PRINCIPLES OF BEST PRACTICE

A World Union of Wound Healing Societies' Initiative

Vacuum assisted closure: recommendations for use

A consensus document

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FOREWORD

This timely initiative draws on both the research evidence and the consensus opinion of an international group of experts (see below) to provide guidance on the successful integration of vacuum assisted closure therapy (V.A.C.® Therapy) into clinical practice. The document specifically reviews its potential use in the following selected indications*: diabetic foot ulcers, complex leg ulcers, pressure ulcers, dehisced sternal wounds, open abdominal wounds and traumatic wounds. In addition, it considers quality of life and cost-effectiveness, both of which are gaining importance when evaluating treatment. This document highlights questions for future research and is designed to be practical and adaptable for local use in countries worldwide.

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* This document provides recommendations for the use of VAC therapy in six selected wound types. It should be noted, however, that VAC therapy has a role in other wound types, which are not included in this document.

RECOMMENDATIONS FOR USE

Vacuum assisted closure (VAC) therapy has helped to improve wound care outcomes and has led to a number of dramatic changes in clinical practice over the past decade[1,2]. VAC therapy must be used as part of an individualised, comprehensive treatment plan and is indicated for both acute and chronic wounds.

PLANNING TREATMENT

In all situations the underlying wound aetiology and comorbidities must first be addressed and treated. It is essential to optimise all aspects of the patient's physical, nutritional and psychosocial wellbeing to ensure treatment is suitable and of maximum benefit.

Before starting VAC therapy it is important to define treatment aims, objectives and clinical endpoints[1]. In some circumstances the objective will be to avoid further complications and to control symptoms, rather than to influence time to healing. Examples of clinical endpoints for VAC therapy include 50% volume reduction[3], 80% granulation tissue formation or complete closure.

In general, **the key aims** are to:

- remove exudate and reduce periwound oedema
- increase local microvascular blood flow/test vascularity
- promote formation of granulation tissue
- reduce complexity/size of the wound
- optimise the wound bed prior to and following surgery
- reduce complexity of surgical wound closure procedures[4].

In addition, the application of the VAC dressing system creates a closed, moist wound environment, which may act as a barrier to bacteria and patient/caregiver interference. VAC therapy may also help to promote patient independence, mobility and comfort.

Identifying responders to VAC therapy

In **chronic wounds**, it may be helpful to use the factors listed in Table 1 to assess whether the wound is likely to have a positive response to VAC therapy. It must be noted, however, that in many circumstances the patient/wound will not exhibit these attributes and yet VAC may still have an important role. A good example of this, is the diabetic foot ulcer (see page 3) where the patient often has multiple comorbidities and the wound has a poor blood supply.

For acute wounds, it is important to adequately debride the wound and follow recommended guidelines for specific wound types (eg dehisced sternal wounds) before commencing therapy.

Table 1 | Factors that may increase success of therapy

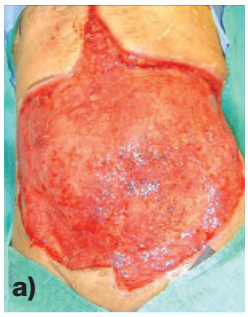
Wound factors	Patient factors
■ Wound has good blood supply ■ Wound has healthy, granular bed ■ Wound as been freshly debrided (as recommended*) ■ Wound produces high levels of exudate ■ Wound is greater than 2cm wide	■ Patient has been maximally medically stabilised (eg nutrition, blood pressure, blood glucose, fluid balance, infection) ■ Patient has few or well-controlled comorbidities ■ Patient is comfortable (eg not in pain) ■ Patient is adherent with therapy

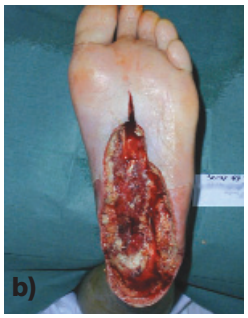
*NB: Occasionally, in some chronic wounds, surgical debridement may not be appropriate. Prior to starting VAC therapy it is important to ensure that the wound has a clean wound bed and that it does not contain necrotic tissue or excessive debris

There may be benefits to starting VAC therapy as early as possible. Delaying therapy may allow the wound to deteriorate before being treated effectively

1. European Wound Management Association (EWMA). Position Document: *Topical negative pressure in wound management.* London: MEP Ltd, 2007.
2. Banwell P. Topical negative pressure therapy in wound care. *J Wound Care* 1999; 8(2): 79-84.
3. Ennis WJ, Lee C, Vargas M, Meneses O. Wound outcomes from a single practice at a subacute wound care unit and two hospital based outpatient wound clinics. *Wounds* 2004; 16(5): 164-72.
4. Beier JP, Horch R. Surgical management of pressure ulcers. In: Banwell P, Harding K (Eds). *Vacuum Assisted Closure™ Therapy: Science and practice*. London: MEP Ltd, 2006.

An example of: a) an acute wound (abdomen); **b)** a chronic wound (diabetic foot) suitable for VAC therapy.





EVALUATING TREATMENT

It is important to review progress regularly. This will involve an accurate and reproducible method of wound measurement[5]. If there is a reduction in wound area (eg around 15%) after one or two weeks[6], strong consideration should be given to continuing VAC therapy with **ongoing clinical evaluation**. Reassess again after a further week of therapy. If there is no improvement, discontinue VAC therapy and begin an alternative treatment. VAC therapy may be reconsidered at a later stage.

In **chronic wounds**, an effective general assessment measure is to:

- examine the wound margins for inflammation after the first application of VAC therapy. If there is increased inflammation consider discontinuing treatment
- re-examine the wound margins for a thin white epithelium after the second and subsequent applications: this indicates healing
- evaluate the overall appearance of the wound bed. A beefy, granular appearance is a positive outcome, while a dusky bed indicates inadequate tissue perfusion. Granulation tissue should increase by around 3–5% per day.

Under ideal conditions (especially in the absence of infection), well perfused wounds will respond quickly (ie within one week) with evidence of granulation tissue formation. This can be used to test vascularity and suitability of VAC therapy.

Adverse reactions have, on occasion, been reported (eg adherence to deep tissue structures). These can often be avoided by following recommendations (see box below), involving appropriately trained staff and by developing effective communication strategies. Specialist involvement will be required in certain situations

Factors to consider in the presence of infection:

- Debridement
- Antibiotic therapy
- Patient optimisation
- Frequent patient/wound assessment
- More frequent dressing changes
- Appropriate pressure settings
- Periwound skin protection
- Fenestrated antimicrobial dressings

VAC THERAPY AND WOUND INFECTION

VAC therapy is not recommended as a stand-alone treatment for wound infection. However, it may be used with **extra caution** in infected wounds as long as this is in addition to appropriate treatment of the infection (see box left).

In the presence of persistent infection or deterioration, or in wounds exhibiting no clinical progress towards healing (ie odour continues or becomes apparent), perform a thorough patient and wound reassessment (including microbiological investigations), discontinue VAC therapy and change treatment. Always consider whether systemic antibiotic therapy and/or appropriate debridement is required and treat the wound infection according to local protocols.

If infection develops during therapy, consider systemic antibiotic treatment and discontinue VAC therapy to allow monitoring of the wound. On specific occasions, an advanced modification of VAC therapy (V.A.C. Instill®) may be considered for use in severely infected wounds (eg infected hip and knee implants and orthopaedic hardware). This involves instilling an appropriate fluid into the wound bed, such as a topical antibacterial solution[7].

VAC THERAPY IN PRACTICE

To date almost all published clinical trials on topical negative pressure therapy[2] have used the V.A.C.® Therapy system. This fully integrated system incorporates a polyurethane (V.A.C.® GranuFoam® and V.A.C. GranuFoam Silver®) or polyvinyl alcohol (V.A.C.® WhiteFoam Dressing) foam dressing and a microprocessor controlled unit that establishes a uniform distribution of pressure across the entire wound. It is this specific system that is referred to throughout this document. For further information on the safe use of this system (including appropriate pressure and therapy settings) and relevant patient safety information, please go to www.kci-medical.com or contact your local KCI representative.

5. Mouës CM, Vos MC, Jan-Gert CM, et al. Bacterial load in relation to vacuum-assisted closure wound therapy: A prospective randomised trial. *Wound Rep Reg* 2004; 12: 11-17.
6. Attinger CE, Janis JE, Steinburg J, et al. Clinical approach to wounds: debridement and wound bed preparation including the use of dressings and wound-healing adjuvants. *Plast Reconstr Surg* 2006; 117 (7 Suppl): 72s-109s.
7. Plikaitis CM, Molnar JA. Subatmospheric pressure wound therapy and the vacuum-assisted closure device: basic science and current clinical success. *Expert Rev Med* 2006; 3(2): 175-84.

DIABETIC FOOT ULCERS

Clinicians may sometimes wrongly consider all diabetic foot ulcers to be the same for treatment purposes. In fact, there is considerable variation and the decision to use VAC therapy will depend on the wound subtype. VAC therapy can be considered for deep complex wounds, for post-surgery wounds and, occasionally, for superficial wounds in addition to standard treatments (see *Application to practice* box below). For patients with ischaemic wounds, referral to a vascular surgeon should be considered prior to VAC therapy.

DEEP COMPLEX DIABETIC FOOT WOUNDS

VAC therapy can be used in a number of ways to manage the complex diabetic foot wound:

- **Reduce complexity/size** – ie simplify the wound. In non-infected, non-ischaemic, deep complex diabetic foot ulcers, VAC therapy can be used to reduce the surface area of the wound by encouraging granulation tissue formation over exposed bone, tendon or tissue. This may help to avoid the need for skin grafting and/or flaps or to reduce the complexity of the subsequent surgical closure procedure[8,9]. A special dressing technique should be used to prevent further pressure damage in plantar wounds when applying VAC therapy[10].
- **Promote deep healing** – Experience has shown that on occasions VAC therapy can be used for longer periods in combination with other treatment modalities (eg systemic antibiotics) to allow complete healing of an underlying osteomyelitis before skin closure. This avoids the problem of ulcer recurrence with residual osteomyelitis (ie where skin heals before the underlying bone).

NB: There are currently no studies on using VAC therapy in poorly perfused wounds

In poorly perfused wounds where revascularisation is not possible, using VAC therapy for a trial period allows the clinician to observe the response to therapy and assess the viability of the tissue. Even when a positive outcome is unlikely, VAC therapy used in this way has shown unexpected and encouraging results. The clinician should strive for the most distal amputation level that achieves healing and a functional outcome[8].

VAC therapy is not recommended if the tissue is grossly infected; is ischaemic on presentation; or in the presence of untreated osteomyelitis

Planning treatment

The planned duration of therapy for diabetic foot wounds will depend on the specific treatment goal. In many cases an initial one- to two-week period of therapy is recommended. After this time, the wound should be evaluated for progress or deterioration, and:

- **if progress is good** – ie there is a daily increase in healthy granulating tissue formation, decreasing wound depth, a good blood supply and no infection – continue VAC therapy until the treatment goal is achieved
- **if progress is poor** or there is deterioration, consider alternative treatments or breaks ('time-outs') in VAC therapy. During this time the clinician should re-evaluate perfusion, focus on optimising medical therapy and use other wound modalities until the tissue quality improves. Often at this time VAC therapy can be successfully reinstated.

APPLICATION TO PRACTICE

Use VAC therapy only after any underlying disease has been diagnosed and managed and after appropriate debridement of non-viable tissue

VAC therapy can be an effective adjunct to revascularisation in diabetic foot wounds

VAC therapy should be used only after surgical drainage of any infection with conconmitant systemic antibiotic therapy according to local protocols

VAC therapy should be combined with effective offloading and good wound care

8. Armstrong D, Lavery L. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. *Lancet* 2005; 366: 1704-10.
9. Blume PA, Walters J, Payne W, et al. Comparison of negative pressure wound therapy utilizing vacuum-assisted closure to advanced moist wound therapy in the treatment of diabetic foot ulcers. A multicenter, randomized controlled trial. *Diabetes Care* 2008; 31(4): 631-36.
10. Edmonds ME, Doxford M. Practical management of diabetic foot ulcers. In: Banwell P, Harding K (Eds). *Vacuum Assisted Closure™ Therapy: Science and practice*. London: MEP Ltd, 2007.

POST-SURGERY DIABETIC FOOT WOUNDS

Randomised controlled trials (RCTs) support the use of VAC therapy for the following:

- after open partial foot amputation (from open toe/ray/to metatarsal level)[8]
- to aid fixation or bolstering of skin grafts[11].

Split-skin grafting and bioengineered tissue replacements, particularly acellular matrices, have been used in combination with VAC therapy as a practical alternative to flap closure in deep complex wounds[11]. VAC therapy promotes vascular perfusion, which has been shown to enhance skin graft take[12].

Planning treatment

It is not always appropriate to start VAC therapy immediately following surgery and it may be beneficial to observe the wound for 1–2 days prior to application[13]. The decision to select VAC therapy will depend on:

- viability of the skin edge and the tissue immediately below it
- whether there is capillary bleeding
- whether infection has been addressed and necrotic tissue has been removed
- treatment goals and patient factors.

VAC therapy should be stopped after the clinical endpoint is achieved (eg an appropriate reduction in volume or adequate wound bed preparation for subsequent skin grafting).

SUPERFICIAL DIABETIC FOOT WOUNDS

VAC therapy is not recommended as a first-line treatment in superficial wounds. However it may be considered along with other advanced therapies where there has been a poor response to other treatments (ie effective offloading, management of infection and local dressings).

Use VAC therapy with caution if the $TcpO_2$ is between 20 and 30mmHg and there is impaired sensation (in such cases use lower pressure settings)

Summary of key (SIGN level 1) studies of VAC therapy in diabetic foot ulcers

Study	Interventions	Design	Selection criteria	Clinical outcomes
Armstrong DG, Lavery LA. *Lancet* 2005; 366; 1704-10.	VAC therapy vs modern moist wound therapy for 16 weeks	Multicentre, randomised controlled trial n=162	Diabetic foot amputation to transmetatarsal level, with adequate perfusion	VAC therapy achieved wound healing in 56% vs 39% (p=0.04) of patients with a median wound bed preparation time of 42 days vs 84 days (p=0.02) compared with controls
Eginton MT, et al. *Ann Vasc Surg* 2003; 17: 645-49.	VAC therapy for 2 weeks vs conventional moist gauze dressings for 2 weeks	Randomised controlled crossover trial n=10	Large diabetic foot wounds with adequate perfusion, sharply debrided before entry	VAC therapy reduced wound volume and depth by 59% vs 0% (p<0.005) and 49% vs 8% (p<0.05) respectively, when compared with controls over the observation period
McCallon SK, et al. *Ostomy Wound Manage* 2000; 46: 28-34.	VAC therapy vs saline-moistened gauze	Randomised controlled pilot study n=10	Non-healing (>1 month) postoperative diabetic foot wounds, surgically debrided before treatment. Patients with venous disease, active infection or coagulopathy were excluded	VAC therapy produced an average decrease in wound surface area of 28.4% vs a 9.5% increase for controls, and an average time to satisfactory wound healing of 22.8 days vs 42.8 days for controls. Delayed primary closure was achieved in four of five patients with VAC therapy compared with two of five controls (p values not given)

Note: Although traditional gauze has been used as the comparator in many trials, the largest of these studies (Armstrong and Lavery, 2005) used a wide variety of moist wound dressings in the control group. Further studies using modern wound products vs VAC therapy have been published[8] or are in progess. For further information about SIGN levels of evidence visit www.sign.ac.uk

11. Moisidis E, Heath T, Boorer C, et al. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. *Plast Reconstr Surg* 2004; 114: 917-22.
12. Jeschke MG, Rose C, Angele P, et al. Development of new reconstructive techniques: use of Integra in combination with fibrin glue and negative-pressure therapy for reconstruction of acute and chronic wounds. *Plast Reconstr Surg* 2004; 113(2): 525-30.
13. Wu S, Armstrong DG. Surgical management of diabetic foot ulcers. In: Banwell P, Harding K (Eds). *Vacuum Assisted Closure™ Therapy: Science and practice*. London: MEP Ltd, 2007.

COMPLEX LEG ULCERS

It is recognised that compression therapy is regarded as the first-line treatment for venous leg ulcers[14]. However, there is a role for VAC therapy in inflammatory or complex therapy-resistant leg ulcers that are unsuitable for compression. The use of portable VAC systems may also allow ambulatory patients to be treated at home and can reduce the need for hospitalisation.

For complex leg ulcers it is important to assess the wound thoroughly using bacterial culture and biopsy to confirm the diagnosis. Surgical debridement should be performed prior to the application of VAC therapy to increase the potential for success.

If the wound deteriorates after the first dressing change discontinue VAC therapy

INFLAMMATORY ULCERS

In patients with inflammatory ulcers, VAC therapy can be used to enhance wound bed preparation before definitive surgical closure or delayed secondary healing. These patients historically have hard-to-heal wounds with high rates of skin graft failure. Ulcers may occur in the following situations:

- scleroderma
- systemic lupus erythematosus
- hypercoagulation disorders
- rheumatoid arthritis
- vasculitic conditions.

If the underlying clinical condition is resistant or inadequately treated, inflammatory ulcers will usually not heal despite optimal wound management. In addition, as treatment usually involves non-steroidal anti-inflammatory drugs, healing may be further impaired. In non-infected ulcers, a short trial of VAC therapy can be considered to determine whether it is likely to be beneficial. VAC therapy should be applied for 1–3 days and then removed while the response is evaluated.

COMPLEX THERAPY-RESISTANT ULCERS

VAC therapy can be considered for complex therapy-resistant leg ulcers including:

- highly exuding ulcers
- anatomically challenging ulcers (where the application and stabilisation of dressings is difficult)
- wounds requiring skin grafting (VAC therapy is used here for preoperative wound bed preparation and postoperative graft stabilisation).

Note: In a non-healing chronic ulcer in which other treatments have not been successful, granulation tissue may not be seen for up to two weeks when using VAC therapy.

14. European Wound Management Association (EWMA). Position Document: *Understanding compression therapy*. London: MEP Ltd, 2003.

Summary of key (SIGN level 1) study of VAC therapy in chronic leg ulcers

Study	Interventions	Design	Selection criteria	Clinical outcomes
Vuerstaek JD, et al. *J Vasc Surg* 2006; 44: 1029-37.	VAC therapy vs standard wound care and compression therapy (including surgical debridement and punch skin graft transplantation in both groups)	Randomised controlled trial n=60	Patients hospitalised with complex leg ulcers (>6 months) after failure of surgical and extensive ambulatory treatment options. Patients were followed-up for a period of 12 months	VAC therapy achieved a wound bed preparation time of 7 days vs 17 days (p=0.005), a median time to complete healing of 29 days vs 45 days (p=0.0001) and a skin graft take rate of 83% vs 70% (p=0.011) compared with controls. VAC therapy reduced total nursing time (232 mins vs 386 mins, p=0.001) and treatment costs ($3,881 vs $5,452) compared with controls

Note: Further medium and long-term follow-up studies are required to demonstrate ulcer recurrence rates, together with the durability and maintenance of stable soft tissue cover following successful VAC therapy. The role of VAC therapy in oedema management also requires clarification.

PRESSURE ULCERS

The main role of VAC therapy in pressure ulcers is in reducing the volume of a large cavity wound. VAC therapy may also have an important role in promoting comfort (eg reduction in dressing changes, exudate and odour), improving patient quality of life and facilitating the nursing management of these complex wounds. It is not generally recommended for grade/stage 2 ulcers and should not be used where there is suspected deep tissue injury under intact skin.

GRADE/STAGE 3 AND 4 PRESSURE ULCERS

VAC therapy is recommended as a first-line treatment for grade/stage 3 and 4 pressure ulcers in certain situations[15] and should be used as part of a comprehensive treatment plan. The entire base of the wound should be visible and examined before inserting the foam. These are often complex wounds with multiple tracts; if appropriate, the wound must be debrided prior to commencing VAC therapy, with excision of bony osteomyelitis, and be fully explored to allow access to all deeper extensions.

Failure to open subcutaneous wound spaces is a frequent cause of treatment failure

Optimising the wound

VAC therapy can be used preoperatively to precondition wounds for reconstruction or to allow a smaller and/or less complex flap to be used. This may help to reduce the operative time, postoperative risk and donor site morbidity. The effect of VAC therapy should be assessed continuously for a period of up to two weeks. Duration of VAC therapy will be defined by the initial wound size and the available volume of tissue for reconstruction. Post-surgery, VAC therapy may be used to manage small dehiscences as well as to improve perfusion of a marginally viable flap.

Improving mobility/symptom control

In patients who develop pressure ulcers following a major life event (eg a traumatic spinal cord injury in an active patient), frequent dressing changes and long-term bed rest can have a critical impact on their sense of wellbeing. VAC therapy may allow patients to mobilise in a wheelchair earlier and to return to rehabilitation programmes more quickly. Further research is required.

Some patients with pressure ulcers, such as those who have had multiple flap reconstructions, benefit from longer periods (eg three weeks) of VAC therapy to control symptoms. This can, for example, reduce exudate and allow a period of comfort before managing the wound with conservative measures. VAC therapy may also have a palliative role providing improved quality of life for terminally ill patients with pressure ulcers.

15. Gupta S, Baharestani MM, Baranoski S, et al. Guidelines for managing pressure ulcers with negative pressure wound therapy. *Adv Skin Wound Care* 2005; 17(Suppl 2): 1-16.

NB: For further information on staging/grading of pressure ulcers see www.npuap.org and www.epuap.org

Practical tips:

- VAC therapy is not a substitute for good basic care and should be combined with appropriate pressure redistribution and good skin care
- Insertion and removal of the foam dressing is easier in wounds >2cm
- For sacral pressure ulcers in close proximity to the anus, application of VAC therapy requires additional expertise

Summary of key studies of VAC therapy in pressure ulcers

Study	Interventions	Design	Selection criteria	Clinical outcomes
Schwien T, et al. *Ostomy Wound Manage* 2005; 51: 47-60.	VAC therapy vs various wound care therapies	Retrospective matched group analysis (SIGN level 2) n=60 vs n=2288	Patients with a stage 3 or 4 pressure ulcer in the home healthcare setting	Thirty-five percent of patients receiving VAC therapy were hospitalised compared with 48% in the control group (p<0.05). Emergent care for wound-related problems was lower in the VAC therapy group (0% vs 8%; p<0.01)
Joseph E, et al. *Wounds* 2000; 12: 60-67.	VAC therapy vs saline wet-to-moist gauze dressings for 6 weeks	Randomised controlled trial (SIGN level 1) n=24	Open wounds (79% pressure ulcers) in any location that had not closed or shown signs of healing within 4 weeks despite treatment	VAC therapy achieved a mean wound volume reduction of 78% vs 30% (p=0.38) compared with controls. VAC therapy was associated with fewer complications (17% vs 44%; p=0.0028)

Further reading: **Baharestani, et al.** Consensus Statement: A practical guide for managing pressure ulcers with negative pressure wound therapy. *Adv Skin Wound Care* 2008; 21(Suppl 1): 1-20. **Ford CN, et al.** Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the Healthpoint System in the management of pressure ulcers. *Ann Plast Surg* 2002; 49(1); 55-61: 11-17. **Wanner MB, et al.** Vacuum-assisted closure for cheaper and more comfortable healing of pressure sores: a prospective study. *Scand J Plast Reconstr Surg Hand* 2003; 37: 28-33.

Note: Further high-quality, prospective studies are needed to compare VAC with other advanced therapies in this patient group.

DEHISCED STERNAL WOUNDS

VAC therapy should be considered as a first-line treatment for dehisced sternal wounds following cardiac surgery[16,17]. This can be used as a bridge to definitive surgical closure or to achieve delayed primary closure or flap reconstruction and closure. In addition, VAC therapy may have the following benefits:

- stabilises the sternum
- facilitates sternal salvage
- facilitates drainage of the anterior mediastinum
- enables patients to be extubated and mobilised early
- decreases long-term mortality.

PLANNING TREATMENT

In deep infected sternal wounds debridement of bone is essential before applying VAC therapy. In suspected sternal wound infection, prompt action should involve irrigation, debridement, bone biopsy, tissue cultures and antibiotic therapy. It is important to protect underlying structures using a non-adherent interposed layer and to position the foam dressing correctly to reduce complications[16,17].

VAC therapy can be carried out initially for 48 hours. The viability of the wound tissue and culture results will then guide the decision to continue. Further cultures should be taken at each dressing change. Daily levels of serum C-reactive protein may also be used to guide therapy[18]. In most patients 5–12 days of VAC therapy will be appropriate.

Dehisced sternal wounds are complex, involve major organs and complications can be life-threatening. Involvement of a cardiothoracic surgeon with relevant expertise is essential. VAC therapy must be combined with appropriate use of antibiotics and other treatments

16. Fuchs U, Zittermann A, Stuettgen B, et al. Clinical outcome of patients with deep sternal wound infection managed by vacuum-assisted closure compared to conventional therapy with open packing: a retrospective analysis. *Ann Thorac Surg* 2005; 79(2): 526-31.
17. Fleck T, Gustafsson R, Harding K, et al. The management of deep sternal wound infections using vacuum assisted closure™ (V.A.C.®) therapy. *Int Wound J* 2006; 3: 273-280. **NB:** This paper is based on consensus guidelines for deep sternal wound infections – available from KCI.
18. Gustafsson R, Johnsson P, Algotsson L, et al. Vacuum assisted closure therapy guided by C-reactive protein level in patients with deep sternal wound infection. *J Thorac Cardiovasc Surg* 2002; 123: 895-900.

Summary of key (SIGN level 2) studies of VAC therapy in dehisced sternal wounds

Study	Interventions	Design	Selection criteria	Clinical outcomes
Sjögren J, et al. *Ann Thorac Surg* 2005; 79: 2049-55.	VAC therapy vs conventional treatment (rewiring, open moist saline gauze dressings, closed irrigation, pectoral muscle flaps or omentum flaps)	Retrospective controlled study n=101	Patients with post-sternotomy mediastinitis (defined according to US Centers for Disease Control and Prevention (CDC) guidelines)	VAC therapy achieved 100% survival compared with 85% in controls at 90 days ($p<0.01$) and decreased the need for surgical interventions (0% vs 57.5%). Patients receiving VAC therapy had a reduced failure rate in response to first-line treatment (0% vs 37.5% failures; $p<0.001$) compared with controls
Sjögren J, et al. *Ann Thorac Surg* 2005; 80: 1270-75.	VAC therapy for mediastinitis post-coronary artery bypass grafting (CABG) vs cases without mediastinitis post-CABG	Retrospective controlled study n=46 vs n=4781	Patients undergoing CABG divided into those developing post-sternotomy mediastinitis (defined according to US CDC guidelines) and those not developing mediastinitis	Patients with mediastinitis post-CABG, who received VAC therapy demonstrated similar early and late survival rates compared with patients without mediastinitis post-CABG, although this did not achieve statistical significance
Kutschka I, et al. *Zentralbl Chir* 2004; 129 (Suppl 1): S33-34.	VAC therapy for post-sternotomy infection	Retrospective controlled study n=10	Patients with severe post-sternotomy mediastinitis and sternal bone necrosis	Patients with mediastinitis receiving VAC therapy demonstrated increased lung function (51.3% forced expiratory volume vs 46.1%; $p=0.02$, and 48.4% vital capacity vs 42.7%; $p=0.02$) compared with controls
Fleck TM, et al. *Ann Thorac Surg* 2002; 74: 1596-600.	VAC therapy for mediastinitis post-cardiac surgery	Retrospective controlled study n=11	Patients with mediastinitis post-cardiac surgery (CABG, aortic valve replacement, or ascending aortic replacement)	Complete healing was achieved in all 11 patients. Patients treated with pectoralis flap closure with VAC therapy had a shorter intensive care unit stay than those not receiving VAC treatment (median 1 day vs 9.5 days) (p values not given)

Note: Further high-quality, prospective studies are needed to confirm improved survival rates in this patient group.

OPEN ABDOMINAL WOUNDS

VAC therapy has revolutionised the treatment of open abdominal wounds, yet historically there have been obstacles to its use in this challenging group of patients (eg the diverse aetiologies). It can be used to achieve delayed primary closure with fascia or to accelerate granulation tissue formation prior to skin grafting[19]. VAC therapy may have the following benefits:

- improves survival
- decreases number of dressing changes
- enables a higher rate of total abdominal wall closure
- decreases the need for secondary surgical reconstruction
- reduces complications (eg incisional hernia, infection).

The complexity of the open abdomen means VAC therapy should be used only by specialists with appropriate training and expertise (see Kaplan et al, 2005).

Exposed bowel must be adequately protected using a non-adherent interposed layer to prevent fistula formation or other complications

PLANNING TREATMENT

Training, education and experience in using VAC therapy in the open abdomen all positively affect outcomes. The frequency of dressing changes is also important. Dressings must be changed every 48–72 hours in the absence of wound infection. However, the exact frequency is dependent on the individual patient's circumstances, but ideally should not be less than three times a week.

Patients with existing fistulae should be referred to a specialist centre as special techniques are required when applying VAC therapy in this situation. These include excluding the fistula before applying negative pressure to the remaining wound, and covering a small fistula with the foam dressing. The choice of technique will be influenced by the type and volume of fluid present as well as the treatment goal. **These methods have been reported only as case studies and have not been formally tested in clinical trials.**

Note: Some authors suggest that VAC therapy should be used with extra caution in patients with bowel anastomoses or enterotomy repairs[20]; however the technique used may be important in preventing adverse events[21].

19. Swan M, Banwell PE. *Topical Negative Pressure: Advanced management of the open abdomen.* Oxford Wound Healing Society, 2003.
20. Rao M, Burke D, Finan PJ, Sagar PM. The use of vacuum-assisted closure of abdominal wounds: a word of caution. *Colerectal Dis* 2007; 9(3): 266-68.
21. Wild T, Goetzinger P, Telekey B. VAC and fistula formation. *Colerectal Dis* 2007; 9(6): 572-73.

Summary of key (SIGN level 2) studies of VAC therapy in open abdominal wounds

Study	Interventions	Design	Selection criteria	Clinical outcomes
Wild T, et al. *Zentralbl Chir* 2006; 131 (Suppl 1): S111-14.	VAC abdominal dressing vs classic VAC therapy vs conventional open therapies (laparostoma)	Retrospective controlled study n=62	Patients with an open abdomen following surgery for secondary peritonitis	VAC therapy was associated with a reduced mortality rate compared with conventional open packing (14% mortality VAC abdominal dressing group vs 21% classic VAC therapy vs 59% conventional therapy group; p<0.0009)
Kaplan M, et al. *Wounds* 2005; 17 (Suppl): 1-24.	VAC therapy vs other techniques (eg polypropylene, polyglactin/polycolic, Bogota bag and vacuum pack method)	Data compilation from published literature n=2080	Patients with open abdominal wounds or abdominal compartment syndrome	VAC therapy achieved a 79% fascial closure rate compared with 58% for the vacuum pack method (p<0.001), 34% for polypropylene and 18% for the Bogota bag. VAC therapy also had a lower incidence of fistula formation (eg 2.6% vs 7% for the vacuum pack method (p=0.034), 13% for the Bogota bag and 21% for polypropylene)
Kaplan M, et al. *Ostomy Wound Manage* 2004; 50 (11A Suppl): 20S-25S.	VAC therapy vs 'vac pack' method	Retrospective controlled study n=22	Patients with abdominal compartment syndrome or at high risk of abdominal compartment syndrome. Patients had their abdomen open for >48 hours	VAC therapy achieved primary closure of abdominal wall in 78% vs 12.5% patients, with a median time to wound closure of 12 vs 23 days compared with controls. VAC therapy also reduced hospital stay (30 vs 40.75 days) and incidence of acute respiratory distress syndrome (9% vs 50%) (no p values given)

Note: Retrospective studies have shown some advantage in using VAC therapy in the management of the open abdomen. Further high-quality prospective studies are needed to confirm its role as the standard of care in this wound type.

TRAUMATIC WOUNDS

VAC therapy can be used in the staged management of trauma wounds to:

- stabilise soft tissue
- minimise degree of secondary damage
- aid salvage of compromised tissue
- stimulate granulation tissue formation
- reduce oedema
- reduce rates of infection
- reduce wound size and complexity
- reduce complexity of the reconstructive procedure and scar formation
- reduce number and frequency of dressing changes (to optimise patient care and comfort)

*See further reading below

One of the most important roles for VAC therapy is in the treatment of complex traumatic wounds. It should be used in combination with a comprehensive surgical assessment, exploration and debridement, which will be different for each wound type. In heavily contaminated wounds, delayed closure can be performed following repeated debridement and reapplication of VAC therapy.

Trauma wounds are diverse in relation to wound type, location, size and complexity. A multi-disciplinary approach is required, with the involvement of orthopaedic, plastic and trauma surgeons. VAC therapy is used traditionally to treat large soft tissue loss. In addition, it has an emerging role in the management of open fractures of the lower extremity, high and low-energy trauma wounds, fasciotomy wounds, degloving injuries and burns. It can facilitate the following:

- Stabilisation of **skin grafts** and improved donor site healing[11]. VAC therapy is now recommended for fixation of dermal substitutes (Molnar et al, 2004*).
- Stabilisation of **high-energy injuries** (eg bomb-blast, gunshot wounds) or **low-energy** road traffic accident injuries, either on the battlefield (in the case of war wounds) or at an emergency department, allowing safe transfer of the patient to an appropriate centre.
- Management of **open fractures**. While the role of vascularised soft tissue cover remains the gold standard treatment of lower limb fractures, VAC therapy has been used to reduce the need for complex surgery. In an ongoing French study, 700 patients developed good granulation tissue cover after 3–7 days of receiving VAC therapy (see www.stic-tpn.fr). The duration of VAC therapy is defined by the intended treatment outcome (eg definitive closure, volume reduction or temporising during stabilisation of the patient or underlying fracture). It also allows monitoring of open fractures to assess the viability of tissue prior to final closure by flap surgery.
- Prevention of the progression of **partial-thickness burns** injuries (Kamolz et al, 2004*). It may also be used for excised **full-thickness burns** prior to skin grafting (Téot et al, 2004*).

These large, complex wounds require nursing and rehabilitation expertise together with skilled application of dressings (eg to accommodate external orthopaedic hardware)

Summary of key studies of VAC therapy in traumatic wounds

Study	Interventions	Design	Selection criteria	Clinical outcomes
Stannard JP, et al. *J Trauma* 2006; 60: 1301-06.	VAC therapy vs pressure dressing or standard postoperative dressing	Randomised controlled trial (SIGN level 1) (i) n=44 (ii) n=44	Patients with (i) traumatic injury with subsequent surgical incision or with (ii) surgical incision following a high-risk fracture after high-energy trauma	VAC therapy reduced the duration of drainage in patients with haematomas or high-risk fractures compared with controls (mean 1.6 days vs 3.1 days for haematomas, p=0.03; and 1.8 days vs 4.8 days for high-risk fractures, p=0.02)
Yang CC, et al. *J Surg Orthop Adv* 2006; 15: 19-23.	VAC therapy vs traditional saline-soaked wet-to-dry dressings	Retrospective controlled study (SIGN level 2) n=68	Patients undergoing fasciotomies for documented, traumatic compartment syndrome of the leg	Overall time to definitive wound closure by delayed primary closure with sutures or split-thickness skin graft coverage was 6.7 days for VAC therapy and 16.1 days for traditional dressings (p=0.0001)
Labler L, et al. *Eur J Trauma* 2004; 30: 305-12.	VAC therapy vs standard treatment (Epigard)	Retrospective controlled study (SIGN level 2) n=23	Patients with severe open fractures of the lower extremity (type IIIA or IIIB) admitted as an emergency	VAC therapy achieved a lower rate of infection than Epigard (15% vs 55%), although this was not found to be statistically significant

Further reading: **Banwell PE, et al.** Vacuum therapy in degloving injuries of the foot: technical refinements. *Br J Plast Surg* 2002; 55(3): 264-66. **Dedmond BT, et al.** The use of negative-pressure wound therapy (NWPT) in the temporary treatment of soft-tissue injuries associated with high-energy open tibial shaft fractures. *J Orthop Trauma* 2007; 21(1): 11-17. **Genecov DG, et al.** A controlled subatmospheric pressure dressing increases the rate of skin graft donor site reepithelialization. *Ann Plast Surg* 1998; 40(3): 219-25. **Kamolz LP, et al.** Use of subatmospheric pressure therapy to prevent burn wound progression in human: first experiences. *Burns* 2004; 30(3): 253-58. **Labler L, Trentz O.** The use of vacuum-assisted closure in soft tissue injuries after high energy pelvic trauma. *Langenbecks Arch Surg* 2007; 392(5): 601-9. **Leininger B, et al.** Experience with wound VAC and delayed primary closure of contaminated soft tissue injuries in Iraq. *J Trauma* 2006; 61(5): 1207-11. **Molnar JA, et al.** Acceleration of Integra incorporation in complex tissue defects with subatmospheric pressure. *Plast Reconstr Surg* 2004; 113(5): 1339-46. **Parren BM, et al.** Lower extremity trauma: trends in the management of soft-tissue reconstruction of open tibia-fibula fractures. *Plast Reconstr Surg* 2006; 117(4): 1323-24. **Stone P, et al.** Bolster versus negative pressure wound therapy for securing split-thickness skin grafts in trauma patients. *Wounds* 2004; 16(7): 219-23. **Téot L, et al.** *Surgery in Wounds*. Berlin Heidelberg: Springer-Verlag 2004.

Note: Further, high-quality, prospective studies are needed to confirm outcomes in these complex wounds.

MEASURING IMPACT OF VAC THERAPY

There is no doubt that VAC therapy can have a positive impact on a patient's quality of life[22]. Table 2 identifies how VAC therapy can improve a patient's experience of living with a wound. However, in order to justify the use of this intervention in everyday practice where resources are limited, the clinician needs to be able to present a robust economic argument for its use. This is complicated by the seemingly high acquisition costs of the system. It is suggested that clinicians need to focus on using factors other than unit costs (eg reduction in hospital stay, staff labour and reduction in adverse events) to measure economic benefits. This model has been used for the diabetic foot wound, where there is evidence that VAC therapy is associated with lower overall costs of care[23]. Future practice needs to find ways of developing more user-friendly condition-specific tools for measuring quality of life and cost-effectiveness in wound care.

Table 2 | Measuring impact of VAC therapy

Factor	Measure
Quality of life	**Advantages** ■ Control of odour and exudate in many wound types (ie social benefits) with less frequent dressing changes ■ Able to participate in daily living activities, physical therapy and rehabilitation ■ Faster return to reduced dependency and normal living ■ Improvement in adherence (eg with offloading) ■ Improvement in anxiety and depression **Disadvantages** ■ Noise of the VAC therapy unit (can be intrusive and difficult to tolerate)* ■ Weight of the VAC therapy unit (mobility can be a problem, especially in older people)* **Other considerations** ■ Duration of treatment ■ Clinician's level of expertise and confidence in using the technology ■ Setting in which the treatment is given (home or secondary care) ■ Communication (benefits need to be explained/patients' expectations assessed)
Cost-effectiveness[24-27]	■ Reduction in use of resources and labour ■ Reduction in complexity and number of surgical procedure/adverse events ■ Reduction in length of treatment and hospital stay/number of hospitalisations ■ Improvement in clinical outcome

*NB: Newer generation models may help to reduce noise/mobility problems

FUTURE DEVELOPMENTS

Further research is needed to increase understanding of the therapeutic effects of VAC therapy to give clinicians stronger arguments to support its use[28,29]. In particular, future trials should focus on the generation of level 1 evidence and further comparative data for specific indications. This will help to clarify the potential for VAC therapy in different wound types and to enhance clinical decision making in various population groups. For example:

- There is a small but emerging use of VAC therapy in the paediatric population. Clarification is needed on the type of foam dressing and pressure settings to be used in these patients.
- Further research is needed to establish the relationship between negative pressure and blood flow and the optimal pressure for wound healing[30].
- The economic impact of VAC therapy requires further evaluation to justify the increased cost of treatment against the overall benefit of shorter healing times.
- As new negative pressure devices are developed, there will be a need to compare the effectiveness of the V.A.C.® Therapy system with these emerging systems.
- Where dramatic improvements in outcome have been observed using VAC therapy (eg open abdomen) there are clearly ethical challenges in running comparative studies using less beneficial treatments. Prospective, multicentre studies with a common protocol should be performed and are needed.

22. Augustin M, Zschoke I. [Evaluation of patient benefits of ambulatory and stationary use of V.A.C.® Therapy]. *MMW-Fortschritte der Medizin Originalien Nr.1* 2006; 148: S25-32.
23. Apelqvist J, Armstrong DG, Lavery LA, et al. Resource utilization and economic costs of care based on a randomized trial of V.A.C. therapy in the treatment of diabetic foot wounds. *Am J Surg* 2008 [Epub ahead of print].
24. Braakenburg A, Obdeijin M, Feitz R, et al.The clinical efficacy and cost-effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: a randomized controlled trial. *Plast Reconstr Surg* 2006; 118(2): 390-97.
25. Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. *Ostomy Wound Manage* 2005; 51: 1-11.
26. Vuerstaek JDD, Vainas T, Wuite J. State-of-the-art treatment of chronic leg ulcers: A randomised controlled trial comparing vacuum-assisted closure (V.A.C.) with modern wound dressings. *J Vasc Surg* 2006; 44: 1029-37.
27. Mouës CM, van den Bemd GJCM, Meerding WJ, et al. An economical evaluation of the use of TNP on full-thickness wounds. *J Wound Care* 2005; 14: 224-27.
28. Topical negative pressure for chronic wounds. *Drug Ther Bull* 2007; 45: 57-61.
29. Hunter JE, Teot L, Horch R, Banwell PE. Evidence-based medicine: vacuum-assisted closure in wound care management. *Int Wound J* 2007; 4(3): 256-69.
30. Timmers MS, Le Cessie S, Banwell P, Jukema GN. The effects of varying degrees of pressure delivered by negative pressure wound therapy on skin perfusion. *Ann Plast Surg* 2005; 55(6): 665-71.