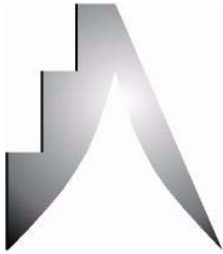


ASERNIP/S



Australian Safety
and Efficacy
Register of New
Interventional
Procedures-Surgical

Vacuum-Assisted Closure for the Management of Wounds: An Accelerated Systematic Review

ASERNIP-S REPORT NO. 37

December 2003

**Australian Safety & Efficacy Register of
New Interventional Procedures - Surgical**

The Royal Australasian College of Surgeons

Vacuum-assisted closure for the management of wounds: an accelerated systematic review

C Pham

P Middleton

G Maddern

ISBN 0 909844 61 5

Published December 2003

The ASERNIP-S Programme

Under the auspices of the Royal Australasian College of Surgeons, ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures – Surgical) conducts systematic reviews of new and emerging surgical techniques and technologies. ASERNIP-S is supported by the Commonwealth of Australia Department of Health and Ageing.

Accelerated Systematic Reviews

Accelerated systematic reviews are produced in response to a pressing need for a systematic summary and appraisal of the available literature for a new or emerging surgical procedure. This need may arise if the uptake of the new technique or technology appears to be inappropriate given the evidence available at the time (it may be diffusing too quickly or too slowly). Alternatively there may be uncertainty or controversy regarding the clinical or cost effectiveness of the new procedure, or there may be significant concerns regarding its safety or indications for use in particular populations. Accelerated systematic reviews use the same methodology as full systematic reviews, but may restrict the types of studies considered (for example, by only including comparative studies and not case series) in order to produce the review in a shorter time period than a full systematic review.

This report should be cited in the following manner:

Pham CT, *et al.* Vacuum-Assisted Closure for the Management of Wounds: An Accelerated Systematic Review. ASERNIP-S Report No. 37. Adelaide, South Australia: ASERNIP-S, December 2003.

Copies of these reports can be obtained from:

ASERNIP-S

The Royal Australasian College of Surgeons

PO Box 688,

North Adelaide, SA 5006

AUSTRALIA

Ph: 61-8-8239 1144

Fax: 61-8-8239 1244

E-Mail: College.asernip@surgeons.org

<http://www.surgeons.org/asernip-s>

The Accelerated Systematic Review of Vacuum-Assisted Closure for
the Management of Wounds was ratified by:

The ASERNIP-S Management Committee on
November 11, 2003

The Executive of the Council of the Royal Australasian College of
Surgeons in
December 2003

Table of Contents

Summary	4
1. Introduction	6
Background	6
The Technique	7
Patient Group	10
2. Methodology	12
Data Extraction and Synthesis.....	14
3. Results	16
Efficacy.....	16
Complications	19
4. Discussion	22
Cost Considerations	23
5. Conclusions	25
References	26
Appendix A	30
Tables of Key Efficacy and Safety Findings	30

Summary

Background

Delayed wound healing is a significant health problem, particularly in older adults. In addition to the pain and suffering, failure of the wound to heal also imposes social and financial burdens. Vacuum-assisted closure (VAC) therapy has been developed as an alternative to the standard forms of wound management, which incorporates the use of negative pressure to optimise conditions for wound healing and requires fewer painful dressing changes.

Objective

To assess whether the management of non-healing wounds using VAC therapy will result in improved efficacy and safety outcomes compared with conventional methods.

Methods

MEDLINE, PREMEDLINE, EMBASE, Current Contents and PubMed were searched from inception up to July 2003 and The Cochrane Library Issue 3, 2003 was searched for randomised controlled trials (RCTs) comparing VAC with an alternative treatment. The York (UK) Centre for Reviews and Dissemination databases, Clinicaltrials.gov, National Research Register, Grey Literature Reports, relevant online journals and the Internet were searched in July 2003. The search terms were as follows: (*vacuum* or *suction*) and (*wound healing*), (*vacuum assisted* or *vacuum-assisted*) and (*wound* or *closure*), *topical negative pressure*, (*subatmospheric* or *sub-atmospheric*) and *pressure*. Studies containing safety and efficacy data on the VAC technique in the form of randomised controlled trials (RCTs), other controlled or comparative studies and case series with consecutive patients and stating the type of wound, were included.

Results

Six randomised controlled trials of vacuum-assisted closure covering four indications – two on pressure sores and ulcers, one on diabetic foot ulcers, one on skin grafts and two on chronic and complex wounds, were reviewed. Also included in the review were four non-randomised comparative studies (three on sternal wounds and one on skin grafts) and seven case series studies (two each on skin grafts and chronic wounds and one each for pressure sores and ulcers, diabetic foot ulcers and sternal wounds). For management of pressure sores and ulcers, no difference could be detected between VAC and use of traditional gauze dressings or the Healthpoint (HP) system. Foot ulcers managed with VAC significantly decreased by 28.4% in surface area as opposed to those managed with saline-moistened gauze, which increased by 9.5% ($p=0.004$). VAC therapy appeared to be more effective than Opsite and bolster dressings in skin graft management. Patients managed with VAC

had increased rate of reepithelialisation and fewer patients required repeat split thickness skin graft to the same site. VAC was more effective at treating various chronic and complex wounds than WM gauze, as there was a significantly greater reduction in wound volume, depth and treatment duration. Comparative studies on sternal wounds suggests that VAC may be more cost-effective than traditional dressings or closed drainage and irrigation, as VAC required a reduced number of dressing changes and number of flaps to close the wound, and a shorter treatment duration and length of hospital stay. This has the potential to reduce health care costs, for both hospital and patient, and enhance patient satisfaction and quality of life. A major complication for patients whose wounds failed to heal with VAC was amputation. This occurred in one patient with a pressure ulcer who developed sepsis and three patients with diabetic foot ulcers who required higher level amputation. Cases of periwound maceration and infection were also reported; however, it is unclear whether these complications were VAC-related. Some patients reported minor discomfort with the application of pressures greater than 100 mmHg.

Conclusions

Although most studies were probably too small to detect significant differences, some results did show VAC to result in better healing than standard methods, with few serious complications. More rigorous studies with larger sample sizes assessing the use of VAC therapy on different wound types are required. With proper training to ensure appropriate and competent use, VAC is simple to use and appears to be a promising alternative for the management of various wound types.

1. Introduction

Background

Delayed wound healing is a significant health problem, particularly in older adults (Flicker 1996). In addition to the pain and suffering, failure of the wound to heal also imposes social and financial burdens. Vacuum-assisted closure (VAC) therapy, which has been developed as an alternative to the standard forms of wound management, incorporates the use of negative pressure to optimise conditions for wound healing. It can be used for the early management of acute trauma or when other more conventional conservative methods have failed.

An acute wound is defined as any interruption in the continuity of the body's surface (Kranke *et al.* 2003), for example burns, crushing injuries and lacerations (MacLellan 2000). A wound is deemed chronic when it requires a prolonged time to heal, does not heal, or recurs (Kranke *et al.* 2003). The prevalence of chronic wounds is age dependent with a prevalence of 1.3% in the Australian adult population, rising to 3.6% for those aged 65 years and over (Rauchberger 2002). As we age, there is a gradual decline in the function of sensory nerves that have an important role in tissue repair (Flicker 1996).

Wound healing is a highly orchestrated process (Flicker 1996), which commences with the removal of debris and control of infection (Joseph 2000). Inflammation clears the area for angiogenesis (new blood vessel growth) to occur to increase blood flow to the wound site (Joseph 2000). Subsequently, the wound heals through deposition of granulation tissue, wound contraction and maturation (Joseph 2000). When one of these steps fails, the wound is unable to heal. Other factors such as pressure, trauma, venous insufficiency, diabetes mellitus, vascular disease and prolonged immobilisation will influence wound healing (Joseph 2000).

Standard wound management consists of initial surgical debridement (a rapid and effective technique to remove devitalised tissue) (Bowler 2002), then either wet-to-moist (WM) gauze dressings or Opsite (Smith and Nephew Inc., Columbia, SC) dressings, which need to be changed at least twice daily, can be used to cover the wound (Joseph 2000). These dressings are relatively inexpensive, readily available and easy to apply (McCallon 2000). However, there are some disadvantages: non-selective debridement with dressing removal, possible wound desiccation, and the need for frequent dressing changes (McCallon 2000). The Healthpoint System (HP) involves the use of three Food and Drug Administration (FDA)-approved gel products, Accuzyme, Iodosorb and Panafil. Accuzyme, a papain-urea debridement ointment, is used initially unless the wound has been surgically debrided. Wounds with substantial exudate are managed with Iodosorb gel, which contains hydrophilic beads that soak up bacteria and cellular debris. Clean, granulating ulcers receive Panafil, a papain-

urea-chlorophyllin-copper ointment (Ford 2002). Other approaches to cleanse and prepare the wound involve the use of topical enzymes, biosurgical therapy and topical antimicrobial agents (Bowler 2002). However, the use of these techniques are beyond the scope of this review. Vacuum-assisted closure has been suggested as an alternative that may promote faster wound healing with fewer painful dressing changes.

The vacuum-assisted closure (VAC®) device (KCI, San Antonio, TX) was pioneered by Dr Louis Argenta and Dr Michael Morykwas in 1993 (Rosser *et al.* 2000). It is a development from the standard surgical procedure, which uses vacuum-assisted drainage to remove blood or serous fluid from an operation site to provide a drier surgical field and control blood flow (Thomas 2001). In VAC therapy, the application of topical negative pressure (vacuum) removes blood and serous fluid, reduces infection rates (closed/sealed system creates a hypoxic environment) and increases localised blood flow, thereby supplying the wound with oxygen and nutrition to promote accelerated healing (Vacuum therapy in wound management 2001, Genecov 1998). Alternative names for VAC include topical negative pressure, sub-atmospheric pressure, sealed surface wound suction, vacuum sealing and foam suction dressing (Vacuum therapy in wound management 2001).

The Technique

The classic VAC® system (KCI, San Antonio, TX) comprises the vacuum pump (negative pressure unit), canister, tubing to connect the dressing to the pump and VAC dressing pack (foam and occlusive drapes) (Collier 2003). Current canisters have a maximum volume of 250 ml; recent pump models now have 500 ml canisters. When the canister is full, an alarm system located on the pump will sound. The alarm will also sound if there are leaks, tube blockage and if the desired pressure is not reached (Collier 2003).

The VAC® Advanced Therapy System (ATS) has recently been introduced. In addition to the classic system, it has a therapeutic regulated accurate care (TRAC) pad and tubing that uses a continuous feedback loop to the microprocessor control to monitor and maintain target negative pressure. Two portable devices are also available, mini-VAC® and VAC® Freedom, for mobile patients with minimal to moderate levels of exudate (Collier 2003).

The VAC® devices (KCI, San Antonio, TX) are available in Australia and are registered with the Therapeutic Goods Administration (TGA).

Sequence of Procedure (see Fig.1):

1. Wound Preparation

Any dressings from the wound are removed and discarded. If required, a culture swab for microbiology should be taken before wound irrigation with normal saline. Surface slough or necrotic tissue should be surgically removed (surgical debridement) and adequate haemostasis achieved. Prior to application of the drape, it is essential to prepare the peri-wound skin and ensure that it is dry (Vacuum therapy in wound management 2001). A degreasing medical cleansing agent is available to clear the skin of perspiration, oil or body fluids that will make the skin moist, and a skin protectant should be used to protect the skin around the wound (Mendez-Eastman 2001).

2. Placement of Foam

Sterile, open-cell foam dressing is gently placed into the wound cavity. Open-pore, reticulated medical-grade foams are used as they are the most effective at transmitting mechanical forces across the wound and provide an even distribution of negative pressure over the entire wound bed to aid in wound healing (Vacuum therapy in wound management 2001). There are two different types of foam available, black (applied into the wound) or white (applied over the wound) (Vacuum therapy in wound management 2001). Black foam, polyurethane ether (PU), has larger pores, is lighter, easily collapsible and hydrophobic with a pore size of 400 to 600 μm . It is used when stimulation of granulation tissue and wound contraction is required. White foam, polyvinylalcohol (PVA), is used for restricted formation of granulation tissue, as it is denser with smaller pores, requires higher negative pressures to collapse, and is hydrophilic (absorbs exudate) with a pore size of approximately 250 μm . Embedded in the foam is a fenestrated evacuation tube, which is connected to a computer-controlled vacuum pump that contains a fluid collection canister. The amount of pressure applied will depend on which type of foam is used, with the white foam requiring higher negative pressure as it is denser.

3. Sealing with Drapes

The site is then sealed with an adhesive drape. There are three main drapes available: commercial VACTM dressings with a useful double layer, iodine-impregnated abdominal drapes (Ioban, 3M, St. Paul, MN), and anatomical dressings that are specifically designed to mould to the hand or foot (Vacuum therapy in wound management 2001).

Drapes should cover the foam and tubing and at least three to five centimetres of surrounding healthy tissue to ensure a seal. The manufacturer recommends dressings (foam + drapes) to be changed every 48 hours or sooner if the wound is infected.

Some dressings have been left for four to five days before changing (Banwell 1999). However, the speed of tissue growth should be monitored to prevent adherence to the wound bed. For meshed grafts, dressings are left in place for four to five days (Patel *et al.* 2000). Dressing changes may be done under general anaesthesia in theatre, depending on the location and type of wound. Care must be taken when removing the adhesive drape to avoid irritating the periwound skin. There is a topical adhesive remover available (Mendez-Eastman 2001). Normal saline solution can be used to loosen the foam for removal from the wound bed. For patients experiencing pain with dressing changes, 1% lidocaine solution may be introduced either via the tubing or injection into the foam with the pump on low pressure (50 mmHg) (KCI Medical Australia 2003).

4. The Application of Negative Pressure

Controlled pressure is uniformly applied to all tissues on the inner surface of the wound (McCallon 2000). The foam dressing should compress in response to the negative pressure. The pump can deliver either continuous or intermittent pressures, ranging from 50 to 125 mmHg (adjustable up to 200 mmHg) (Vacuum therapy in wound management 2001). Intermittent delivery consists of a seven-minute cycle of two minutes off and five minutes on, while the negative pressure is maintained. The ideal pressure setting is 125mmHg, but particularly painful chronic wounds such as chronic leg ulcers are usually managed with lower therapeutic pressures of 50 to 75 mmHg. Higher pressures of 150 mmHg plus are used for large cavity wounds such as acute traumatic wounds, as they produce copious amounts of exudate (Collier 2003). The pressure is set to continuous for the first 48 hours and the pressure is changed as required thereafter. Guidelines on target pressure, cycle (continuous/intermittent), foam type and dressing change interval for different wound types are presented in the VAC® Therapy Clinical Guidelines (KCI Medical Australia 2003).

The manufacturer has cautioned that premature cessation of treatment after 48 hours may result in a rebound phenomenon, that is, the involution or regression of any granulation tissue formed. They suggest continuing therapy for a further period of time to circumvent this.

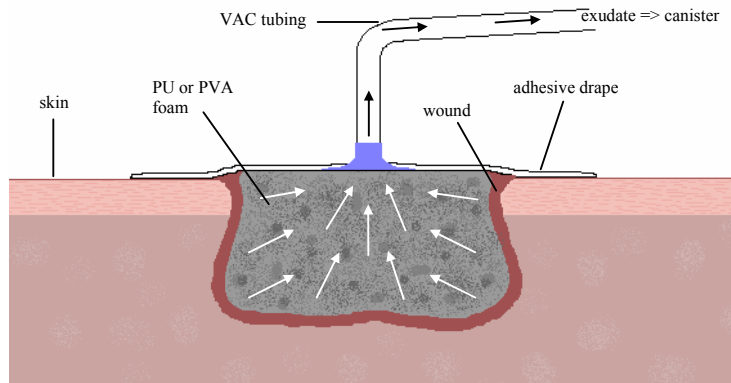


Fig.1 Cross-section of a wound with the VAC dressing in place.

Patient Group

Vacuum therapy can be applied to various types of wounds to patients of all ages. However the wound must have the basic capacity to heal. Vacuum therapy should not be initiated in patients who have an inadequate nutritional status, an untreated infection, or if death is imminent (i.e. the patient is unlikely to live more than six months) (Mendez-Eastman 2001).

Wounds treated with VAC include:

- diabetic foot ulcers
- pressure ulcers
- pressure sores
- skin graft fixation
- burns
- hand injuries
- sternal wound breakdown
- abdominal dehiscence
- flap salvage
- exposed tendon in lower limb trauma
- fistulae
- donor sites
- Hidradenitis Suppurativa
- fasciotomy wounds
- animal bites
- extravasation injury
- frostbite
- spinal cord injuries
- osteomyelitis.

The US Food and Drug Administration (FDA) approved the use of VAC for the treatment of non-healing wounds in 1995. In January 2000 the approval was updated to include chronic, acute, traumatic and subacute wounds, flaps and grafts (Mendez-Eastman 2001).

VAC has also been used in combination with other therapeutic modalities, such as hyperbaric oxygen and growth factors (Fabian *et al.* 2000, Hopf *et al.* 2001), and following oncological surgery (Argenta *et al.* 2002).

The portable VAC® devices are recommended for venous stasis ulcers, lower extremity diabetic ulcers, pressure ulcers, lower extremity flaps, dehisced incisions and grafts (Thomas 2001).

Vacuum therapy is contraindicated in patients with malignancy in the wound, untreated osteomyelitis, fistulae to organs or body cavities, presence of necrotic tissue and those with exposed arteries or veins (Vacuum therapy in wound management 2001). It is recommended that extra care should be taken for patients with blood dyscrasias (an imbalance of components of the blood), and patients on anticoagulants or with actively bleeding wounds (KCI Concepts 2002). Also, when placing dressings in proximity to blood vessels, it is important to ensure that all vessels are adequately protected with overlying fascia, tissue or other protective barrier, especially for weakened, irradiated or sutured blood vessels (KCI Concepts 2002).

2. Methodology

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed and Cochrane Library using Boolean search terms was conducted, from the inception of the databases until July 2003. The York (UK) Centre for Reviews and Dissemination databases, Clinicaltrials.gov, National Research Register, Grey Literature Reports, relevant online journals and the Internet were searched in July 2003. Searches were conducted without language restriction. The vacuum therapy website (www.vacuumtherapy.co.uk/index.htm) was also searched for product information and relevant trials.

Articles were obtained on the basis of the abstract containing safety and efficacy data on the vacuum-assisted closure technique in the form of randomised controlled trials (RCTs), other controlled or comparative studies and case series with consecutive patients and stating the type of wound. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. The English abstracts from foreign language articles were also included if they met the study inclusion criteria and contained safety and efficacy data. In the case of duplicate publications, the latest and most complete study was included.

List of Studies Included

Total number of studies:	21
Systematic Reviews	2
Randomised controlled trials	6
RCTs in progress – preliminary analysis	2
Non-randomised comparative studies	4
Case series	7

Table 1 provides a descriptive summary of the included studies. The two systematic reviews do not appear in the table, since all their included RCTs are listed separately.

Table 1. Included Studies

Study	Source of Data	Follow-up	Study Type	Intervention	N
Pressure Sores and Ulcers					
Wanner 2003	Paper	42 days	RCT	VAC WM Gauze	11 11
Ford 2002§	Paper	3 to 10 months	RCT	VAC Healthpoint System	20 15
Greer 1999 – preliminary analysis	Abstract	~20 days	RCT	SPD WM Gauze	8 3
Deva 2000	Paper	At least 3 months	Case Series	VAC	30
Diabetic Foot Ulcers and Wounds					
McCallon 2000§	Paper	43 days	RCT	VAC WM Gauze	5 5
Armstrong 2002	Paper	12 months	Case Series	VAC	31
Skin Grafts					
Genecov 1998§	Paper	7 days	RCT	VAC Opsite Dressing	10*
Heath 2002 – preliminary analysis	Abstract	2 weeks	RCT	VAC Standard Pressure	10#
Scherer 2002	Paper	Up to 58 days	Comparative	VAC Bolster Dressings	34 27
Avery 2000	Paper	2 weeks	Case Series	VAC	15
Meara 1999	Paper	12 days	Case Series	VAC	9^
Chronic Wounds and Complex/Severe Wounds					
Joseph 2000§	Paper	6 weeks	RCT	VAC WM Gauze	18† 18†
Davydov 1994	Paper	48 hours	RCT	VAC Conventional Dressings	26 53
Lang 1997	Paper	13 months	Case Series	VAC	96
Mooney 2000	Paper	Not stated	Case Series	VAC	27
Sternal Wounds					
Song 2003	Paper	8 days	Comparative	VAC Traditional Dressings	17 18
Doss 2002	Paper	5 weeks	Comparative	VAC Conventional Dressings	20 22
Catarino 2000	Paper	6 months	Comparative	VAC CDI	9 11
Gustafsson 2002	Paper	Up to 120 days	Case Series	VAC	16

Table Legend: Paper refers to publication in peer reviewed journal and abstract to an abstract from a conference proceedings or presentation; *10 patients – each patient had two donor

sites, one managed with VAC and the other managed with Opsite dressings; #Surgical wounds were divided into halves, proximal and distal, with one half was treated with standard pressure, the other with VAC; ^9 separate degloving injuries in 5 patients; †36 wounds in 24 patients; §These RCTs were partially funded by KCI, the manufacturer of the VAC® device; Abbreviations: VAC – vacuum-assisted closure, WM – wet-to-moist gauze dressings, SPD – sub-atmospheric pressure dressing, RCT – randomised controlled trial, CDI – closed drainage and irrigation.

Unpublished RCTs

There are three RCTs that have recently been completed but not yet published:

- Walker P. North Lincolnshire, UK: A randomised, prospective trial of standard Medinorm wound drainage system versus constant vacuum drainage to determine whether there is any effect on the amount of wound exudate, haemoglobin and wound bruising. This study aimed to recruit 48 patients.
- Adams TST. Aylesbury, UK: The effect of topical negative pressure on donor site wound healing P003. This was a prospectively randomised study of donor site healing treated post-operatively by one of two dressing regimens: semi-permeable membrane dressings or topical negative pressure.
- Fryer J. New York, USA: Investigation of sub-atmospheric pressure dressing on pressure ulcer healing. The objectives of this study were to evaluate the effectiveness of sub-atmospheric pressure dressing (SPD) in healing pressure ulcers versus conventional saline wet-to-moist dressing techniques and to establish indications and contraindications for use of SPD in treating pressure ulcers. The study aimed to recruit 120 patients.

Articles on surgical drainage were excluded as the technique is different to VAC. In some cases, suction drainage was used as another term for VAC. Thus, each paper had to be obtained to determine whether the technique described was VAC. There was an overlapping of randomised controlled trials included in this review and in the two systematic reviews, therefore it was unnecessary to also tabulate the data from the systematic reviews. Studies excluded from tabulation are listed in the annex following the reference list, with reasons for their exclusion.

Data Extraction and Synthesis

Data were extracted by one researcher and checked by a second and checked by a second using standardised data extraction tables that were developed *a priori*. Included studies were examined in terms of design or execution for factors that may have introduced bias. Major efficacy and safety outcomes were not pooled, as the outcome measures reported differed between studies. In some cases, odds ratios or

mean differences were calculated using Review Manager 4.2 (The Cochrane Collaboration 2003).

3. Results

See Appendix A

The quality of all the RCTs available for review were poor. Only three RCTs provided a description on the method of allocation. Randomisation of patients was by either coin flipping initially and then alternating groups (McCallon 2000) or based on a table of random letters generated before the trial began (Ford 2002). Joseph and colleagues (Joseph 2000) randomised wounds instead of patients by pulling out marked files randomly organised in a locked cabinet; however, it is unclear whether treatment allocation was adequately concealed. Outcome assessors were blinded in two of the RCTs (Ford 2002, Joseph 2000), in two other RCTs (Genecov 1998, Wanner 2003) neither patients nor assessors were blinded and in the remaining two RCTs (Davydov 1994, McCallon 2000) blinding status was not stated. Follow-up times varied across studies.

Efficacy

Pressure Sores and Ulcers

RCTs

For pressure sores treated with either VAC or traditional gauze dressings, the volume of the wound was measured, instead of the surface area, to determine the reduction in wound size due to newly-formed granulation tissue and wound contracture. There were no significant differences in mean time to reach 50% of the initial wound volume and in the mean wound volume after 42 days were observed (Wanner 2003). No significant difference in the mean reduction in ulcer volume was detected either for ulcers treated with VAC or HP (Ford 2002).

Analysis of soft-tissue biopsies showed a decrease in polymorphonuclear (PMN) granulocytes and lymphocytes in ulcers treated with VAC and an increase in the same leukocytes for wounds treated with HP (Ford 2002). An increase in number of capillaries was also noted for ulcers treated with both VAC and HP, but the magnitude of the increase was greater for VAC (Ford 2002).

Greer and colleagues (Greer 1999) also published a preliminary analysis of their RCT. However, only results from the pressure ulcers treated with sub-atmospheric pressure dressing were given with no comparison to the control (saline wet-to-moist gauze dressings). With VAC, the average ulcer area decreased by 42% over an average of 20 days.

Case Series

Satisfactory wound healing was reported in 26 of 30 (87%) patients with pressure sores who underwent VAC treatment, six by secondary healing, 11 by cavity obliteration, one by direct wound closure and eight by split skin graft (Deva 2000). The remaining four failed due to patient compliance issues.

Diabetic Foot Ulcers and Wounds**RCT**

In a single RCT comparing VAC with saline-moistened gauze (control) for management of foot ulcers by McCallon and colleagues (McCallon 2000). A 28.4% decrease in the surface area of the foot ulcer was observed for VAC patients compared with a 9.5% increase in control group patients ($p=0.004$). Foot ulcers healed more quickly in patients managed with VAC than those in the control group (22.8 days versus 42.8 days), although this difference was not statistically different.

Case Series

Healing at the level of debridement without the need for further bony resection was reported in 90.3% of diabetic foot wounds managed with VAC in a mean of 8.1 weeks (Armstrong 2002).

Skin Grafts**RCTs**

VAC significantly increased the rate of reepithelialisation in skin grafts compared with Opsite dressing ($p\leq 0.013$) (Genecov 1998). Seven of the ten donor sites treated with VAC were noted to reepithelialise faster than the Opsite-treated donor sites. Two patients reported no difference in the rate of reepithelialisation of the donor sites, and one reported more rapid reepithelialisation for the Opsite-treated site.

Preliminary results from a current RCT by Heath and colleagues (Heath 2002) suggest VAC to be as effective as standard pressure dressings for skin grafts.

Non-Randomised Comparative

Significantly fewer patients treated with VAC required repeat split thickness skin grafts (STSG) to the same site compared with grafts managed with bolster dressings (3% versus 19%, $p=0.04$) (Scherer 2002). However, the bolster managed grafts were applied to larger wounds than the wounds managed with VAC. There were no significant differences between the treatment arms for graft take, total length of stay and post-STSG length of stay.

Case Series

Graft take was 100% at five days in all 15 patients with large donor site defects of the radial forearm treated with VAC (Avery 2000). Mean graft take in VAC patients with degloving injuries was 92.3% per graft and 94.6% per patient, with a mean treatment duration of 6.1 days (Meara 1999).

Chronic Wounds and Complex/Severe Wounds**RCTs**

After six weeks, various chronic wounds treated with VAC had a significantly greater percent reduction in wound volume and depth than wounds treated with WM gauze ($p=0.038$ and $p=0.00001$, respectively) (Joseph 2000). A majority of these wounds were caused by pressure.

For patients with postoperative ventral hernia wounds, treatment with VAC lasted for an average of 9.5 days, which was significantly less than patients treated with conventional dressings (11.04 days, $p<0.00001$) (Davydov 1994). The time to suture removal was also less for VAC patients but this was not significantly different to control group patients.

Case Series

All complex paediatric wounds healed with VAC therapy, 15 by wound closure and coverage with STSG, five by delayed primary technique, four by secondary intention, two with pedicled flaps and one with a cross extremity flap (Mooney 2000). All patients tolerated VAC treatment.

At six weeks, 54 ankle injuries healed (61% by secondary suture and 39% by skin transplantation) and 38 foot injuries healed (42% by secondary suture, 45% by skin transplantation and 13% by spontaneous epithelialisation) with VAC (Lang 1997). Treatment for ankle injuries lasted for a mean of 11.2 days and a mean of 12.1 days for foot injuries.

Sternal Wounds**Non-Randomised Comparative**

For sternal wounds, the mean number of dressing changes was significantly less for VAC patients than patients with traditional dressings ($p<0.05$), as was the number of flaps required to close the wound ($p<0.05$) (Song 2003). Patients in the VAC group only used one type of flap for reconstruction, whereas control patients required a combination of types of flaps for definitive closure (Song 2003). No significant differences were seen in the number of patients who underwent definitive closure or days between initial debridement and definitive closure.

Treatment duration was significantly shorter for post-sternotomy osteomyelitis (SOM) patients managed with VAC compared with patients managed conventionally (17.2 days versus 22.9 days, $p=0.009$), thus resulting in a shorter length of hospital stay (mean 27.2 days versus 33.0 days, $p=0.03$) (Doss 2002). A shorter length of hospital stay was also observed in post-sternotomy mediastinitis (PSM) patients, 27 days for VAC and 50 days for those managed with closed drainage and irrigation (CDI) ($p=0.04$) (Catarino 2000). There was no significant difference in the duration of treatment for the same set of patients though (11 days for VAC versus 13 days for CDI) (Catarino 2000).

The formation of granulation tissue and therefore the reduction in wound size appears to be greater for SOM patients managed with VAC (4.63 cm²/day reduction) than those managed with conventional treatment (3.2 cm²/day reduction). However, this difference was not significant (Doss 2002).

Case Series

VAC treatment of deep sternal wounds lasted for a median nine days with a median hospital stay of 22 days (Gustafsson 2002).

Complications

Pressure Sores and Ulcers

RCTs

One complication was reported where a VAC patient with a lateral malleolar (ankle joint on the outer side) ulcer developed sepsis and required amputation (Ford 2002). No complications were reported for the control group.

Diabetic Foot Ulcers and Wounds

RCT

Some VAC patients reported pain with initial foam collapse and/or with foam dressing removal, but both were brief in duration (<30 seconds) and no pain was reported with subsequent VAC therapy (McCallon 2000). There was some minor bleeding with dressing removal.

Case Series

The 3/31 (9.7%) wounds that failed to heal with VAC required higher level amputation^a (one below knee amputation and two transmetatarsal

^a Amputation a second time at a higher level.

amputations).(Armstrong 2002) Other complications included periwound maceration (19.4%), periwound cellulitis (3.2%) and deep space infection (3.2%).

Skin Grafts

RCTs

There were no differences in pain associated with either treatment (VAC or Opsite dressing) and no infections reported (Genecov 1998). No significant complications were reported in either the non-randomised comparative (Scherer 2002) or the case series (Avery 2000) study, although some patients experienced minor discomfort at the wound site due to large wounds or suction pressures over 100 mmHg (Avery 2000). Two additional patients experienced graft failure and were excluded from the analysis (Scherer 2002).

Chronic Wounds and Complex/Severe Wounds

RCTs

Two of three complications reported for VAC treated wounds were unrelated to VAC therapy and were a result of patients ambulating on the wounds against medical advice (Joseph 2000). The other reported VAC complication was osteomyelitis. Patients treated with WM gauze dressings reported two fistulas (11%), six wound infections (33%) and two had osteomyelitis (11%) (Joseph 2000). No complications were reported in either treatment arm for patients with postoperative ventral hernia wounds (Davydov 1994).

Case Series

Two patients with ankle injuries and three patients with foot injuries experienced infection (Lang 1997). Five patients with foot injuries had small skin defects but this resolved with spontaneous epithelialisation after 24 days (Lang 1997). Three patients required amputation at the first reconstruction trial and one polytraumatised patient died of causes unrelated to VAC.

Sternal Wounds

Non-Randomised Comparative

Of the patients managed with VAC, one had a chronically draining wound (Song 2003) and one developed mediastinitis in a previously sterile wound (Song 2003). Some patients with SOM managed with VAC reported pain with the initial application of sub-atmospheric pressure, but none of the patients had late fistulas or sinus formation (Doss 2002). No recurrent wound infections and re-interventions were reported in PSM patients managed with VAC (Catarino 2000).

Complications in the control groups include: one chronically draining wound (Song 2003), one recurrent mediastinitis (Song 2003), two omental flap losses (Song 2003), one intestinal evisceration (Song 2003), one hernia (Song 2003), eight required closed chest irrigation drainage (Doss 2002) and three underwent secondary pectoralis major muscle advancement flap procedures (Doss 2002).

Four deaths were reported in patients treated with VAC; three were unrelated to therapy (Song 2003) and one was of unknown cause (Doss 2002). Three deaths occurred in the control groups, two were unrelated to treatment (Catarino 2000, Song 2003) and one was of unknown cause (Doss 2002).

Case Series

Two patients required further surgical intervention due to fistulas after rewiring of the sternotomy. However, both recovered and their wounds healed (Gustafsson 2002). None of the patients with deep sternal wounds experienced haemodynamic instability, bleeding tendency, arrhythmia or chest pain (Gustafsson 2002). Some air leakage was noticed but this was resolved with additional adhesive drape (Gustafsson 2002).

4. Discussion

Although most studies were probably too small to detect significant differences, some did show VAC to result in better healing than standard methods, with few serious complications. VAC appears to be a promising alternative for management of wounds.

VAC therapy appeared to be more effective than Opsite and bolster dressings in skin graft management. VAC was also more effective at treating various chronic and complex wounds than WM gauze, with a significantly greater reduction in wound volume, depth and treatment duration for VAC. Foot ulcers managed with VAC significantly decreased in surface area compared with those managed with saline-moistened gauze; however, this is relying on data from a small pilot study. For management of pressure sores and ulcers, no difference could be detected between VAC and use of traditional gauze dressings or the HP system. To appropriately assess the efficacy of VAC therapy on different wound types, RCTs with larger sample size and adequate randomisation method are required for each wound type.

The treatment of sternal wounds suggests that VAC may be more cost-effective than traditional dressings or CDI, as VAC required a reduced number of dressing changes and number of flaps to close the wound, and a shorter treatment duration and length of hospital stay. This has the potential to reduce health care costs, for both hospital and patient, and enhance patient satisfaction and quality of life.

A list of possible complications have been outlined by the manufacturer (Vacuum therapy in wound management 2001):

- Pain and discomfort when suction is applied initially (this usually resolves as therapy continues).
- Bleeding.
- Allergies to the adhesive drape.
- Excoriation (chafing) of the skin if foam is not correctly cut to size.
- Fulminant or incipient skin necrosis.

Although the studies included in this review did not report many of these types of complications, patients should be monitored to prevent discomfort.

Several potential biases have been recognised in the included studies that may have affected the results reported. Due to lack of a gold standard in measuring wound size, various techniques, such as photographs, alginate casts and plaster moulds, have been used, and the validity of these measurements are unknown. In some of the RCTs the method of treatment allocation and whether the patients and assessors were blinded were unclear. It is also important to note that four of the six RCTs

included in this review were partially funded by KCI, the manufacturer of the VAC® device.

Advantages of VAC therapy include:

- Reduced frequency of dressing changes, thus reducing nursing time for wound care and increasing patient comfort (Wanner 2003).
- Reduced hospital length of stay (Catarino 2000, Doss 2002).
- Availability of portable VAC® devices.
- Reduced bacterial cell count (Deva 2000).
- Enhanced dermal perfusion (blood flow to the wound).
- Removal of interstitial fluid to allow tissue decompression.
- Provision of a closed, moist wound healing environment.

The initial application of negative pressure to the wound can cause pain, but this usually resolves by either starting at a lower pressure and then increasing to the target pressure, or with continued therapy. Another disadvantage of VAC therapy is that patients who are not eligible to use the portable VAC® device (e.g. those with acute and traumatic wounds or chronic open wounds) have restricted mobility, as they need to be attached to the mains powered VAC for 22 hours each day. An issue of concern for sternal wounds is the possible adherence of the epicardium, cardiovascular bypass grafts and great vessels to the foam placed within the wound. To prevent this adherence, the VAC technique has been modified to include use of a silicone sheet. This sheet is placed between the epicardium and foam (held in place by attachment to foam with sutures) (Harlan 2002). Treatment failure appears to be rare with failures usually due to lack of patient compliance (Deva 2000).

It is imperative that patients and/or their carers are taught to manage the system independently to ensure maximum effectiveness and safety. Although VAC is simple to apply, inappropriate and incorrect use will result in a non-healing wound and pain and discomfort to the patient. Information has been provided by the manufacturer to help patients and their carers achieve optimum benefit from VAC therapy (KCI Medical Australia 2003). For example, active negative pressure therapy should be maintained for 22 to 24 hours per day and if therapy is turned off for longer than two hours, the dressing must be removed and replaced with a traditional dressing. It is also recommended that patients receive regular clinical evaluations to monitor progress and a nutritional evaluation to ensure adequate nutritional status.

Cost Considerations

Daily rental of the pump ranges from \$58 AUD for the mini-VAC® to \$65 AUD for the Advanced Therapy System (KCI Medical Australia, SA: personal communication,

2003). The dressing (foam, drape and tubing) are purchased separately. To date, no studies on the cost-effectiveness of VAC in Australia have been published.

There are few studies available on the cost-effectiveness of VAC therapy. Garner *et al.* (Garner *et al.* 2001) looked at the cost to treat open abdomen wounds with VAC. In 2001, daily rental of the vacuum pump was \$101 USD and the dressing (foam, drape and tubing) \$69 USD. As fascial closure was achieved in ten days, the average total cost per patient was \$1286 USD (includes three dressing changes). They found that the cost of these dressing changes were comparable to that of other methods (Garner *et al.* 2001).

Philbeck and colleagues (Philbeck Jr *et al.* 1999) compared the cost-effectiveness of negative pressure wound therapy (NPWT) and saline-soaked gauze. They reported that a 22.2 cm² pressure ulcer located on the trunk and trochanter would take approximately 97 days to completely heal with a wound closure rate of 0.23 cm² per day^a. In order to make a comparison, they referred to a study by Ferrell *et al.* (Ferrell *et al.* 1993) to obtain a wound closure rate for wound healing using saline-soaked gauze. With a wound closure rate of 0.09 cm², it was calculated that it would take 247 days to completely heal a 22.2 cm² the same wound (compared with 97 days for NPWT). Cost analyses indicated NPWT to be more cost-effective with total treatment costs amounting to \$14 546 USD compared with \$23 465 USD for saline-soaked gauze. Furthermore, wounds treated with NPWT healed 61% faster than wounds treated with saline-soaked gauze. Even though the cost of materials for NPWT was more expensive, the reduction in days required for complete wound healing reduced the overall cost of treatment by 38% (Philbeck Jr *et al.* 1999). Major limitations of this study affect the validity of the results reported. The effect of the use of another study as the control group on the validity is unclear, as patient groups and methods may differ between studies (eg. the management of patients). This study was also funded by KCI, the manufacturer of the VAC® device. Further investigation of the cost-effectiveness of VAC therapy compared with conventional methods of wound management are required.

^a Days to heal = 22.2cm² (pressure ulcer size) / wound closure rate

5. Conclusions

There is a paucity of high quality RCTs on VAC therapy for wound management with sufficient sample size and adequate power to detect differences, if there are any, between VAC and standard dressings. More rigorous studies with larger sample sizes assessing the use and cost-effectiveness of VAC therapy on different wound types are required, as the available evidence is of poor quality. However, based on the data from the small studies available, VAC does appear to result in better healing, with few serious complications, and thus looks to be a promising alternative for the management of various wounds. The cost of VAC will vary and depend on the length of hospital stay, cost of supplies and if specialised home care with a skilled nurse is required. The application of VAC is simple, but requires training to ensure appropriate and competent use.

References

- Vacuum therapy in wound management. Vacuum Therapy. Last updated 2001. <http://www.vacuumtherapy.co.uk/woundcare.htm> Accessed June 2003.
- Argenta PA, Rahaman J, Gretz HF, III, Nezhat F, Cohen CJ. Vacuum-assisted closure in the treatment of complex gynecologic wound failures. *Obstetrics & Gynecology*. 2002;**99**(3):497-501.
- Armstrong DG, Lavery LA, Abu-Rumman P, Espensen EH, Vazquez JR, Nixon BP, Boulton AJ. Outcomes of subatmospheric pressure dressing therapy on wounds of the diabetic foot. *Ostomy/Wound Management*. 2002;**48**(4):64-68.
- Avery C, Pereira J, Moody A, Gargiulo M, Whitworth I. Negative pressure wound dressing of the radial forearm donor site. *International Journal of Oral & Maxillofacial Surgery*. 2000;**29**(3):198-200.
- Banwell PE. Topical negative pressure therapy in wound care. *Journal of Wound Care*. 1999;**8**(2):79-84.
- Bowler PG. Wound pathophysiology, infection and therapeutic options. *Annals of Medicine*. 2002;**34**(6):419-427.
- Catarino PA, Chamberlain MH, Wright NC, Black E, Campbell K, Robson D, Pillai RG. High-pressure suction drainage via a polyurethane foam in the management of poststernotomy mediastinitis. *Annals of Thoracic Surgery*. 2000;**70**(6):1891-1895.
- Collier M. Topical negative pressure therapy. *Nursing Times*. 2003;**99**(5):54-55.
- Davydov YA, Abramov AY, Darichev AB. Regulation of wound process by the method of vacuum therapy in middle-aged and aged patients. *Khirurgiia (Mosk)*. 1994;**9**:7-10.
- Deva AK, Buckland GH, Fisher E, Liew SCC, Merten S, McGlynn M, Gianoutsos MP, Baldwin MAR, Lendvay PG. Topical negative pressure in wound management. *MJA*. 2000;**173**:128-131.
- Doss M, Martens S, Wood JP, Wolff JD, Baier C, Moritz A. Vacuum-assisted suction drainage versus conventional treatment in the management of poststernotomy osteomyelitis. *European Journal of Cardio-Thoracic Surgery*. 2002;**22**(6):934-938.
- Fabian TS, Kaufman HJ, Lett ED, Thomas JB, Rawl DK, Lewis PL, Summitt JB, Merryman JI, Schaeffer TD, Sargent LA, Burns RP. The evaluation of subatmospheric pressure and hyperbaric oxygen in ischemic full-thickness wound healing. *American Surgeon*. 2000;**66**(12):1136-1143.

- Ferrell BA, Osterweil D, Christenson P. A randomised trial of low-air-loss beds for treatment of pressure ulcers. *JAMA*. 1993;**269**(4):494-497.
- Flicker L. Tissue healing in older people - focus on sensory nerves. National Ageing Research Institute. Last updated October 1996.
<http://www.mednwh.unimelb.edu.au/aginwell/index.htm#wound.htm~info>
Accessed June 2003.
- Ford CN, Reinhard ER, Yeh D, Syrek D, De Las Morenas A, Bergman SB, Williams S, Hamori CA. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers. *Annals of Plastic Surgery*. 2002;**49**(1):55-61.
- Garner GB, Ware DN, Cocanour CS, Duke JH, McKinley BA, Kozar RA, Moore FA, Albrecht R, Feliciano DV, Biffi W, Parks S, Stewart R, Saffle J, Asensio J, Wyland D. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. *American Journal of Surgery*. 2001;**182**(6):630-638.
- Genecov DG, Schneider AM, Morykwas MJ, Parker D, White WL, Argenta LC. A controlled subatmospheric pressure dressing increases the rate of skin graft donor site reepithelialization. *Annals of Plastic Surgery*. 1998;**40**(3):219-225.
- Greer SE, Longaker MT, Margiotta M. Preliminary results from a multicentre randomised controlled study of the use of subatmospheric pressure dressing for pressure ulcer healing. *Wound Repair and Regeneration*. 1999;**7**(4):A255.
- Gustafsson R, Johnsson P, Algotsson L, Blomquist S, Ingemansson R. Vacuum-assisted closure therapy guided by C-reactive protein level in patients with deep sternal wound infection. *Journal of Thoracic & Cardiovascular Surgery*. 2002;**123**(5):895-900.
- Harlan JW. Treatment of open sternal wounds with the vacuum-assisted closure system: a safe, reliable method. *Plastic & Reconstructive Surgery*. 2002;**109**(2):710-712.
- Heath T, Moisisidis E, Deva A. A prospective controlled trial of vacuum assisted closure (VAC) in the treatment of acute surgical wounds requiring split skin grafting. *Fourth Australian Wound Management Association Conference* 2002.
- Hopf HW, Humphrey LM, Puzifferri N, West JM, Attinger CE, Hunt TK. Adjuncts to preparing wounds for closure: hyperbaric oxygen, growth factors, skin substitutes, negative pressure wound therapy (vacuum-assisted closure). *Foot & Ankle Clinics*. 2001;**6**(4):661-682.
- Joseph E, Hamori CA, Bergman S, Roaf E, Swann NF, Anastasi GW. A prospective randomized trial of vacuum-assisted closure versus standard therapy of chronic nonhealing wounds. *Wounds*. 2000;**12**(3):60-67.

- KCI Concepts I. VAC: An advanced therapy system for wound healing. TX: KCI USA, Inc., 2002.
- KCI Medical Australia. V.A.C. Therapy Clinical Guidelines. KCI USA, Inc., 2003.
- Kranke P, Bennett M, Roeckl-Wiedmann I, Debus S. Hyperbaric oxygen for chronic wounds. *The Cochrane Library*, Issue 2, 2003. Oxford: Update Software.
- Lang E, Bauer G, Becker U, Bischoff M. The vacuum sealing technique in the treatment of foot and ankle trauma with severe soft-tissue damage. *Aktuelle Traumatologie*. 1997;**27**(5):223-227.
- MacLellan DG. Chronic Wound Management. *Australian Prescriber*. 2000;**23**(1):6-9.
- McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. *Ostomy/Wound Management*. 2000;**46**(8):28-32.
- Meara JG, Guo L, Smith JD, Pribaz JJ, Breuing KH, Orgill DP. Vacuum-assisted closure in the treatment of degloving injuries. *Annals of Plastic Surgery*. 1999;**42**(6):589-594.
- Mendez-Eastman S. Guidelines for using negative pressure wound therapy. *Advances in Skin & Wound Care*. 2001;**14**(6):314-325.
- Mooney JF, III, Argenta LC, Marks MW, Morykwas MJ, DeFranzo AJ. Treatment of soft tissue defects in pediatric patients using the V.A.C. system. *Clinical Orthopaedics & Related Research*. 2000;**376**:26-31.
- Patel CT, Kinsey GC, KoperskiMoen KJ, Bungum LD. Vacuum-assisted wound closure. *AJN, American Journal of Nursing*. 2000;**100**(12):45-48.
- Philbeck Jr TE, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare medicare patients. *Ostomy/Wound Management*. 1999;**45**(11):41-50.
- Rauchberger L. Alfred/Medseed Wound Imaging System. Powerpoint Presentation. Last updated July 2002.
http://www.medseed.com/download/amwis_demo.ppt Accessed June 2003.
- Rosser CJ, Morykwas MJ, Argenta LC, Bare RL. A new technique to manage perineal wounds. *Infections in Urology*. 2000;**13**(2):45-55.
- Scherer LA, Shiver S, Chang M, Meredith JW, Owings JT. The vacuum assisted closure device: a method of securing skin grafts and improving graft survival. *Archives of Surgery*. 2002;**137**(8):930-933.

Song DH, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M. Vacuum assisted closure for the treatment of sternal wounds: the bridge between debridement and definitive closure. *Plastic & Reconstructive Surgery*. 2003;**111**(1):92-97.

Thomas S. An introduction to the use of vacuum assisted closure. World Wide Wounds. Last updated May 2001.
<http://www.worldwidewounds.com/2001/may/Thomas/Vacuum-Assisted-Closure.html> Accessed June 2003.

Wanner MB, Schwarzl F, Strub B, Zaech GA, Pierer G. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. *Scandinavian Journal of Plastic & Reconstructive Surgery Hand Surgery*. 2003;**37**(1):28-33.

ANNEX: Studies that met the inclusion criteria but were not tabulated.

Evans D and Land L. Topical negative pressure for treating chronic wounds (Cochrane Review). In: *The Cochrane Library*, Issue 2, 2003. Oxford: Update Software.

Reason for not tabulating: overlapping of RCT data included in this review.

Fisher A and Brady B. Vacuum assisted wound closure therapy. *Issues in Emerging Health Technologies* 2003; **44**: 1-6.

Reason for not tabulating: overlapping of RCT data included in this review.

Appendix A

Tables of Key Efficacy and Safety Findings

Abbreviations used in tables:

CDI	closed drainage and irrigation
95% CI	95% confidence interval
DM	diabetes mellitus
ESRD	end stage renal disease
HP	healthpoint system
MD	mean difference
MRI	magnetic resonance imaging
MSOF	multiple systems organ failure
OR	odds ratio
PMNs	polymorphonuclear granulocytes
pns	p-value not significant
PSM	post-sternotomy mediastinitis
QOL	quality of life
SD	standard deviation
SOM	post-sternotomy osteomyelitis
SPD	sub-atmospheric pressure dressing
SSG	split skin grafting
STSG	split thickness skin grafts
TNP	topical negative pressure
Tx	treatment
VAC	Vacuum-Assisted Closure
WM	wet-to-moist gauze dressing

Appendix A: Key Efficacy and Safety Findings - Randomised Controlled Trials

Author, Date, Location, Number of Patients, Length of Follow-Up, Selection Criteria	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments																								
<p>Wanner 2003, SWITZERLAND</p> <p>January 1998 to May 1999.</p> <p>22 patients.</p> <p>Follow-up: 42 days.</p> <p><i>Comparison:</i></p> <p>VAC: 11 patients (mean age 49 years; range 25-73) treated with VAC (dressings were changed after 2-7 days); Gauze: 11 patients (mean age 53 years; range 34-77) treated with traditional wet-to-dry/wet-to-wet technique (gauze soaked in Ringer's solution; dressings were changed 3 times per day).</p> <p><i>Inclusion criteria:</i></p> <p>Consecutive paraplegic or tetraplegic patients with pressure sores in the pelvic region. Ulcers had to be deeper than grade 2, i.e. at least subcutaneous fat penetration.</p> <p><u>Mean [SD] (range) initial wound volume (ml):</u></p> <p>VAC: 50 [33] (3-132); Gauze: 42 [16] (5-68).</p> <p><i>Continued over...</i></p>	<p><u>Mean [SD] time to cover 50% of the initial volume (days):</u></p> <p>VAC: 27 [10]; Gauze: 28 [7].</p> <p>MD: -1 day, 95% CI -8.21 to 6.21 ($p=0.79$)</p> <p><u>Mean wound volume (%) after intervention (read from graph):</u></p> <table border="1"> <thead> <tr> <th>Days</th> <th>VAC</th> <th>Gauze</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>100</td> <td>100</td> </tr> <tr> <td>7</td> <td>114</td> <td>110</td> </tr> <tr> <td>14</td> <td>72</td> <td>90</td> </tr> <tr> <td>21</td> <td>65</td> <td>72</td> </tr> <tr> <td>28</td> <td>60</td> <td>60</td> </tr> <tr> <td>35</td> <td>50</td> <td>45</td> </tr> <tr> <td>42</td> <td>47</td> <td>35</td> </tr> </tbody> </table> <p>MD at 42 days: 12% larger, 95% CI -76 to 2476 ($p=0.07$)</p> <p>There was no significant difference between the two groups ($p=0.9$) for all time periods.</p>	Days	VAC	Gauze	0	100	100	7	114	110	14	72	90	21	65	72	28	60	60	35	50	45	42	47	35	<p>Not reported.</p>	<p><i>Potential for bias:</i></p> <p>Small sample size.</p> <p>Method of allocation not stated.</p> <p>Neither assessors nor patients were blinded.</p> <p>Losses to follow-up: 2.</p> <p><i>Outcome measures and their validity:</i></p> <p>The volume was calculated by covering the ulcer with a transparent, elastic polymer. The sheet was punctured at the highest point and 0.9% saline solution was injected through a second puncture with a hypodermic needle until no air was left in the cavity. The injected volume was measured. The validity of this measurement is not stated.</p> <p><i>Other comments:</i></p> <p>One person made all the measurements.</p> <p>A summarised preliminary analysis of costs in their hospital, including time needed for changing the dressings, indicates that VAC is cheaper than the traditional dressings, if it is kept longer than 2 days on the wound.</p> <p>It is important to note that the frequency of dressing changes is dependent on the wound area. Sensate</p>
Days	VAC	Gauze																									
0	100	100																									
7	114	110																									
14	72	90																									
21	65	72																									
28	60	60																									
35	50	45																									
42	47	35																									

MD: + 8ml, 95% CI -13.67 to 29.67
(p=0.47)

Exclusion criteria:

Pressure sore was not in the pelvic region,
and the depth of the pressure sore was less
than grade 3.

areas can be painful when changing
dressings and so are changed every 2-5
days instead of 3 times a day. This
would increase QOL and save time for
the nursing staff.
The investigators were unable to show
the equivalence of the groups.

Appendix A: Key Efficacy and Safety Findings - Randomised Controlled Trials

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments																																													
<p>Joseph 2000, USA</p> <p>January 1998 to May 1999.</p> <p>36 chronic, non-healing wounds in 24 patients.</p> <p>Follow-up: 6-week study period, but patients were followed up until complete wound closure for each patient.</p> <p><i>Comparison:</i></p> <p>VAC: 18 wounds (mean age 56 years) treated with VAC (dressings were changed every 48 hours);</p> <p>Gauze: 18 wounds (mean age 49 years) treated with WM gauze dressing (dressings were changed 3 times per day).</p> <p><i>Inclusion criteria:</i></p> <p>Patients identified with chronic, non-healing wounds, defined as an open wound in any anatomic location that had failed to close or show signs of healing within 4 weeks or greater.</p> <p><i>Exclusion criteria:</i></p> <p>Patients with infection (urinary tract, pneumonia, wound infection); albumin <3.0gm/dl; renal, pulmonary, or other chronic disease requiring ongoing therapy</p> <p><i>Continued over...</i></p>	<p><u>Final % change in wound volume over time:</u></p> <p>VAC: 78% reduction; Gauze: 30% reduction, p=0.038.</p> <p><u>Change in volume (% reduction of volume) over time (weeks):</u></p> <table border="1"> <thead> <tr> <th></th> <th>3 weeks</th> <th>6 weeks</th> </tr> </thead> <tbody> <tr> <td>VAC</td> <td>22%</td> <td>46%</td> </tr> <tr> <td>Gauze</td> <td>15%</td> <td>39%</td> </tr> </tbody> </table> <p>VAC had a significant positive impact in the overall change in volume of the wound at 6 weeks (p=0.038).</p> <p><u>Change in depth (% reduction of volume) over time (weeks):</u></p> <table border="1"> <thead> <tr> <th></th> <th>3 weeks</th> <th>6 weeks</th> </tr> </thead> <tbody> <tr> <td>VAC</td> <td>40%</td> <td>66%</td> </tr> <tr> <td>Gauze</td> <td>10%</td> <td>20%</td> </tr> </tbody> </table> <p>VAC was more effective for deep wounds, with a significant change in depth over time compared with WM at 6 weeks (p=0.00001).</p> <p><u>Change in width (% reduction of volume) over time (weeks):</u></p> <table border="1"> <thead> <tr> <th></th> <th>3 weeks</th> <th>6 weeks</th> </tr> </thead> <tbody> <tr> <td>VAC</td> <td>37%</td> <td>64%</td> </tr> <tr> <td>Gauze</td> <td>4%</td> <td>35%</td> </tr> </tbody> </table> <p>VAC was more effective in shrinking the widths of the wounds over time compared with WM (p=0.02).</p>		3 weeks	6 weeks	VAC	22%	46%	Gauze	15%	39%		3 weeks	6 weeks	VAC	40%	66%	Gauze	10%	20%		3 weeks	6 weeks	VAC	37%	64%	Gauze	4%	35%	<p>VAC Gauze</p> <p><u>Complications</u></p> <table border="1"> <thead> <tr> <th></th> <th>No (%)</th> <th>No (%)</th> </tr> </thead> <tbody> <tr> <td>Fistulas</td> <td>0 (0)</td> <td>2 (11)</td> </tr> <tr> <td>Wound infection</td> <td>0 (0)</td> <td>6 (33)</td> </tr> <tr> <td>Osteomyelitis</td> <td>1 (5)</td> <td>2 (11)</td> </tr> <tr> <td>Calcaneal fractures*</td> <td>2 (11)</td> <td>0 (0)</td> </tr> <tr> <td>Totals</td> <td>3 (17)</td> <td>10 (55)</td> </tr> </tbody> </table> <p>*In the case of VAC treatment, the calcaneal fractures were not related to the therapy, since the patients ambulated on the wounds against medical advice.</p>		No (%)	No (%)	Fistulas	0 (0)	2 (11)	Wound infection	0 (0)	6 (33)	Osteomyelitis	1 (5)	2 (11)	Calcaneal fractures*	2 (11)	0 (0)	Totals	3 (17)	10 (55)	<p><i>Potential for bias:</i></p> <p>Treatment allocation was by pulling out files marked with silver (VAC) or black (WM) labels on the inside panel randomly organised in a locked cabinet. It is not clear whether this resulted in adequate allocation concealment. Unit of randomisation was wound, not patient. 12 patients had multiple wounds, 3 of which were randomised to both therapies. Evaluators were blinded to which treatment group the patient had been assigned and all wounds were evaluated by a blinded pathologist.</p> <p><i>Outcome measures and their validity:</i></p> <p>Wounds were photographed and measured by volume displacement of alginate impression molds. The validity of this measurement is not stated.</p> <p><i>Other comments:</i></p> <p>Independent wound evaluators were recruited from the nursing staff, medical students, and residents from the hospital, who were not involved in the daily care of the study patients. Causes of wounds: 28/36 (78%) due to pressure; 3/36 (8%) due to dehiscence; 2/36 (5.5%) due to trauma;</p>
	3 weeks	6 weeks																																														
VAC	22%	46%																																														
Gauze	15%	39%																																														
	3 weeks	6 weeks																																														
VAC	40%	66%																																														
Gauze	10%	20%																																														
	3 weeks	6 weeks																																														
VAC	37%	64%																																														
Gauze	4%	35%																																														
	No (%)	No (%)																																														
Fistulas	0 (0)	2 (11)																																														
Wound infection	0 (0)	6 (33)																																														
Osteomyelitis	1 (5)	2 (11)																																														
Calcaneal fractures*	2 (11)	0 (0)																																														
Totals	3 (17)	10 (55)																																														

ASERNIP-5 ACCELERATED REVIEW OF VACUUM ASSISTED WOUND CLOSURE - NOV 2003

for stabilisation, uncontrolled diabetes mellitus, thyroid disease, or hypertension; systemic steroids, other immunosuppressive therapy or anticoagulants; pregnant or breastfeeding; osteomyelitis as determined by bone biopsy; malignant or neoplastic diseases in wound margin; fistulas (rectal, stomal, or urethral fistulas to the wound). Patients whom the investigators consider uncooperative or unsuitable candidates for participation in dressing changes.	There was no significant difference in the change in length over time.	2/36 (5.5%) due to venous insufficiency; 1/36 (3%) due to radiation.
--	--	---

Appendix A: Key Efficacy and Safety Findings - Randomised Controlled Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>McCallon 2000, USA</p> <p>10 patients. Follow-up: ~43 days.</p> <p><i>Comparison:</i> VAC: 5 patients (mean age 55.4 [12.8] years) treated with VAC (dressings were changed every 48 hours); Gauze: 5 patients (mean age 50.2 [8.7] years) treated with saline-moistened gauze (dressings were changed twice a day).</p> <p><i>Inclusion criteria:</i> Diabetic patients 18 to 75 years of age with a non-healing foot ulceration which had been present for longer than one month.</p> <p><i>Exclusion criteria:</i> Patients presenting with venous disease, with active infections not resolved by initial debridement, and patients with coagulopathy.</p>	<p><u>Days to achieve satisfactory healing:</u> VAC: 22.8 [17.4] Gauze: 42.8 [32.5] MD: -20.0 days, 95% CI -52.31 to 12.31 (p=0.23)</p> <p><u>Average percent change in surface area:</u> VAC: 28.4% [24.3] decrease Gauze: 9.5% [16.9] increase MD: -37.9%, 95% CI -63.84 to -11.96 (p=0.004)</p> <p><u>Definitive closure by delayed primary intention (suture closure, skin graft, or muscle flap):</u> VAC: 4/5 (80%) Gauze: 2/5 (40%) OR: 6, 95% CI 0.35 to 101.57 (p=0.21)</p> <p><u>Wound healed by secondary intention:</u> VAC: 1/5 (20%) Gauze: 3/5 (60%) OR: 0.17, 95% CI 0.01 to 2.82 (p=0.21) These patients were deemed poor candidates for delayed primary closure due to their inability to satisfy the surgeon's criteria:</p> <ol style="list-style-type: none"> 1. The presence of granulation tissue with a beefy red appearance, or 2. A wound bed with little or no areas of necrotic/devitalised tissue. 	<p><u>Complications:</u> Pain was reported by some VAC patients with initial foam collapse and/or with foam dressing removal. Both of these events were brief in duration (<30 seconds) and no pain was reported with subsequent VAC therapy. Frequently, granulation tissue growth into the pores of the foam would result in minor capillary disruption with VAC foam dressing removal. All bleeding was stopped with direct pressure without the need for other measures.</p>	<p><i>Potential for bias:</i> Treatment was allocated by coin flipping initially, thereafter by alternating groups. It is not stated whether assessors and/or patients were blinded. This was a pilot study of small sample size.</p> <p><i>Outcome measures and their validity:</i> The size of the wound was determined by tracing the border of the wound onto a piece of clear acetate film using a fine-tipped marker. The tracings were later used to obtain surface area measurements. Photography was also used extensively to assess the progress of the wound. The validity of these measurements are not stated.</p> <p><i>Other comments:</i> All patients were kept on bedrest or strict non-weight bearing status for the affected lower extremity to prevent wound healing complications due to excessive pressure with ambulation. Satisfactory healing was defined as definitive closure of the wound by one of two methods:</p> <ol style="list-style-type: none"> 1. Delayed primary intention – split-thickness skin graft, myocutaneous flap, or suture closure by surgeon. 2. Secondary intention – granulation tissue formation and epithelialisation.

Appendix A: Key Efficacy and Safety Findings - Randomised Controlled Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Genecov 1998, USA</p> <p>10 patients – age range 39-81 years (15 were enrolled but 5 did not complete the study).</p> <p>Follow-up: 7 days.</p> <p><i>Comparison:</i></p> <p>For each patient, grafts were harvested with a dermatome from both thighs, except for 2 patients where the donor sites were located on the same thigh with an area of intact skin between the sites. Donor sites on one thigh (or half the sites for the 2 patients with donor sites on the same thigh) were covered with Opsite. The other thigh was covered with VAC dressings and a vacuum pressure of 125mmHg was applied.</p> <p><i>Selection criteria:</i></p> <p>Patients who required coverage of denuded surfaces with split-thickness skin grafts. Wounds were of sufficient size (32-380 cm²) to require more than one donor site.</p>	<p>7/10 (70%) of the VAC-treated donor sites were noted to reepithelialize faster than the Opsite-treated control sites by day 7.</p> <p>2/10 (20%) showed no difference in the rate of reepithelialisation of the donor sites by day 7.</p> <p>1/10 (10%) patient showed more rapid reepithelialisation for the Opsite-treated site.</p> <p>VAC significantly increased the rate of reepithelialisation compared with Opsite dressing (p≤0.013).</p>	<p>None of the patients who completed the study noted any difference in pain associated with either treatment.</p> <p>2/10 patients who had their Opsite dressings replaced with Xeroform both reported that the Opsite-treated site was more painful.</p> <p>No infections were noted for any of the donor sites treated in the study.</p>	<p><i>Potential for bias:</i></p> <p>Method of allocation not stated. Patients were not blinded.</p> <p>5 patients did not complete the study:</p> <p>1 patient refused to allow biopsies to be harvested and withdrew;</p> <p>1 patient left the hospital against medical advice;</p> <p>1 patient's pump was accidentally disconnected for more than 8 hours;</p> <p>2 patients with large control sites had leakage of fluid from under the dressing, which prompted the nursing staff to remove the Opsite and cover the sites with petroleum-impregnated gauze.</p> <p><i>Outcome measures and their validity:</i></p> <p>6mm-diameter biopsies were harvested prior to dressing application and on days 4 and 7 to determine the degree of reepithelialisation and maturation of the epidermis on a scale of 0-4 (no evidence of reepithelialisation to complete, mature-appearing epithelium). Patients were also asked which site, if either, was more painful and the answer was recorded.</p>

Appendix A: Key Efficacy and Safety Findings - Randomised Controlled Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Davydov 1994, RUSSIA</p> <p>79 patients. Follow-up: 48 hours.</p> <p><i>Comparison:</i> VAC: 26 patients treated with VAC; Control: 53 patients treated with conventional dressings.</p> <p><i>Selection criteria:</i> Elective surgery patients, postoperative ventral hernia repair.</p>	<p><u>Time to suture removal:</u> VAC: 8.52 [23] days; Control: 8.64 [0.20] days. MD: -0.12 days, 95% CI -8.96 to 8.72 ($p=0.98$)</p> <p><u>Duration of treatment:</u> VAC: 9.5 [0.40] days; Control: 11.04 [0.47] days. MD: -1.54 days, 95% CI -1.74 to -1.34 ($p<0.00001$)</p>	<p>Not reported.</p>	<p><i>Potential for bias:</i> Method of allocation not stated. Blinding status of assessors and patients was not stated.</p> <p><i>Outcome measures and their validity:</i> Outcome measures of unknown validity.</p>

Appendix A: Key Efficacy and Safety Findings - Randomised Controlled Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments																
<p>Ford 2002, USA</p> <p>41 full-thickness decubitus ulcers in 28 patients (age range 18 to 80 years) were enrolled. 22 patients with 35 wounds completed the trial.</p> <p>Follow-up: ranged from 3 to 10 months.</p> <p><i>Comparison:</i> VAC: 20 full-thickness ulcers (mean patient age 41.7 years) treated with VAC (dressings changed every Monday, Wednesday and Friday); HP: 15 full-thickness ulcers (mean patient age 54.4 years) treated with Healthpoint (HP)* system (dressings changed once or twice daily).</p> <p><i>Inclusion criteria:</i> Presence of stage III or IV ulcer for ≥ 4 weeks, albumin ≥ 2.0, age 21 to 20 years, and ulcer volume after debridement between 10 to 150ml.</p> <p><i>Exclusion criteria:</i> Fistulas to organs or body cavities, malignancy in the wound, pregnant or lactating female, Hashimoto thyroiditis, Graves disease, iodine allergy, systemic sepsis, electrical burn, radiation exposure,</p> <p><i>Continued over...</i></p>	<p><u>Number of ulcers that completely healed during the treatment period (8 to 10 weeks):</u> VAC: 2/20 (10%); HP: 2/15 (13%).</p> <p><u>Mean reduction in ulcer volume:</u> VAC: 51.8%; HP: 42.1%, p=0.46.</p> <p><u>Mean reductions in wound dimensions (cm):</u></p> <table border="1"> <thead> <tr> <th></th> <th>VAC</th> <th>HP</th> <th>P-value</th> </tr> </thead> <tbody> <tr> <td>Length</td> <td>36.9</td> <td>18.7</td> <td>0.10</td> </tr> <tr> <td>Width</td> <td>40.0</td> <td>19.0</td> <td>0.11</td> </tr> <tr> <td>Depth</td> <td>33.6</td> <td>31.0</td> <td>0.90</td> </tr> </tbody> </table> <p>3/15 (20%) wounds treated with HP showed improved osteomyelitis (two by bone biopsy and one by MRI). For VAC, there was no improvement in osteomyelitis by bone biopsy or by MRI.</p> <p>3 patients with 3 wounds completed one 6-week trial of treatment followed by a second 6-week trial of the opposing treatment. For this cohort: <u>Mean reduction in ulcer volume:</u> VAC: 57%; HP: 25%.</p>		VAC	HP	P-value	Length	36.9	18.7	0.10	Width	40.0	19.0	0.11	Depth	33.6	31.0	0.90	<p>1/20 (5%) diabetic, hypertensive and vascular insufficient patient in the VAC group with a lateral malleolar ulcer developed sepsis and required amputation.</p>	<p><i>Potential for bias:</i> Criteria only includes patients ages 21 to 80, however the text reports that patients enrolled were between 18 and 80 years. Randomisation of patients was based on a table of random letters, V or H, generated before the trial began. Blinded clinic staff, including nurses, medical students and interns, measures wounds and obtained plaster impressions. 3 patients were lost to follow-up, 1 patient was deemed noncompliant with treatment and was excluded, 1 patient died of coronary artery disease, and 1 patient died of respiratory arrest secondary to Guillain-Barré syndrome.</p> <p><i>Outcome measures and their validity:</i> 3-week evaluation included a photograph of the wound site, a plaster wound impression, and measurement of wound dimensions. 6-week evaluation was the same as at 3 weeks with the addition of a soft tissue biopsy. If a bone biopsy and MRI were performed pre-treatment, then these tests were repeated at 6 weeks.</p> <p><i>Other comments:</i> *With HP, iodisorb gel and iodoflex pads were used for wounds with substantial exudate and Panafil for those</p>
	VAC	HP	P-value																
Length	36.9	18.7	0.10																
Width	40.0	19.0	0.11																
Depth	33.6	31.0	0.90																

ASERNIP-5 ACCELERATED REVIEW OF VACUUM ASSISTED WOUND CLOSURE - NOV 2003

chemical exposure, cancer, connective tissue disease, chronic renal or pulmonary disease, uncontrolled diabetes, corticosteroids or immunosuppressive agents, cardiac pacemaker, ferromagnetic clamps, and recent placement of orthopaedic hardware.	<u>Mean changes in leukocytes per high-power field from soft-tissue biopsies over the course of 6 weeks:</u>			with clean, granulating ulcers. Accuzyme was not required as all wounds were surgically debrided.	
		<u>VAC</u>	<u>HP</u>		<u>P-value</u>
	PMNs	-37.0	22.7		0.13
	Lymphocytes	-6.2	45.0		0.41
Capillaries	-5.1	-7.6	0.75		

Appendix A: Key Efficacy and Safety Findings - RCTs in Progress - Preliminary Analysis

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Greer 1999, USA</p> <p>11 patients have been enrolled (160 patients will be enrolled).</p> <p><i>Comparison:</i> Sub-atmospheric pressure dressing (SPD): 8 patients treated with SPD at 125mmHg constant suction; Gauze: 3 patients treated with 0.9% normal saline WM.</p> <p><i>Inclusion criteria:</i> Stage 3 or 4 pressure ulcers in the sacrum, ischium, or trochanter >2cm² and <100cm².</p> <p><i>Exclusion criteria:</i> Inability to follow dressing care instructions, MSOF, ESRD, liver failure, malignancy, recent chemotherapy, immunocompromised, DM, steroids, and current smokers.</p>	<p><u>SPD patients:</u> Average ulcer area decreased by 42% over an average of 20 days; Ulcers decreased in bacterial count by as much as 10⁴; 1/8 (12.5%) ulcer has been successfully skin grafted.</p>	<p>No sterile ulcers became infected.</p>	<p><i>Potential for bias:</i> This is only a preliminary analysis. Method of allocation not stated.</p> <p><i>Outcome measures and their validity:</i> Quantitative bacterial cultures to determine the infection rate. Alginate casts, digital colour photographs, and maximum depth and wound area measurements to determine the healing rate and the percent of patients receiving successful STSG coverage. The validity of these measurements is not stated.</p> <p><i>Other comments:</i> Stratification groups have been formed to control for variables affecting wound healing, such as malnutrition (albumin, pre-albumin, total lymphocyte count), ulcer stage, and wound infection diagnosed by quantitative bacterial culture.</p>

Appendix A: Key Efficacy and Safety Findings - RCTs in Progress - Preliminary Analysis

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Heath 2002, AUSTRALIA</p> <p>Analysis of first 10 patients (30 patients will be enrolled). Follow-up: 2 weeks.</p> <p><i>Comparison:</i> Surgical wounds were divided into halves: proximal and distal. One half was treated with skin graft plus standard pressure dressings; the other half with skin graft plus VAC.</p> <p><i>Selection criteria:</i> Surgical wounds (all causes) judged clinically ready for skin grafting.</p>	<p>All wounds (both pressure and VAC) healed completely and none required repeat skin grafting.</p> <p>There was no significant difference between the treatment modalities in terms of percent epithelialisation at 2 weeks, but there were trends towards more complete epithelialisation and there was subjectively improved quality of engraftment following VAC therapy.</p>	<p>Not reported.</p>	<p><i>Potential for bias:</i> This is only a preliminary analysis. The plastic surgeon was blinded as to which half of the wound received VAC therapy. The half of the wound for VAC dressing was randomised. The method of randomisation was not stated.</p> <p><i>Outcome measures and their validity:</i> Assessments of percent epithelialisation were performed at weeks 2-4 by a plastic surgeon.</p> <p><i>Other comments:</i> Both dressings were left for the first 5 days. After this, both sides of the wound received the same (vaseline gauze) dressing.</p>

Appendix A: Key Efficacy and Safety Findings - Non-Randomised Comparative Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Scherer 2002, USA</p> <p>61 patients. Follow-up: up to 58 days.</p> <p><i>Comparison:</i> VAC: 34 patients (mean age 33 [23] years) had grafts managed with VAC (continuous -125mmHg suction); Control: 27 patients (mean age 41 [20] years) had grafts managed with bolster dressings.</p> <p><i>Selection criteria:</i> Consecutive patients at a level 1 trauma centre requiring split thickness skin graft (STSG) placements due to traumatic or therapeutic tissue loss during an 18-month period.</p> <p><i>Graft size (cm²):</i> VAC: 387 [573]; Control: 984 [996], p=0.006.</p>	<p><u>Graft take:</u> VAC: 33/34 (97%); Control: 22/27 (81.5%), pns.</p> <p><u>Total mean length of stay (days):</u> VAC: 27 [16]; Control: 32 [25], pns.</p> <p><u>Post-STSG length of stay (days):</u> VAC: 14 [10]; Control: 19 [15], pns.</p> <p><u>Number (%) of patients requiring repeated STSG to same site:</u> VAC: 1 (3); Control: 5 (19), p=0.04.</p>	<p>No dressing-related complications were identified in the VAC group.</p>	<p><i>Potential for bias:</i> This was a non-randomised, retrospective study. Observer bias with retrospective evaluation of the percentage of graft take. The control group had a larger mean graft size. The need for grafting may have been due to the type and location of the wound, e.g. 11 patients in the VAC group and 21 in the Control group had burns. 2 additional patients in the control group had graft failure, but both refused repeated skin grafts. These 2 patients were excluded from the repeated STSG analysis.</p> <p><i>Outcome measures and their validity:</i> Outcomes measures of unknown validity. Repeated skin grafting due to failure of the initial graft. Secondary outcomes included dressing-associated complications, percentage of graft take and length of hospital stay.</p> <p><i>Other comments:</i> Bolster dressings consisted of circumferential staples followed by a fine mesh gauze covering, then entire site covered with bulky cotton gauze dressing, wrapped with a cotton gauze bandage, and kept moist with 5% mafenide solution. Dressings in both groups were left for in place until the 4th postoperative day unless there were signs of wound infection.</p>

Appendix A: Key Efficacy and Safety Findings - Non-Randomised Comparative Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Song 2003, USA</p> <p>March 1999 to March 2001.</p> <p>35 patients.</p> <p>Follow-up: 8 days.</p> <p><i>Comparison:</i> VAC: 17 patients (mean age 63 years; 31-88) treated with VAC therapy alone; Control: 18 patients (mean age 63 years; range 23-77) treated with traditional twice-a-day dressing changes.</p> <p><i>Selection criteria:</i> Patients who had median sternotomy complications, and all sternal wounds involved the tissues superficial and deep to the sternum.</p>	<p><u>Patients who underwent definitive closure:</u> VAC: 14/17 (82%); Control: 17/18 (94%).</p> <p>1/17 (6%) VAC patient was allowed to close by secondary intention.</p> <p><u>Mean [SD] number of days between initial debridement and definitive closure:</u> VAC: 6 [5.4]; Control: 8 [12.3], pns.</p> <p><u>Mean [SD] number of dressing changes:</u> VAC: 3 [2.5]; Control: 17 [25.0], p<0.05.</p> <p><u>Mean [SD] number of flaps needed to close the wound:</u> VAC: 0.9 [0.3]; Control: 1.5 [0.4], p<0.05.</p> <p>8/17 (47%) Control patients needed more than 1 flap for definitive closure. Patients in the VAC group only used 1 type of flap for reconstruction (the pectoralis advancement flap). 13 flaps to close 14 wounds.</p>	<p>All deaths from both groups were unrelated to the treatment of their sternal wounds.</p> <p><u>Death before closure:</u> VAC: 3/17 (18%) – 2 from aspiration pneumonia and 1 from multi-system organ failure; Control: 1/18 (5.5%) – due to aspiration pneumonia.</p> <p><u>Complications:</u> VAC – 1/14 (7%) patient had a chronically draining wound; 1/14 (7%) patient developed mediastinitis in a previously sterile wound.</p> <p>Control – 1/17 (6%) patient had a chronically draining wound; 1/17 (6%) patient had recurrent mediastinitis; 2/17 (12%) patients had omental flap losses; 1/17 (6%) patient had intestinal evisceration; 1/17 (6%) patient had a hernia.</p>	<p><i>Potential for bias:</i> This was a non-randomised, retrospective study. No blinding. Baseline characteristics stated to be similar.</p> <p><i>Outcome measures and their validity:</i> Outcome measures of unknown validity.</p> <p><i>Other comments:</i> Control patients used 4 different combinations of flaps for reconstruction: rectus alone (2/18), rectus with pectoralis flaps (4/18), omentum with pectoralis flaps (4/18), and bilateral pectoralis advancement flaps (6/18). There was a mixture of infected and sterile wounds.</p>

Appendix A: Key Efficacy and Safety Findings - Non-Randomised Comparative Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments																																	
<p>Doss 2002, GERMANY</p> <p>1998 to 2000.</p> <p>42 patients.</p> <p>Follow-up: 5 weeks.</p> <p><i>Comparison:</i> VAC: 20 patients (median age 66 years; range 45-82) treated by VAC (dressing changes every 2-3 days); Control: 22 patients (median age 66 years; range 50-83) treated by conventional wound management.</p> <p><i>Selection criteria:</i> Patients who developed post-sternotomy osteomyelitis (SOM) and required open wound management.</p>	<p><u>Mean [SD] (range) duration of treatment (days):</u> VAC: 17.2 [5.8] (10-31); Control: 22.9 [10.8] (9-50), p=0.009.</p> <p><u>Mean [SD] (range) total hospital stay (days):</u> VAC: 27.2 [6.5] (17-41); Control: 33.0 [11.0] (19-60), p=0.03.</p> <p><u>Mean (range) reduction in wound size (cm²/day):</u> VAC: 4.63 (2.9-6.5); Control: 3.2 (2.7-3.6).</p> <p><u>Speed of secondary wound healing (wound area cm²):</u></p> <table border="1"> <thead> <tr> <th>Tx Day</th> <th>VAC</th> <th>Control</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td><td>3</td></tr> <tr><td>2</td><td>9</td><td>7</td></tr> <tr><td>3</td><td>14</td><td>10</td></tr> <tr><td>4</td><td>18</td><td>13</td></tr> <tr><td>5</td><td>23</td><td>16</td></tr> <tr><td>6</td><td>28</td><td>19</td></tr> <tr><td>7</td><td>33</td><td>23</td></tr> <tr><td>8</td><td>37</td><td>26</td></tr> <tr><td>9</td><td>42</td><td>29</td></tr> <tr><td>10</td><td>47</td><td>32</td></tr> </tbody> </table>	Tx Day	VAC	Control	1	5	3	2	9	7	3	14	10	4	18	13	5	23	16	6	28	19	7	33	23	8	37	26	9	42	29	10	47	32	<p><u>Complications in Control group:</u> 8/22 (36%) patients required closed chest irrigation drainage; 3/22 (14%) patients underwent secondary pectoralis major muscle advancement flap procedures; 1/22 (4.5%) patient required repetitive wound debridement.</p> <p><u>Complications in VAC group:</u> Some patients reported pain when sub-atmospheric pressure was applied.</p> <p>None of the patients developed late fistulas or sinus formation involving sequestered pockets of infected or necrotic tissues.</p> <p><u>Hospital mortality:</u> VAC: 1/20 (5%); Control: 1/22 (4.5%).</p>	<p><i>Potential for bias:</i> Allocations to treatment groups was left to the surgeon's discretion and occurred in a non-randomised fashion. This study was retrospective, with the two groups operated upon in series by several surgeons. Small sample size. Patients allocated to VAC had less severe infection. Baseline characteristics reported to be similar.</p> <p><i>Outcome measures and their validity:</i> The technique used to measure wound size was not stated. Other measures were of unknown validity.</p> <p><i>Other comments:</i> Conventional treatment consisted of re-exploration, removal of sternal wiring and debridement of all non-viable tissues. The wound was then washed with hydrogen peroxide and rinsed with saline solution.</p>
Tx Day	VAC	Control																																		
1	5	3																																		
2	9	7																																		
3	14	10																																		
4	18	13																																		
5	23	16																																		
6	28	19																																		
7	33	23																																		
8	37	26																																		
9	42	29																																		
10	47	32																																		

Appendix A: Key Efficacy and Safety Findings - Non-Randomised Comparative Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Catarino 2000, UK</p> <p>September 1998 to August 1999 (VAC); September 1997 to August 1998 (Closed Drainage and Irrigation (CDI)).</p> <p>20 patients. Follow-up: 6 months.</p> <p><i>Comparison:</i> VAC: 9 patients[#] (median age 68 years; range 64-74) treated by VAC (dressings changed every 48 to 72 hours); CDI: 11 patients (median age 66 years; range 46-75) treated by CDI.</p> <p><i>Selection criteria:</i> Patients with post-sternotomy mediastinitis (PSM) and had positive bacteriologic cultures from mediastinal tissue samples.</p> <p>[#]First 2 patients were initially treated with CDI.</p>	<p><u>Duration of primary treatment (days)*:</u> VAC: 11 (6-26); CDI: 13 (8-20), pns.</p> <p><u>Length of hospitalisation after start of treatment (days)*:</u> VAC: 15 (12-34); CDI: 40.5 (14-89), p=0.02.</p> <p><u>Total length of hospitalisation (days)*:</u> VAC: 27 (22-49); CDI: 50 (27-98), p=0.04.</p> <p>*Values are expressed as Median (Range).</p> <p><u>Treatment failure:</u> VAC: 0/9 (0%); CDI: 5/10 (50%), p=0.03.</p> <p>All patients with treatment successes had a satisfactory functional and cosmetic outcome and were well at follow-up after 6 months.</p>	<p>For patients treated with VAC, there were no recurrent wound infections and no re-interventions.</p>	<p><i>Potential for bias:</i> This was a non-randomised comparative study with historical controls. No blinding. 1/11 (9%) patient allocated to CDI died 14 days post-op of a cause largely unrelated to PSM and was excluded from the study.</p> <p><i>Outcome measures and their validity:</i> Observational measures of outcome.</p> <p><i>Other comments:</i> CDI consisted of the insertion of two 16 Charrière catheters for irrigation and two 28 Charrière Argyle drains. Irrigation with normal saline was continued at a rate of 1L every 6 hours until the effluent was microbiologically clear. After 1 to 4 weeks of VAC, when the wounds were considered to be clean with evident granulation tissue and negative microbiological cultures, delayed primary closure was performed in theatre.</p>

Appendix A: Key Efficacy and Safety Findings - Case Series Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Lang 1997, GERMANY</p> <p>January 1992 to March 1996.</p> <p>96 consecutive patients. Follow-up: mean, 13 months (range, 1.5 to 38 months).</p> <p><i>Inclusion criteria:</i> Patients with severe soft-tissue damage of the ankle (n=55) and of the foot (n=41).</p> <p><i>Exclusion criteria:</i> Primary treatment was in another department, or patient required primary or secondary amputation. Polytraumatised patients who required subsequent treatment in another department or died.</p>	<p>54 ankle injuries healed at 6 weeks: 33/54 (61%) by secondary suture; 21/54 (39%) by skin transplantation.</p> <p>38 foot injuries healed at 6 weeks: 16/38 (42%) by secondary suture; 17/38 (45%) by skin transplantation; 5/38 (13%) by spontaneous epithelization.</p> <p><u>Mean duration of treatment:</u> For ankle injuries: 11.2 days; For foot injuries: 12.1 days.</p>	<p>1/96 (1%) polytraumatised patient died 3 days post-op. 3/96 (3%) patients required amputation at first reconstruction trial.</p> <p>2/54 (4%) patients with ankle injuries experienced infection.</p> <p>3/38 (8%) patients with foot injuries experienced infection; 5/38 (13%) patients had small skin defects but after 24 days this resolved with spontaneous epithelization.</p>	<p><i>Potential for bias:</i> No comparator group.</p> <p><i>Outcome measures and their validity:</i> Outcome measures of unknown validity.</p> <p><i>Other comments:</i> Dressings were changed on the fourth post-op day, then weekly thereafter.</p>

Appendix A: Key Efficacy and Safety Findings - Case Series Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments																																																				
<p>Deva 2000, AUSTRALIA</p> <p>November 1997 to December 1998.</p> <p>30 consecutive patients (mean age 50.7 years; range 15.4 to 88.3). Follow-up: at least 3 months.</p> <p><i>Inclusion criteria:</i> At least grade III pressure sores with full-thickness ulceration down to but not through deep fascia, deemed unsuitable for surgical closure.</p> <p><i>Exclusion criteria:</i> Patients receiving full anticoagulation therapy or with exposure of abdominal or thoracic viscera at the base of their wounds.</p> <p><u>Mean (range) wound size at the start of treatment (cm):</u></p> <table border="1"> <tr> <td>Width</td> <td>5.7 (1.7-22)</td> </tr> <tr> <td>Length</td> <td>9.9 (1.9-27)</td> </tr> <tr> <td>Depth</td> <td>3.0 (0.5-9)</td> </tr> <tr> <td>Volume</td> <td>171cm³ (16.1-2228cm³)</td> </tr> </table> <p><i>Continued over...</i></p>	Width	5.7 (1.7-22)	Length	9.9 (1.9-27)	Depth	3.0 (0.5-9)	Volume	171cm ³ (16.1-2228cm ³)	<p>26/30 (87%) patients had satisfactory outcomes:</p> <p>6/30 (20%) by secondary healing; 11/30 (37%) by cavity obliteration; 1/30 (3%) by direct wound closure; 8/30 (27%) by split skin graft to a surface wound.</p> <p>In 4/30 (13%) patients, TNP failed due to lack of patient compliance: 2/30 (6.5%) patients suffered dementia and repeatedly disconnected themselves from therapy; 2/30 (6.5%) patients discharged themselves from medical care because of social difficulties with inpatient treatment.</p> <p>Both nursing staff and patients found therapy to be comfortable and easy to apply.</p> <p><u>Percentage of initial volume over time:</u></p> <table border="1"> <tr> <td></td> <td>Acute (n=15)</td> <td>Chronic (n=11)</td> <td>Failures (n=4)</td> </tr> <tr> <td><u>Week</u></td> <td></td> <td></td> <td></td> </tr> <tr> <td>0</td> <td>100</td> <td>100</td> <td>100</td> </tr> <tr> <td>1</td> <td>60</td> <td>86</td> <td>105</td> </tr> <tr> <td>2</td> <td>32</td> <td>70</td> <td>120</td> </tr> <tr> <td>3</td> <td>24</td> <td>50</td> <td></td> </tr> <tr> <td>4</td> <td>15</td> <td>41</td> <td></td> </tr> <tr> <td>5</td> <td>4</td> <td>30</td> <td></td> </tr> <tr> <td>6</td> <td></td> <td>6</td> <td></td> </tr> <tr> <td>7-12</td> <td></td> <td>5</td> <td></td> </tr> <tr> <td>13-17</td> <td></td> <td>5</td> <td></td> </tr> </table>		Acute (n=15)	Chronic (n=11)	Failures (n=4)	<u>Week</u>				0	100	100	100	1	60	86	105	2	32	70	120	3	24	50		4	15	41		5	4	30		6		6		7-12		5		13-17		5		<p>No adverse effects of therapy were reported.</p> <p>No recurrences were observed during the 3-month follow-up period.</p>	<p><i>Potential for bias:</i> No comparator group.</p> <p><i>Outcome measures and their validity:</i> Wounds were measured and photographed before the commencement of therapy and at each subsequent dressing change. Wound volumes were estimated using the size of foam dressing used to fill the wound cavity. The validity of this measure is unknown. The tolerance of both patient and staff to the VAC dressings was recorded.</p> <p><i>Other comments:</i> Dressings were changed every 48 hours. Continuous suction was applied for the first 48 hours at a pressure of 75 to 125mmHg, followed by intermittent suction. 17/30 (57%) patients had acute wounds of <6 weeks' duration; 13/30 (43%) patients had chronic wounds of >6 weeks' duration.</p>
Width	5.7 (1.7-22)																																																						
Length	9.9 (1.9-27)																																																						
Depth	3.0 (0.5-9)																																																						
Volume	171cm ³ (16.1-2228cm ³)																																																						
	Acute (n=15)	Chronic (n=11)	Failures (n=4)																																																				
<u>Week</u>																																																							
0	100	100	100																																																				
1	60	86	105																																																				
2	32	70	120																																																				
3	24	50																																																					
4	15	41																																																					
5	4	30																																																					
6		6																																																					
7-12		5																																																					
13-17		5																																																					

Mean time to achievement of endpoints:

Overall: 35 days (range, 8-124 days);

Acute wounds: 28 days;

Chronic wounds: 43 days.

Acute vs chronic, $p < 0.001$.

25/26 (96%) patients with successful outcomes showed a decrease in the number of bacterial species throughout the duration of treatment.

Decrease in colony density:

8/25 (32%) heavy to moderate;

17/25 (68%) heavy to scant.

Appendix A: Key Efficacy and Safety Findings - Case Series Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Avery 2000, UK</p> <p>January 1999 to June 1999.</p> <p>15 consecutive patients. Follow-up: 2 weeks.</p> <p><i>Selection criteria:</i> Patients with relatively large donor site defects of the radial forearm, treated with meshed split skin grafts.</p> <p>The mean donor site defect was 36cm².</p>	<p>Graft take was 100% at 5 days in all patients.</p> <p>The mean time to wound healing* in this series was 2 weeks.</p>	<p>There have been no significant complications.</p> <p>Some patients experienced minor discomfort at the wound site, usually with large wounds or suction pressures over 100mmHg.</p>	<p><i>Potential for bias:</i> Small sample size. No comparator group.</p> <p><i>Outcome measures and their validity:</i> Dressings were changed on day 5 and the size of the donor site and percentage of graft take were measured using a transparent sterile grid. The validity of this measure is unknown.</p> <p><i>Other comments:</i> Continuous negative pressure of 50 to 100mmHg was applied. *Wound healing was defined as a dry wound not requiring special dressing.</p>
<p>Meara 1999, USA</p> <p>5 consecutive patients with 9 separate degloving injuries (mean age 58.4 years; range 26 to 83). Follow-up: 12 days.</p> <p><i>Selection criteria:</i> Patients with degloving injuries.</p> <p><u>Mean graft size before treatment:</u> 328.9cm² (range, 30 to 1200cm²)</p>	<p><u>Mean duration of treatment:</u> 6.1 days (range, 4 to 12 days)</p> <p><u>Mean graft take (per graft):</u> 92.3% (range, 60 to 100%)</p> <p><u>Mean graft take (per patient):</u> 94.6% (range, 80 to 100%)</p>	<p>Not reported.</p>	<p><i>Potential for bias:</i> Small sample size. No comparator group.</p> <p><i>Outcome measures and their validity:</i> The measurement of graft size is not described.</p> <p><i>Other comments:</i> Patients were treated by 3 separate plastic surgeons during a 12-month period in a single facility. Continuous pressure of 50 to 150mmHg was applied. Dressings were left for 3 to 6 days before being discontinued or changed.</p>

Appendix A: Key Efficacy and Safety Findings - Case Series Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Armstrong 2002, USA</p> <p>31 consecutive patients (mean age 56.1 [11.7] years). Follow-up: 12 months.</p> <p><i>Selection criteria:</i> Patients with diabetic foot wounds presenting for care at two large, multidisciplinary, referral-based wound care centres. All wounds were converted to stage “A” (non-infected, non-ischaemic) before device application.</p> <p><u>Mean wound size at start of treatment:</u> 27.9 [19.5] cm²</p> <p><u>Mean duration of wounds before therapy:</u> 25.4 [23.8] weeks</p>	<p><u>Mean duration of treatment:</u> 4.7 [4.2] weeks</p> <p>28/31 (90.3%) wounds healed at the level of debridement without the need for further bony resection in a mean 8.1 [5.5] weeks.</p> <p>The remaining 3/31 (9.7%) wounds went on to higher level amputation.</p> <p>Gender did not significantly influence healing time or proportion of patients healing (p=0.2 and 0.6, respectively).</p> <p>There was no significant association between age (p=0.4) or duration of the wound (p=0.9) and time to wound healing (p=0.4).</p> <p>There was also no association between wound size and time to healing (p=0.5).</p>	<p><u>Complications:</u> 6/31 (19.4%) periwound maceration; 1/31 (3.2%) periwound cellulitis; 1/31 (3.2%) deep space infection; 1/31 (3.2%) below knee amputation; 2/31 (6.5%) transmetatarsal amputation.</p>	<p><i>Potential for bias:</i> This was a retrospective study with small sample size. Authors were unable to control for vascular status, degree of glucose control, nutritional status, or activity level.</p> <p><i>Outcome measures and their validity:</i> Evaluation included time to complete wound closure, proportion of patients achieving wound healing at the level of initial debridement and complications associated with use of the device.</p> <p><i>Other comments:</i> Pressure of 125mmHg was applied with dressing changes every 48 hours. 1/31 (3.2%) patient had a superficial wound (not including tendon, capsule or bone); 14/31 (45.2%) patients had wounds with exposed tendon, and/or closed joint capsule; 16/31 (51.6%) patients had wounds with bone or open joint exposed.</p>

Appendix A: Key Efficacy and Safety Findings - Case Series Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Mooney 2000, USA</p> <p>1993 to 1997.</p> <p>27 consecutive paediatric patients (age range 3 days to 18 years). Follow-up: not stated.</p> <p><i>Selection criteria:</i> Paediatric patients (≤ 18 years of age) with complex wounds, after unsuccessful surgical closure.</p>	<p>15/27 (55.5%) patients experienced wound closure and coverage with split thickness skin grafting.</p> <p>5/27 (18.5%) wounds were closed by delayed primary technique.</p> <p>4/27 (15%) wounds were allowed to granulate and close by secondary intention.</p> <p>2 pedicled flaps were used in cases of sternal dehiscence.</p> <p>1 foot and leg wound was treated with a cross extremity flap after granulation.</p> <p>Patients treated on an inpatient basis underwent an average of 4.8 dressing changes (range, 1 to 8).</p> <p>All patients tolerated VAC treatment.</p>	<p>There were no complications observed in this pediatric group beyond minimal bleeding attributable to disrupted granulation tissue at the time of system changes.</p> <p>There were no skin injuries caused by the suction system or the use of the adherent drape.</p>	<p><i>Potential for bias:</i> Retrospective study.</p> <p><i>Outcome measures and their validity:</i> Outcome measures of unknown validity.</p> <p><i>Other comments:</i> Continuous negative pressure of 125mmHg was applied. Dressings were changed intraoperatively or with the patient under conscious sedation every 3 days.</p> <p>11/27 (41%) patients had acute extremity wounds; 9/27 (33%) patients had chronic extremity wounds; 7/27 (26%) patients had chronic axial wounds.</p>

Appendix A: Key Efficacy and Safety Findings - Case Series Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
<p>Gustafsson 2002, SWEDEN</p> <p>February 1999 to December 2000.</p> <p>16 consecutive patients. (13/16 (81%) were male; mean age 68 years; range, 49 to 82 years); (3/16 (19%) were female; mean age 67 years; range, 63 to 73 years). Follow-up: up to 120 days.</p> <p><i>Selection criteria:</i> Patients with post-operative deep sternal wound infection after cardiac surgery.</p>	<p><u>Median duration of treatment:</u> 9 days (range, 4 to 34 days)</p> <p><u>Median hospital stay:</u> 22 days (range, 12 to 120 days)</p>	<p>All patients were alive and free from sternal infection 3 months after secondary closure.</p> <p>2/16 (12.5%) patients required further surgical intervention due to fistulas after rewiring of sternotomy. Thereafter, both patients were stable and their wounds healed.</p> <p>No patients experienced haemodynamic instability, bleeding tendency, arrhythmia and chest pain. Some air leakage was noticed but this was resolved with additional adhesive drape.</p> <p><u>Complications unrelated to treatment:</u> 1/16 (6.25%) patient had a stroke, multiorgan failure and bilateral pneumonia; 1/16 (6.25%) patient had peritonitis and was treated for bowel obstruction caused by chronic peritoneal dialysis; 1/16 (6.25%) patient had massive pectoral muscle necrosis caused by cardiac resuscitation, followed by an emergency valve operation.</p>	<p><i>Potential for bias:</i> This was a retrospective study of small sample size.</p> <p><i>Outcome measures and their validity:</i> Outcome measures of unknown validity.</p> <p><i>Other comments:</i> Continuous negative pressure of 125mmHg was applied. VAC was followed by surgical closure of the wound.</p>