1 | **TNP therapy using the VAC system**

**The system described throughout this document includes the following components:**

A black, hydrophobic PU foam dressing with open pores, which is introduced into the wound. A white, hydrophilic PVA foam dressing with denser, smaller pores may be used instead (choice of foam type depends on wound characteristics and treatment aims)

A transparent, semi-occlusive adhesive drape, which is secured firmly over the foam dressing to the healthy skin around the wound margin. This stops ingress of air and allows a partial vacuum to form within the foam

A pad attached to a drainage tube, which is placed over a small hole cut into the drape. The end of the drainage tube is connected to a suction source

A disposal reservoir, into which wound fluid is withdrawn under negative pressure through the foam via the drainage tube

An electrically powered therapy unit, which creates negative pressure by transferring gas molecules continuously from the inlet to the outlet of the unit by a rotating valve

A microprocessor, which computes signals from the system's components and triggers an alarm if pressure levels are incorrect, there is an air leak etc

The pressure at the wound site is usually lowered by 125mmHg, which is about 10 times lower than the pressure used for normal chest drains in patients following lung surgery

## Increasing blood perfusion and reducing oedema

Morykwas *et al* studied the effect of TNP therapy on blood flow by producing deep tissue defects in pigs and dressing them with PU foam<sup>3</sup>. Their results indicated a maximum fourfold increase in blood flow with a negative pressure of 125mmHg. At higher pressures the risk is that the capillaries will distort and blood flow lessen. Indeed, blood flow was inhibited by applying negative pressures of 400mmHg and above.

Timmers *et al* evaluated the effect of TNP therapy on blood flow in the healthy skin of 10 human volunteers<sup>4</sup>. Blood flow improved by fivefold with PU foam and by threefold with PVA foam with increasing negative pressure up to 300mmHg. The difference is due to the smaller pore size of PVA foam, which reduces the effect of TNP. Various factors affect the pressure achieved at the wound bed, for example clot formation, bleeding and an interposed dressing layer will reduce the pressure level<sup>1</sup>. It is proposed that blood flow is increased directly by the negative pressure and indirectly by removing interstitial fluid.

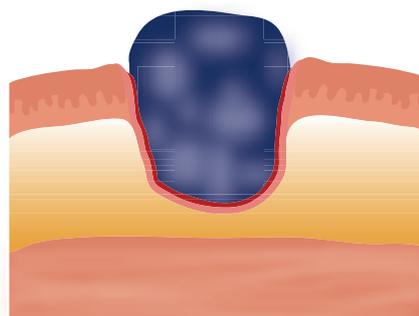
## Stimulating formation of granulation tissue

Using their pig model, Morykwas *et al* also determined the rate of granulation tissue formation during TNP therapy by measuring the reduction in wound volume over time. Compared with control wounds dressed with standard saline-soaked gauze, increased rates of granulation tissue formation were observed with continuous and intermittent application of negative pressure amounting to 63% and 103% respectively<sup>5</sup>. Intermittent

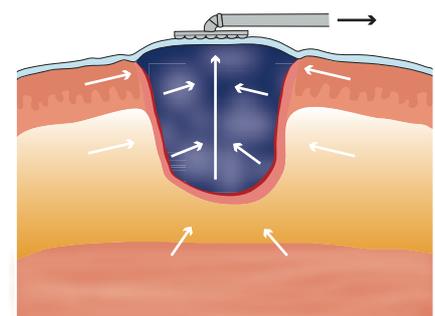
Figure 2 | **Mechanisms of action of the VAC system**

- Oedema is removed from periwound tissues, local blood perfusion increases and angiogenesis is stimulated
- Contraction of the foam draws the wound edges together, stabilises the wound margin and provides an anchor point for muscles and deeper structures
- Exudate, inhibitory substances and fine debris are removed from the wound

1. The PU foam is placed in the wound



2. Following the application of TNP therapy (125mmHg) the foam loses volume but maintains porosity under suction, providing an equal pressure profile across the entire wound bed



treatment is thought to be more effective than continuous treatment because the cells within the wound become accommodated (ie they no longer respond) to the constant physical forces applied with continuous therapy. Proposed mechanisms for the beneficial effects of intermittent therapy include<sup>6</sup>:

- increases tissue perfusion, by inactivating capillary autoregulation (whereby capillaries are shut down if high blood flow is not needed)
- allows the proliferating cells time to rest between cycles of cell division, which is necessary for the production of new cellular components. Constant stimulation with negative pressure may switch off the mitotic (nuclear division) process.

Many clinicians use continuous pressure because it is better tolerated by patients. Some recommend using the continuous setting for the first 48 hours with a target pressure of 125mmHg before switching to the intermittent mode<sup>7</sup>.

### **Stimulating cell proliferation**

Mechanical stress has long been known to induce cell proliferation and division<sup>8</sup>. This effect has been used for many years by plastic and orthopaedic surgeons to expand soft tissues and to lengthen bones<sup>9</sup>. It is also one of the most important features of TNP therapy; a computerised model has shown that the negative pressure induces tissue microdeformations within the wound, and this has also been observed in the clinical setting<sup>10</sup>. This mechanical stretching of the cells stimulates proliferation and accelerates wound healing. In chronic wounds this mechanism stimulates angiogenesis and epithelialisation<sup>11</sup>. Fabian *et al* also observed enhanced angiogenesis and a trend towards increased rates of epithelialisation using TNP therapy in a rabbit model<sup>12</sup>.

### **Other effects**

By removing the harmful components (such as cytokines and matrix metalloproteinases) associated with excess exudate in the non-healing wound, TNP therapy may promote an active healing state where delayed primary closure can be achieved<sup>11,13,14</sup>. It may also help reduce bacterial load<sup>3</sup>. For example, the seal created by the foam and drape reduces the risk of external contamination and the improved blood perfusion may increase resistance to infection. Also, the partial vacuum created by TNP therapy causes the entire foam to shrink and this draws the wound margins to the centre, thereby facilitating wound closure<sup>1</sup>.

### **CONCLUSION**

The mechanisms described above have a substantial impact on many of the factors that are known to promote healing. Used in conjunction with conventional treatments and professional wound assessment, TNP therapy, when used appropriately, has become a valuable tool for the clinician and the patient.

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# Health economics and topical negative pressure therapy

*P Trueman*

## **INTRODUCTION**

In the context of chronic wounds topical negative pressure (TNP) therapy using the vacuum assisted closure (VAC) system is sometimes considered an expensive intervention. For example, the acquisition costs of the dressing, tubing and canister, and the rental costs for home use are considerably more than for alternative dressings. As a result access to TNP therapy is often restricted, particularly outside hospital settings<sup>1</sup>. Yet dressing costs typically make up only a small proportion of the total expense of managing chronic wounds<sup>2</sup>, with nurse time, hospitalisations and adverse events accounting for the majority. This paper explores the possibility of developing an economic case for TNP therapy by considering the costs and outcomes associated with the intervention for treating diabetic foot ulcers and pressure ulcers.

## **COST-EFFECTIVENESS**

Economic evaluation seeks to capture the relative costs and benefits of two or more treatment options, for example advanced wound care dressings versus traditional dressings. Because economic evaluations are usually undertaken to inform healthcare decision making, the majority consider only expenditure directly relevant to the healthcare sector. For a chronic wound such as a diabetic foot ulcer, expenditure might include the costs of wound dressings, nurse time, hospitalisations and adverse events/amputations. While indirect costs, such as productivity losses of patients or informal carers, may be significant, these are not routinely captured in economic evaluations because they do not fall on healthcare budgets.

## **Measuring outcomes**

Most economic evaluations analyse cost-effectiveness, whereby costs are captured in monetary units and outcomes are captured in clinical units<sup>3</sup>. For wound care this might produce outcomes such as cost per additional wound healed or cost per amputation avoided. However, due to demands from health technology assessment agencies (notably in the UK the National Institute for Health and Clinical Excellence) there is an increasing trend towards cost-utility analysis, which captures outcomes in the form of a quality-adjusted life year (QALY). A QALY weights each year of a patient's life by his or her quality of life during that year. Typically, a year of perfect or full health is given a value of 1.0 while death is usually valued at zero. Therefore, if we assume that a diabetic foot ulcer reduces quality of life by 50%, each remaining year of life with this condition yields 0.5 QALYs.

Values for quality of life can be derived in various ways. Standard gamble and time trade-off techniques can be used to elicit values directly from patients. However, more often values are obtained using standardised questionnaires, such as the EuroQol EQ-5D (see [www.euroqol.org](http://www.euroqol.org)) or the Health Utilities Index (see [www.fhs.mcmaster.ca/hug](http://www.fhs.mcmaster.ca/hug)).

QALYs can be used to assess and compare the benefits afforded by various healthcare interventions. By factoring in the associated costs we can measure their cost-utility. The cost-utility approach is technically more demanding than other evaluations, but it allows healthcare planners to compare the value of interventions across disease areas (eg a new wound dressing with a new treatment for heart disease).

## **Limitations in wound care**

There are few robust economic evaluations of wound care, mainly because of the dearth of well-designed, longitudinal or clinical studies in this area. Although economists often extrapolate the results of clinical studies, this relies on having a well-defined biological relationship between interim endpoints and longer-term outcomes. For example, there are well-defined relationships between the risk factors for coronary heart disease and mortality (derived from the Framingham cohort, see [www.framingham.com/heart](http://www.framingham.com/heart)). These allow changes in interim outcomes (eg cholesterol levels) to be extrapolated to longer-term outcomes (eg mortality). Unfortunately, this is not the case for wound care.

Although many routine endpoints used in wound care studies are relevant to clinical decision makers (eg percentage change in wound area) they are relatively meaningless to economists or financial decision makers.

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Research is emerging that links interim endpoints such as wound size and duration to longer-term outcomes<sup>4</sup>, but further data on these relationships are needed for economic studies. In the meantime, clinical studies of wound care should consider how relevant the endpoints are for determining the clinical and cost-effectiveness of interventions. Longer-term measurement of well-defined outcome measures, such as healing, recurrence and amputation, will help in determining the economic value of interventions. The involvement of health economists in the design of clinical protocols will assist in identifying appropriate outcomes that can be incorporated into the protocol.

### Dressing cost analysis

In examining the relative value of dressings, there is a tendency to focus on the cost of dressings rather than the cost of treatment, which may be influenced by other factors such as time to healing. In the 2003 EWMA position document, Franks and Posnett looked at the cost-effectiveness of compression therapy for venous leg ulcers<sup>5</sup>. Based on estimated costs of weekly treatment, using the more expensive individual dressing (ie compression) resulted in a lower total treatment cost over time than the standard cheaper dressing regimen used (1,697 euros per ulcer healed versus 3,558 euros). This was due to the reduced time to healing and the fewer dressing changes with compression therapy.

#### **FACTORS AFFECTING THE COST OF WOUND TREATMENT**

The cost of managing chronic wounds can be influenced by:

- frequency of dressing changes and associated nurse time
- healing rates
- impact on hospitalisations and adverse events

An analysis by Harding *et al* has also illustrated this point and has suggested that dressings make up between 4% and 29% of the total cost of managing pressure ulcers<sup>2</sup>. Furthermore, it found that the dressing with the lowest acquisition cost resulted in the highest total expenditure over the course of wound healing, due to its relative effectiveness. Therefore, they propose that the factors in the box (left) are considered when analysing the cost of dressings. In some cases, these may be sufficient to offset the acquisition cost of premium priced dressings<sup>2</sup>.

Exploring these factors and by extrapolating data from the literature, the following sections examine the possibility of developing a cost-effectiveness argument for using TNP therapy in the management of diabetic foot ulcers and pressure ulcers.

#### **ECONOMIC CONSIDERATIONS OF TNP THERAPY Frequency of dressing changes**

TNP therapy using the VAC system offers an effective intervention for managing heavily exudative wounds. From an economic perspective, if dressings can remain in place for longer than other dressings, this allows a reduction in dressing acquisition costs and nurse time. This theory appears to be borne out in randomised controlled trials (RCTs) comparing TNP therapy with other dressings in patients with diabetic foot ulcers. These studies consistently report that the dressings used with TNP therapy are changed every two days in non-infected wounds in line with the manufacturer's recommendation, whereas other dressings (eg saline gauze<sup>6</sup>, moist wound dressings<sup>7</sup> and other advanced dressings<sup>8</sup>) are changed daily.

Similar comparisons have been made in RCTs in patients with pressure ulcers. These trials have shown the difference between wet-to-moist<sup>9</sup>, Healthpoint system<sup>10</sup> and wet-to-dry/wet-to-moist<sup>11</sup> dressings, which are usually changed two or three times per day, versus TNP therapy, which should be changed every two days.

Recommendations on wear time are not always adopted in practice (eg because of constraints on nursing time or the potential disruptive impact on the wound), and the high frequency of dressing changes reported in these RCTs may not be the experience of many practising healthcare professionals. With this in mind, it is important to note that two of the RCTs of diabetic foot ulcers included only 10 patients<sup>6,7</sup>, while the third included 162 patients<sup>8</sup>. Sample sizes were also small in the pressure ulcer studies (ranging from 24 to 34)<sup>9-11</sup>. This is a major limitation and the results must be interpreted with caution. One trial is further undermined by the use of saline soaked gauze as the comparator, which is considered a relatively outdated treatment in most of Europe<sup>6</sup>. Any decision to extend wear time should be led clinically rather than by potential economic savings.

Table 1 | Comparative healing rates for TNP therapy, alginates and hydrocolloids<sup>12</sup>

Weeks	Percentage of wounds that achieved satisfactory signs of healing		
	TNP therapy	Alginate	Hydrocolloid
<3	30	0	0
3–4	39	37	0
5–10	19	41	79
10–15	7	0	0
>16	4	22	21

**Healing rates**

**Diabetic foot ulcers**

A study by Armstrong *et al* examined the use of TNP therapy after partial diabetic foot amputation<sup>8</sup>. This multicentre RCT of 162 patients compared TNP therapy using the VAC system with standard moist wound care. TNP dressings were changed every two days while standard therapy was based on consensus guidelines. Standard therapy was made up of dressings promoting a moist wound environment, ie with alginates, hydrocolloids, foams or hydrogels, adhering to standard guidelines at the discretion of the attending clinician. Patients were followed for 112 days or until wound healing.

Healing rates at the end of the study were 56% in the TNP therapy arm, compared with 39% in the standard therapy arm (p=0.040). Most patients healed by primary intention and there was no significant difference in the proportion of wounds healed by secondary intention in either arm. The mean time to healing in the TNP therapy arm was 56 days, compared with 77 days in the standard therapy arm. The median time to achieving 76–100% granulation was 42 days in the TNP therapy arm, compared with 84 days in the standard therapy arm (p=0.002).

These findings have important economic implications, suggesting that a higher proportion of patients are likely to heal in a shorter period of time when treated with TNP therapy. These outcomes are directly relevant to economic decision makers in healthcare settings and the impact on budgets can be easily quantified. A full economic analysis of the study findings is expected to be published in 2007.

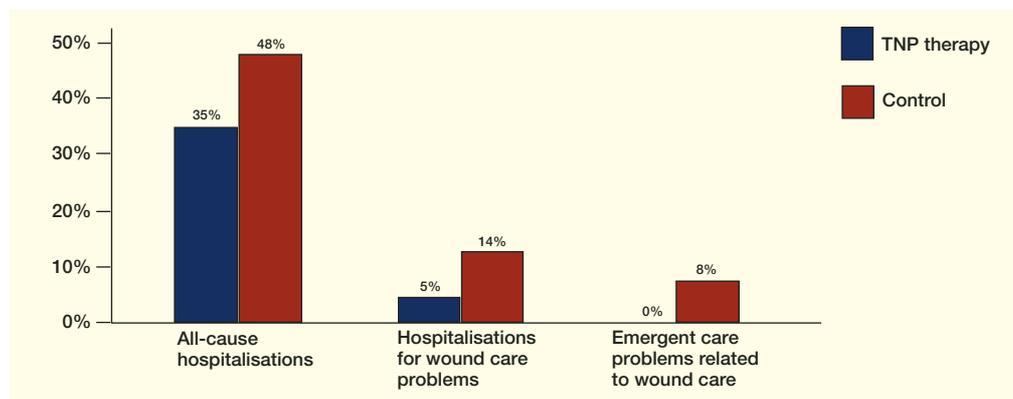
**Pressure ulcers**

The only prospective, comparative study of TNP therapy in pressure ulcers that reported healing rates was conducted by Ford *et al*<sup>10</sup>. It compared TNP therapy using the VAC system with the Healthpoint system, which consists of a papain-urea debridement ointment and a combination of pads and gels containing cadexomer iodine.

Healing rates at six weeks were marginally higher in the Healthpoint system group (13% versus 10%). However, TNP therapy produced a greater (but not statistically significant) percentage change in wound volume (51.8% versus 42.1%, p=0.46) and was better at improving wounds with biopsy-proven osteomyelitis. The authors concluded that TNP therapy has a better rate of wound healing with favourable histological changes in soft tissue and bone compared with the Healthpoint system, although the choice of comparator, the small sample size and the lack of statistical significance of the findings related to healing rates should be borne in mind when considering this evidence.

Smith reviewed the literature on the effectiveness of TNP therapy with alginates and hydrocolloids for treating pressure ulcers<sup>12</sup>. The study found 93% of wounds treated with TNP therapy healed, compared with 63% of wounds treated with hydrocolloids (p<0.002). Table 1 reports the data on time to healing. Most wounds treated with TNP therapy achieved ‘satisfactory’ signs of healing (wound needing little or no further treatment) within four weeks. However, the median time to satisfactory signs of healing

Figure 1 | **Hospitalisation rates for TNP therapy and standard care**<sup>13</sup>



with alginates and with hydrocolloids was five to 10 weeks. Again, the improved time to healing has positive economic implications for TNP therapy.

### Hospitalisations

Several studies of TNP therapy have examined the impact on hospitalisation rates. In a retrospective review of the use of the VAC system in a home setting to treat grade 3 or 4 pressure ulcers, Schwein *et al* compared a matched group of patients using TNP therapy (n=60) with a control group who were not treated with VAC (n=2,288)<sup>13</sup>. The study found that hospitalisation rates in patients treated with TNP therapy were statistically significantly lower than those treated with standard care (p<0.05). Hospitalisation rates were separated into all-cause hospitalisation, hospitalisations related to wound care problems and emergent care problems related to wound care. In all categories, patients treated with TNP therapy experienced lower hospitalisation rates (Figure 1).

Although the design of the study introduces an increased risk of bias compared with an RCT, this more naturalistic design does provide a true reflection of standard practice and overcomes some of the problems associated with protocol-driven events that are experienced in trial settings. Some of the potential for bias in the study has been accounted for by matching patient characteristics in the two arms.

### Adverse events

In addition to the benefits listed above, several studies have suggested that TNP therapy might reduce adverse events, particularly amputations. However, the data remain equivocal. Armstrong *et al* reported a reduction in amputations with TNP therapy compared with the comparator (3% versus 11%, p=0.06), although this did not reach statistical significance<sup>8</sup>. It should also be noted that the patients in this study had already had a prior amputation and this could have affected the likelihood of a further amputation, although the risk is expected to be increased in both arms of the study.

The higher rate of hospitalisations for wound-related problems in the study by Schwein *et al* may also suggest a lower rate of adverse events, although details of this are not provided in the paper<sup>13</sup>. Joseph *et al* also reported lower adverse event rates for TNP therapy compared with saline gauze<sup>9</sup>. The wounds considered were predominantly pressure ulcers. The reported complication rates were 44% in the saline gauze arm, compared with 17% in the TNP therapy arm. Although this was a statistically significant outcome, the total sample size was 36 so the findings should be considered with caution.

### ANALYSIS

Examining the clinical data on TNP therapy highlights a number of economic benefits that may offset the higher acquisition costs of the dressings and rental costs of the TNP therapy unit. A crude analysis of the findings of Armstrong *et al* described earlier helps to demonstrate this<sup>8</sup>. Dressings were changed daily in the standard therapy arm and every two days in the TNP therapy arm. Let us assume that each dressing change required a

## KEY POINTS

1. Emerging research suggests there may be economic as well as clinical advantages to using TNP therapy for chronic wound management.
2. Savings due to faster healing rates and reduced dressing changes, nurse time and hospital stays with TNP therapy may offset higher acquisition costs.
3. TNP therapy may also reduce costs associated with adverse events.
4. Current economic evaluations of wound care are limited by difficulties capturing economically useful clinical outcomes, the dearth of robust studies and lack of data from Europe.

home nurse visit estimated to cost 35 euros per visit<sup>14</sup>, and that nurse visits were needed only while the wound was unhealed. Where a wound was unhealed over the course of the study, dressing changes are assumed to have continued over the entire duration (112 days). In the standard therapy arm 39% of patients healed and are assumed to have had daily visits for 77 days (mean time to healing in this group). The remaining 61% of unhealed patients had daily visits for 112 days. This gives an average nurse cost per patient of 3,443 euros. In the TNP therapy arm, 56% of patients healed and are assumed to have had visits every two days for 56 days (mean time to healing in this group), with the remaining 44% of unhealed patients having visits every two days for 112 days. This gives an average nurse cost per patient of 1,411 euros.

While this is clearly a partial analysis (it takes no account of dressing costs or rental of the TNP therapy unit), it shows that the reduced nurse costs associated with TNP therapy can help to release some 'headroom' to account for the other expenses. A more detailed analysis is needed to determine the net impact of TNP therapy on total treatment costs.

Philbeck *et al* estimated the cost of treating pressure ulcers using estimates of daily wound area reductions for TNP therapy and standard care<sup>15</sup>. Costs of treatment to healing were \$23,465 (18,155 euros) for standard care and \$14,546 (11,256 euros) for TNP therapy. However, the study design is not strong as it uses average wound area reductions derived from published papers and applies these to an average sized wound. It also assumes healing rates are constant over time. As such, the data sources may not be directly comparable.

## CONCLUSION

A growing body of evidence suggests there may be economic as well as clinical benefits to using TNP therapy. Findings seem to imply that the savings accrued due to faster healing, reduced nurse time and hospital stay may offset the additional acquisition cost of TNP therapy dressings. However, there are limitations in the evidence. None of the studies mentioned here provides a full cost-effectiveness analysis capturing both costs and outcomes of care. In particular, studies have focused on measures of clinical outcomes (eg wound healing or wound area reduction) rather than the impact on quality of life. With the exception of a study in venous leg ulcers and a study in surgical wounds there is no economic evidence from European settings<sup>16,17</sup>. Additional research is underway to develop a more robust economic evaluation of TNP therapy and alternative regimens for the treatment of diabetic foot ulcers. This should provide a more thorough analysis of the treatment costs and outcomes of care, including the impact on quality of life.

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# Selecting topical negative pressure therapy in practice

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## **INTRODUCTION**

When considering topical negative pressure (TNP) therapy, the stratification of wound types into acute and chronic is in many ways irrelevant. Acute and chronic wounds of all aetiologies require a holistic assessment of the cause, an understanding of the underlying medical and social conditions that may affect healing and treatment decisions, and a full evaluation of the wound status. This paper uses the concept of wound bed preparation to suggest a therapeutic strategy to help clinicians identify when to use TNP therapy. This approach will aid the integration of this intervention into the management of many types of complex wounds.

## **EVIDENCE FOR TNP THERAPY**

TNP therapy is used for the treatment of acute and chronic wounds in both inpatient and outpatient settings. Recently, the range of indications has been extended on the basis of many scientific publications (over 250 peer-reviewed articles, 330 published abstracts and 42 book chapters). These show that TNP therapy has been used successfully in the management of a wide variety of acute and chronic wounds. Almost all the published evidence relates to the use of the vacuum assisted closure (VAC) system (Kinetic Concepts Inc). Initially much of this evidence was in the form of extended case studies. However, recently the results from a number of randomised controlled trials (RCTs) have been published supporting the findings of the earlier reports<sup>1-9</sup> (see box, below right). Studies soon to be published support that VAC is highly suited to managing trauma wounds with or without loss of bone substance. The key to choosing an appropriate wound management strategy is to carry out a thorough patient assessment and identify the patient and wound specific issues that need addressing. Figure 1 illustrates this approach.

## **WOUND BED PREPARATION AND TNP THERAPY**

Wound bed preparation focuses on tissue management, inflammation and infection control, moisture balance and epithelial edge advancement<sup>10</sup>. By exploring these factors, it is possible to recognise when TNP therapy is an appropriate intervention to promote healing<sup>2,3</sup> or to prepare the wound bed for surgical closure (see Figure 1).

## **Tissue management**

Wound ischaemia is recognised as one of the main causes of delayed healing or non-healing in both acute and chronic wounds. Research has demonstrated through laboratory-based experimental models and clinical work that TNP therapy using the VAC system increases angiogenesis<sup>11,12</sup> and has a direct effect on microvascular blood flow that may benefit healing<sup>13,14</sup>. This effect may go some way towards explaining the benefit seen with TNP therapy when it is used in the management of patients with skin grafts, diabetic foot wounds (whether neuropathic or surgical amputation), complex traumatic wounds where bone and/or tendon is exposed, or exposed implanted prostheses where angiogenesis is seen in the form of granulation tissue developing on relatively or totally avascular structures<sup>15</sup>.

## **Inflammation and infection control**

Overt wound infection has been considered a contraindication to TNP therapy. However, evidence suggests that TNP therapy may have a role in reducing bacterial load within a wound and may reduce levels of potentially damaging exotoxins and endotoxins simply by rapidly removing exudate from the wound bed. Because TNP therapy works as a closed system it also decreases wound odour between dressing changes and reduces environmental bacterial contamination.

There have been isolated reports suggesting an adverse alteration to wound flora with TNP therapy<sup>16</sup>. However, one study found a beneficial effect on bacterial load with VAC<sup>17</sup>. Most case reports relating to TNP therapy in this situation have also been favourable<sup>18-20</sup>.

TNP therapy has been shown to be an efficacious adjunctive method for treating postoperative wound infection after median sternotomy<sup>7,18</sup>. Mehbod *et al* have reported similar positive outcomes for infected spinal surgical wounds even in the presence of implanted material<sup>21</sup>, and Dosluoglu *et al* had encouraging results when using TNP therapy in combination with debridement to manage infected vascular grafts<sup>22</sup>. Schimp *et*

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# TOPICAL NEGATIVE PRESSURE IN WOUND MANAGEMENT

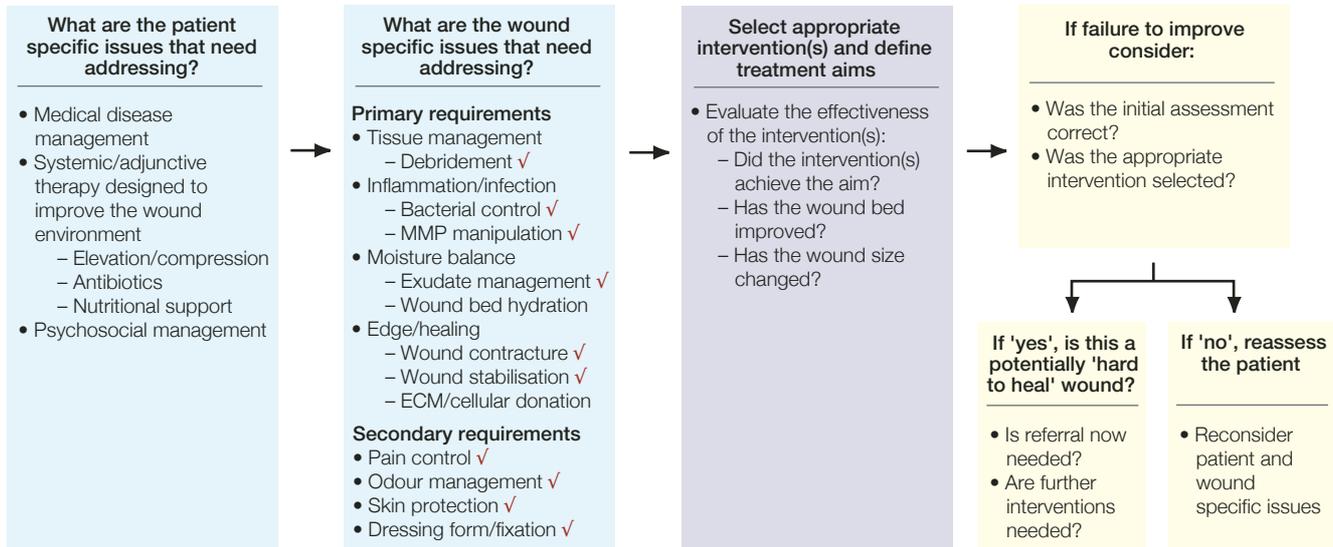


Figure 1 | **Wound specific issues and the role of TNP therapy**

✓ = Areas in which TNP therapy may be of use  
 MMP = Matrix metalloproteinase  
 ECM = Extracellular matrix

## STUDIES USING TNP THERAPY IN VARIOUS WOUND TYPES

- Burn wounds<sup>1</sup>
- Chronic leg ulcers<sup>2</sup>
- Diabetic foot ulcers<sup>3</sup>
- Open abdomen including management of fistulae<sup>4</sup>
- Pressure ulcers<sup>5</sup>
- Securing a skin graft<sup>6</sup>
- Sternal wound infections<sup>7</sup>
- Surgical, non-healing wounds<sup>8</sup>
- Trauma<sup>9</sup>

al also report benefits in managing complicated open gynaecological oncology surgical wounds with TNP therapy<sup>23</sup>. However, these are uncommon complicated wounds and are not a major indication for TNP therapy.

TNP therapy has been used successfully in the management of some cases of osteomyelitis, including foot, lower limb and sternal infections<sup>18,24</sup>. Treatment should be combined with extensive and thorough wound debridement including excision of avascular or clearly infected bone, and appropriate adjuvant therapy such as antibiotics.

Specific infective organisms, such as MRSA and other resistant strains, are not contraindications to TNP therapy. The management strategy should follow that suggested in the 2006 EWMA position document on the management of wound infection<sup>25</sup>. TNP therapy has a favourable effect on matrix metalloproteinase (MMP) levels in chronic wounds (see page 4). This may largely be due to the removal of exudate but could reflect a down-regulation of the inflammatory status of the wound<sup>26</sup>.

## Moisture balance

Clinical experience and research evidence have established that TNP therapy is an effective method for managing exudate; the system removes excess fluid while maintaining a moist wound environment and protecting the surrounding tissues from maceration and exudate damage<sup>27</sup>. In any wound where exudate management is difficult, TNP therapy should be considered as an option along with other treatments. The VAC system has, for example, been found to be an effective method of protecting the skin from fistula effluent, although this falls outside of the manufacturer's suggested range of uses<sup>28,29</sup>.

Correctly applied, it also has the advantage of preventing exudate pooling in the wound and therefore the build up of bacterial load and potentially damaging protease-rich wound fluid in the deeper recesses of a wound. Fluid pooling and spreading sepsis is a significant problem in cavity wounds and this may explain the value of TNP therapy in the management of open minor diabetic foot amputations or pressure ulcers<sup>3,30</sup>.

A similar principle applies when TNP therapy is used in conjunction with skin grafting or a bioengineered skin product, where it has been demonstrated to be of significant value in improving take<sup>15,31,32</sup>. With skin grafts even a small excess of wound fluid developing in

the interface between graft and wound bed can lead to the loss of all or part of a graft, as can excessive shear between dressing, graft and wound bed.

**Epithelial edge advancement**

TNP therapy has been used to reduce wound size by aiding edge closure, and has been shown to hasten fasciotomy wound closure<sup>33</sup>. Using TNP therapy to treat sternotomy wounds has the advantage of creating wound stability and improving pain control. The negative pressure causes the foam to form a soft but rigid anchor point for the deep and superficial compartments of the wound and forms a fixation point for muscles and fascia around the dehisced wound. The technique has been recommended for managing dehisced abdominal wounds<sup>34</sup>, including those with enterocutaneous fistulation<sup>29</sup>.

These effects of TNP therapy with the VAC system (ie wound edge stability and wound contracture) are an obvious advantage in unstable sternal wounds<sup>35</sup>. They are equally as important in the management of chronic cavity wounds such as pressure ulcers and diabetic foot ulcers, especially those involving ray amputation. The fixation/stabilising effect protects the wound from stress and shear damage.

**Controlling wound pain**

It has been suggested that TNP therapy can be effective for controlling wound pain, particularly if there is wound instability and marked edge movement and shear. Butter *et al* found it to be well tolerated in a paediatric population, and that it offered many advantages including fewer dressing changes and an earlier return to daily activities<sup>36</sup>. If pain is noted at dressing changes it may be necessary to place a non-adherent or interposed dressing layer between the foam and the wound.

**TREATMENT OBJECTIVES**

Once the wound specific issues have been identified and the intervention selected, clearly defined treatment objectives must be decided and documented, and progress towards endpoints reviewed frequently. The boxes below provide examples of these.

**TREATMENT OBJECTIVES**

1. Manage excessive exudate because it is affecting care, skin integrity and quality of life
2. Promote rapid improvement in wound bed, eg before surgical wound closure or application of skin graft/bioengineered skin substitute
3. Improve vascularity of wound bed and/or promote granulation tissue, eg to cover relatively avascular tissue or exposed prosthesis
4. Stabilise wound, graft or flap and aid care and rehabilitation, eg dehisced surgical wounds, open amputation sites and for graft fixation
5. Promote healing status when healing is not progressing with conventional dressings

**ENDPOINTS**

1. Fall in exudate levels such that wound can be managed with conventional dressings
  2. Stable healthy wound bed with 100% granulation tissue
  3. Wound bed preparation or healing aims managed more clinically and cost-effectively with alternative dressing
- Note: Recent work in sternal wounds suggests using a fall in inflammatory markers, such as C-reactive protein levels, to monitor effectiveness of care<sup>37</sup>.

**CONTRAINDICATIONS**

The literature reports on the many successes of TNP therapy. There are, however, occasions when inappropriate choice or application of TNP therapy can result in poor clinical outcomes or adverse events. To promote the safe and effective use of the technique, contraindications and precautions to treatment have been described<sup>38</sup>. Some are discussed below.

**Debridement**

Although TNP therapy may assist in the process of maintenance debridement, it is not suitable for wounds with large volumes of necrotic tissue or eschar. It may also decrease the effectiveness of autolytic debridement by removing the necessary enzymes from the wound bed. All wounds must therefore be adequately debrided before treatment with TNP therapy. The intervention may, however, have a role in the management of adherent fibrinous exudate on the wound bed. Loree *et al*, for example, used TNP therapy successfully to treat sloughy venous leg ulcers<sup>39</sup>.

**Precautions** The clinical needs of the patient mean that on occasions TNP therapy has been used with caution successfully outside some of the manufacturer’s recommended indications. Effective use of TNP therapy has been reported in patients with pyoderma gangrenosum<sup>40</sup> even though there is a theoretical risk of ‘pathergy’ (ie an exaggerated inflammatory response). Ford-Dunn reports good symptom control in a patient with a malignant wound<sup>41</sup>, and Kopp *et al* used TNP therapy as an adjunct to resection and complex reconstruction and brachytherapy in soft tissue malignancy<sup>42</sup>. Dosluoglu *et al* have reported the use of TNP therapy in patients with exposed vascular grafts even in the presence of infection<sup>22</sup>. Nonetheless, it is important to note in all these cases careful observation of the wound and the collected exudate has been key to the effective use of TNP therapy. In a palliative care situation particular vigilance and regular observation is required to protect wounds and individuals from potentially detrimental side effects of TNP therapy, such as bleeding or local tumour stimulation. It is noted that in the presence of overt infection TNP therapy should be used with adequate debridement, effective drainage of all areas of the wound and appropriate additional therapy, such as targeted antibiotic therapy.

The anatomical wound site, clinical setting (eg home care/support), patient’s ability to tolerate treatment and availability of trained staff and equipment may also make the use of TNP therapy inappropriate. Table 1 provides useful comments and practical guidance on some of the manufacturer’s contraindications and precautions.

**CONCLUSION** TNP therapy should be regarded in the same way as other wound care interventions: it should be selected if it provides the most clinically and cost-effective method for achieving defined therapeutic goals. Treatment outcomes should be continually re-evaluated. TNP

Table 1 | Comments on some of the contraindications and precautions to treatment with TNP therapy

Manufacturer’s contraindications <sup>38</sup>	Comment/practical points
Direct placement of TNP dressings over exposed organs, blood vessels or tendons	Placing foam directly over a vein graft or denuded blood vessel raises the possibility of erosion into the blood vessel. Carefully observe for bleeding and monitor canister frequently. Take particular care when removing foam at dressing changes. Use of an interposed non-adherent dressing may reduce risk. Deformation of wound bed and surrounding tissues due to contracting effect of dressing and negative pressure may impact on patency of neighbouring vessel or vascular prostheses. Monitor distal perfusion status
Malignancy in wound	Do not use if proliferation of cancer cells is even a remote possibility
Non-enteric or unexplored fistulae	Enteric fistulae are not a contraindication. Primary management is reduction in fistula flow, nutritional support, elimination of distal obstruction and, where possible, surgical closure or resection. TNP therapy may be integrated into management to control fistula drainage and protect the wound bed and surrounding skin. However, specialist management is required and support from the manufacturer’s personnel should be sought. Refer to the manufacturer’s instructions
Manufacturer’s precautions <sup>38</sup>	Comment/practical points
Patients with difficult wound haemostasis/active bleeding and patients who are taking anticoagulants	Clotting disorders, the use of anticoagulants and recent acute or surgical trauma (such as surgical debridement) increase the risk of haemorrhage. Consider if delaying application of TNP therapy for 24 hours after surgery will decrease risk of haemorrhage. If TNP therapy is applied, monitor canister and tubing frequently for signs of bleeding. Take particular care at dressing changes when there is the highest risk of haemorrhage. Use of an interposed non-adherent dressing may reduce risk

**Note:** using TNP therapy outside of the manufacturer’s instructions should be done with caution under close clinical supervision, usually in a hospital environment, and will be the responsibility of the lead clinician.

therapy must be regarded as only one important component of overall wound management, and must be introduced with a defined goal and exit strategy. It should be stopped once the goals have been achieved, if treatment is not meeting defined aims in an acceptable timeframe, or it is unacceptable to the patient or causes complications.

## KEY POINTS

1. Identifying patient and wound-specific issues is key to choosing an appropriate wound management strategy.
2. Once TNP therapy has been selected therapeutic goals should be defined and progress carefully and frequently monitored.
3. The evidence base demonstrates this therapy is applicable to a wide range of acute and chronic wounds.

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# Managing the open abdomen using topical negative pressure therapy

T Wild

## INTRODUCTION

Topical negative pressure (TNP) therapy is increasingly being used as a first-line therapy to manage acute and chronic wounds. The previous article described the scope of wounds for which this technology has been successfully used and proposed a general therapeutic strategy for determining when to use TNP therapy in many complex wound types. However, for treatment to be safe and effective, clinicians need to understand how the specific requirements of individual wound types may affect the application of TNP therapy. This paper illustrates this point using the management of the open abdomen as an example.

## MANAGEMENT OF THE OPEN ABDOMEN

As a result of abdominal dehiscence, trauma, infection or abdominal compartment syndrome (see box, left), the management of the open abdomen presents clinicians with a major clinical challenge and carries significant risks of mortality<sup>3</sup>. There are clear advantages to leaving the abdomen open instead of closing and then possibly reopening it<sup>4</sup>. These include:

- a reduced risk of abdominal wall necrosis associated with forced closure
- better freedom of movement for the diaphragm
- a reduction in abdominal pressure (by reducing oedema and intraperitoneal fluid) to prevent compartment syndrome
- a reduction in bacterial load and in anaerobic infections (by preventing contamination of the open abdomen).

Although there are many advantages to leaving the abdomen open, complications include:

- spontaneous formation of fistulae in the exposed loops of the intestine (although the incidence is lower in trauma patients treated with TNP therapy using the vacuum assisted closure [VAC] system<sup>5</sup>)
- risk of evisceration and massive fluid and protein losses
- potential risk of wound contamination.

There are several recognised treatment strategies for managing the open abdomen. These have been reviewed elsewhere<sup>6</sup>. Among the different solutions to the problem of dressing the open abdomen, TNP therapy is increasingly used as a first-line treatment. The intervention can in some cases allow the wound to close by secondary intention or it can be used to optimise the wound bed allowing delayed primary closure.

### ABDOMINAL COMPARTMENT SYNDROME

Abdominal compartment syndrome is caused by the underperfusion of abdominal organs due to a rise in intra-abdominal pressure. It is defined as a rise in intra-abdominal pressure of over 20mmHg with a rise in ventilation pressure and oliguria<sup>1</sup>. When closing the abdominal wall and during further treatment you should always bear in mind the risk of primary and secondary compartment syndrome<sup>2</sup>.

## TNP THERAPY Delayed primary closure

TNP therapy is effective because it offers the advantages of the open abdomen technique while avoiding many of the complications (Table 1). The intervention provides a closed dressing system that continually removes exudate, bacteria and detritus from the wound,

Table 1 | Advantages of TNP therapy

Reduces the risk of compartment syndrome because the dressing stabilises the abdominal wall without traditional sutures (dynamic sutures may be useful) <sup>7</sup> . Ability to close is correlated to intra-abdominal pressure
Reduces the incidence of surgical fistula formation <sup>5</sup>
Increases the chances of successful primary closure, thereby avoiding the need for reconstructive surgery
Allows patients to be positioned on their front to improve respiration. This is because the system stabilises the abdominal wall, which is necessary for diaphragm supported breathing. This allows extubation to be performed earlier
Reduces mortality compared with conventional therapy. In an ongoing multicentre study of 215 patients with an open abdomen being conducted by the author, mortality in those being managed with conventional therapy (eg wet towels, sterile urological bag protocol) was 75%, compared with 35% in those undergoing treatment with TNP therapy (using a special VAC abdominal dressing [see page 16])
Portable system allows early mobilisation and transfer to the ward. Patients can also shower with VAC dressings in place

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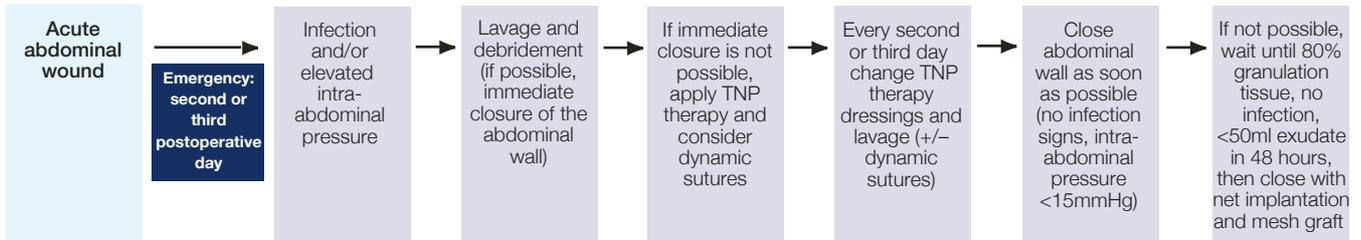


Figure 1 | **An example of a suggested protocol for managing the open abdomen. Note: specific individual practice may vary. Consensus on this technique is awaited**

while facilitating active approximation of the wound edges. This creates good conditions for primary closure of the abdominal wall.

Figure 1 outlines a protocol used by our centre for using TNP therapy to manage the open abdomen. The system should be used at a continuous pressure of 125mmHg. We also use dynamic sutures; if they are not used there is a high risk of abdominal wall retraction, which reduces the chances of primary closure. The first few dressing changes should be performed on the intensive care unit or in the operating theatre. This is because debridement may be needed or there may be a risk of bleeding. TNP therapy should be continued until primary closure of the abdominal wall is possible.

It is important to ensure that the polyurethane (PU) foam dressing is not placed directly over exposed bowel. This is because formation of granulation tissue can cause intestinal adhesions and can make primary closure of the abdominal wall impossible. A special abdominal dressing for use with the VAC system has been developed to avoid these complications. This consists of a meshed, non-adherent dressing (to protect the exposed bowel) which includes an integrated PU foam. The PU foam is placed over the non-adherent layer. This should be applied as shown in Figure 2.

Because the interposed dressing is meshed, it does not interfere with the drainage effect of the VAC system under negative pressure. Exudate is removed and the edges of the wound are drawn together.

Figure 2 | **Applying the VAC abdominal dressing**

(a) The integrated meshed dressing and PU foam are wetted to enhance placement

(b) The integrated dressing is placed between the abdominal wall and the intestinal loops so that they do not adhere to each other. The foam is moved until it is positioned retroperitoneally, deep in the abdomen so that drainage reaches the deep spaces

(c) The standard drape, pads and drainage tubes are attached in the normal way. Using more than one pad may be beneficial (as shown here), for example in very large wounds or if there is a high rate of exudation



## Secondary closure

If primary closure cannot be achieved after the peritonitis has resolved (eg because of a tissue defect or irreversible retraction), TNP therapy can be used to allow the wound to heal by secondary intention. In this situation the VAC system is used with the standard PU dressing and film drape to stimulate the formation of granulation tissue in preparation for mesh graft transplantation and later reconstruction.

## CLINICAL EVIDENCE

A retrospective analysis of the benefits of TNP therapy in the management of the open abdomen was recently carried out at several centres in Austria<sup>3</sup>. Medical records of 62 surgical patients who had been treated with a laparostoma due to peritonitis between 2001 and 2005 were identified. One group (19 patients) underwent TNP therapy with the special VAC abdominal dressing; a second group (16 patients) underwent classic TNP therapy (using the standard PU foam and drape: see Table 1, page 3); and a third group (27 patients) underwent conventional therapy (eg placement of towels or watertight drape).

### KEY POINTS

1. TNP therapy using the VAC abdominal dressing should be considered when managing the open abdomen.
2. TNP therapy may be used to optimise the wound bed for delayed primary closure or to allow closure by secondary intention.
3. Due to the complexity of the open abdomen, TNP therapy should be used only by clinicians trained in its use who will gain regular and continued expertise.

In the group undergoing TNP therapy with the special VAC abdominal dressing, mortality was 14%, compared with 21% in the classic TNP therapy group and 59% in the conventional therapy group ( $p < 0.0009$ ). Although there was an association with age, the study concluded that the abdominal dressing was the most important factor for the difference in clinical outcome. There was no significant difference for survivors in length of stay on the intensive care unit. These first results indicate the need for further prospective evaluation of TNP therapy using the VAC abdominal dressing to determine whether the intervention has set a new standard for managing the open abdomen<sup>3</sup>.

Other studies of TNP therapy have also reported improved clinical outcomes. In a two-year, retrospective study involving 19 patients who had abdominal compartment syndrome (or who had a high risk of this) and who had had their abdomen open for more than 48 hours, there was a higher rate of abdominal wall closure for patients undergoing TNP therapy compared with those undergoing the vacuum pack technique (78% versus 12%)<sup>7</sup>. In another study, higher rates of fascial closure were reported for TNP therapy compared with conventional techniques<sup>5</sup>.

TNP therapy as described here is also associated with a lower rate of complications such as acute respiratory distress syndrome, abdominal compartment syndrome, fistula or sepsis, compared with other techniques<sup>5,7</sup>.

## OTHER CONSIDERATIONS

While TNP therapy should not be the exclusive preserve of particular medical specialties (ie surgeons, angiologists etc) the decision to use it in the open abdomen will be initiated by the lead clinician. Because of the complexity of the open abdomen, TNP therapy should be administered only by healthcare professionals who have received specific training in using the intervention and who will gain expertise in everyday practice.

## CONCLUSION

The open abdomen has traditionally been associated with poor patient outcomes and considerable mortality and morbidity. TNP therapy in the management of this condition offers significant advantages over traditional dressings and interventions. Success depends on good application and monitoring techniques.

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