



**Centre for Clinical Effectiveness**

Enhancing patient outcomes through clinical application of the best available evidence

**EVIDENCE CENTRE**  
**EVIDENCE REPORT**  
Series 2003: Intervention

# **The effectiveness of vacuum assisted closure (VAC) in wound healing**

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## **SUMMARY STATEMENT:**

**Copyright** – please refer to Appendix for information.

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**Publication of materials** – please use the following format when citing this article:

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## REQUEST:

In patients with acute or chronic wounds, what is the effectiveness of vacuum assisted closure in terms of healing time and wound closure, compared to passive wound therapy?

## REQUESTED BY:

**Mr Lars Kristiansson**, RN Division 1, Hospital in the Home, Monash Medical Centre, Clayton

## METHODOLOGY

### Search Strategy

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias. We determine this according to predefined NHMRC criteria (see Appendix 1).

First we search for systematic reviews, evidence-based clinical practice guidelines, or health technology assessments, and randomised controlled trials. If we identify sound, relevant material of this type, the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable, or have other methodologic difficulties. We include case-control and longitudinal cohort studies in our reports. While we cite observational and case series studies, and narrative reviews and consensus statements in our reports, we do not critically appraise them. These studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

### Details of Evidence Request:

Patients:	Hospital in the home patients, patients in hospital or ambulatory care settings with acute or chronic wounds
Interventions:	Vacuum assisted closure
Comparisons:	Passive wound therapy
Outcomes:	Healing time, wound closure, mobility, quality of life

### Search terms

(See Appendix 2 for exact search strategy)

Patients:	Wounds and injuries
Intervention:	Topical negative pressure, sub-atmospheric pressure therapy, vacuum sealing, vacuum assisted closure, VAC, negative pressure dressing, foam suction dressing, vacuum compression, vacuum pack, sealed surface wound suction, sealing aspirative therapy
Comparison:	Any
Outcomes:	Any

## Resources Searched

We searched the following databases and Internet websites:

Resource	Issue or Access Date
The Cochrane Library (Online)	Issue 3, 2003
Biological Abstracts (OVID)	1980 to August 2003
Medline (OVID)	1966 to August Week 3, 2003
EBM Reviews (OVID) -	
Cochrane Database of Systematic Reviews	3 <sup>rd</sup> Quarter, 2003
Database of Abstracts of Reviews of Effectiveness	3 <sup>rd</sup> Quarter, 2003
Cochrane Controlled Trials Register	3 <sup>rd</sup> Quarter, 2003
CINAHL (OVID)	1982 to August week 3, 2003
PREMEDLINE (OVID)	August 19, 2003
Australasian Medical Index	Accessed August 19, 2003
National Guideline Clearinghouse	Accessed August 19, 2003
Scottish Intercollegiate Guideline Network	Accessed August 19, 2003
<a href="http://www.vacuumtherapy.co.uk/index.htm">www.vacuumtherapy.co.uk/index.htm</a>	Accessed August 19, 2003

## Refinements, searching & reporting constraints

We included items that were available to us on 31<sup>st</sup> October 2003. The following inclusion and exclusion criteria were applied:

### *Inclusion criteria*

- Studies comparing vacuum assisted closure with any other for of dressing in patients with acute and chronic wounds

### *Exclusion criteria*

- Level III or IV Evidence (See Appendix 1)
- Studies published in a language other than English
- Studies presenting data published in another report
- Narrative reviews

## RESULTS:

The search strategy yielded a total of 89 pertinent articles, the abstracts of which were retrieved and reviewed. Full text was retrieved for 14 of these articles. Application of the inclusion and exclusion criteria reduced the total number of included studies to three.

Table 1. Reasons for exclusion of studies identified in search

<b>Reason</b>	<b>Number of studies</b>
Level III Evidence – Comparative studies	4
Level IV Evidence – Case series and case reports	1
Article not published in English	2
Data published in another included study	3
Narrative review	1
<b>Total</b>	<b>11</b>

The three articles that met the inclusion criteria consisted of one Cochrane systematic review and two prospective, controlled studies of patients with chronic wounds (Table 2). As a relevant systematic review was identified, only studies published since the review was undertaken (or studies not included in the review) were appraised. No Level I or II studies were identified that investigated the effectiveness of vacuum assisted closure in patients with acute wounds. We are reasonably confident these studies represent the most important findings published to date.

Table 2. Study designs of included articles

<b>Study Design</b>	<b>Number included</b>
<b>Systematic reviews or meta-analyses</b>	<b>1</b>
Evidence-based clinical practice guidelines	0
<b>Randomized controlled trials</b>	<b>2</b>
Controlled trials, cohort or case-control analytic studies	0
Descriptive case series	0
Consensus reports, non-evidence-based clinical practice guidelines	0
Narrative reviews	0
<b>Total</b>	<b>3</b>

## EVIDENCE SUMMARIES

Evidence summaries are in the form of spreadsheets reproduced at the end of this report. Each spreadsheet contains the article citation, the study design with level of evidence available according to NHMRC guidelines (2000), patient description, scientific validity of the article, results, the author's conclusions and comments from the Centre for Clinical Effectiveness reviewer.

### Findings

As the included studies were small and reported different outcome measures, the pooling of results in an effort to arrive at a summary measure of treatment effectiveness was not appropriate. Therefore, a narrative synthesis of results was undertaken. The commentary below summarises the information provided in the Evidence Report Summary Tables.

### *Overall Results*

The three articles identified and included in this report represented four primary studies (2 in the systematic review), with 78 patients randomised to receive vacuum assisted closure (VAC)<sup>1</sup> or another wound dressing.

Overall, the systematic review and one randomised controlled trial suggest that VAC may have advantages compared to other forms of wound dressing studied in terms of chronic wound healing and wound closure, with one trial finding no difference in the time for wounds to reduce in volume by 50 per cent. However, methodological limitations of the two trials included in the systematic review, and of the two further studies appraised in this report limit the validity of any conclusions that can be drawn from them. No studies were identified which reported outcomes such as patient mobility levels or quality of life associated with VAC. Presently, there have been too few reports published of patients randomised to suggest which patient groups may benefit most from VAC, or what regimen is most efficacious. As was highlighted by Evans & Land (2003) and Wanner et al (2003), there is a need for well designed, adequately powered, multi-centre randomised trials to evaluate the contribution of VAC in the management of wounds.

### *Research Methodology*

In a methodologically sound Cochrane systematic review, Evans & Land (2003) concluded that the two trials included suggested vacuum assisted closure may increase healing rates (compared to saline gauze dressings), although results must be viewed with "extreme caution" due to the small and methodologically flawed nature of the trials. These findings were based on two primary studies (Joseph et al 2000 & McCallon et al 2000). Joseph et al (2000) reported data from 24 patients with a total of 36 chronic wounds, resulting from pressure, wound dehiscence, venous stasis or radiation. Twelve of the patients had multiple wounds. Patients were randomised to receive VAC, with continuous suction at 125 mmHg, changed every 48 hours. Control group patients received wet-to-wet/wet-to-moist gauze dressings changed three times per day. Multiple wounds in individuals were treated as separate wounds in the randomisation process, so that one patient could be randomised to both the treatment and control groups. Per cent wound volume was measured at three and six weeks with impression moulds. Histology and culture results were also reported by Joseph et al (2000) but not included in the systematic review. The second study included in the systematic review (McCallon et al 2000) reported ten patients with diabetic foot ulceration, from a randomised parallel group study. Five patients were randomised to either VAC (125 mmHg) using continuous

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<sup>1</sup> A large range of terms has been employed to describe the concept of applying subatmospheric pressure to wounds. In the following discussion VAC is used to encompass all of these synonyms. The Evidence Report Summary Tables adopt the same terminology as the respective studies to which they relate.

suction for 48 hours, followed by intermittent suction, or to saline gauze dressings changed twice daily. The number of days to obtain satisfactory healing was recorded. Also, at two weeks the per cent change in wound surface area was measured.

The study by Wanner et al (2003) reported data from 22 consecutive paraplegic or tetraplegic patients with pelvic pressure sores. Patients were randomised to receive VAC (125 mmHg) with dressings changed every two to seven days, or wet-to-dry/wet-to-wet gauze dressings soaked in Ringers solution, changed three times daily. The primary outcome reported was the time for wound size to reduce to 50 per cent of the initial volume.

Ford et al (2002) reported 28 patients with 41 wounds comprising ischial, sacral, malleolar, trochanteric and calcaneal wounds. Patients were randomised to receive VAC (pressure not stated) with dressings changed Mondays, Wednesdays and Fridays, or to receive the Healthpoint System (HP) of wound dressings. The HP System consisted of three gel products, which were changed once or twice daily. Three of the included patients also crossed over to receive the alternative treatment after six weeks of one therapy, although it was unclear in which order they received the interventions. All patients were reviewed at three and six weeks, with wound volume, wound dimensions, soft tissue and bone biopsies and bone MRI measured.

### *Focused Appraisal*

The Cochrane systematic review conducted by Evans & Land (2003) met all key criteria for validity (focussed question, adequate search strategy, assessment of validity, consistent results and appropriate analysis). The following brief discussion highlights some of the methodological flaws of the included studies that led Evans & Land (2003) to their conclusions. Joseph et al (2000) inappropriately treated individual wounds on patients with multiple wounds as separate from each other, as they used a between subjects study design (as opposed to within subjects). The adequacy of allocation concealment was unclear, and patients or providers were not blinded to treatment used. Assessment of outcome was appropriate and adequately blinded from treatment allocation through use of staff not involved in daily care of patients. It was not reported if there were any withdrawals, and unclear if intention to treat analysis was used. McCallon et al (2000) allocated patients by flipping a coin, and subsequently by alternating groups, and so was not truly randomised and making concealment of allocation impossible. It was not reported whether there was any blinding of patients, clinicians or outcome assessors. Appropriate outcome measures were reported. Although there did not appear to be any losses to follow up, it was unclear if intention to treat analysis was performed.

Wanner et al (2003) randomly allocated patients to groups, though the method of sequence generation was not detailed, and it was not stated whether allocation was concealed from investigators. It was not stated whether patients, clinicians or outcome assessors were blinded to treatment allocation. An appropriate outcome measure was used. No patients were lost to follow up. Intention to treat analysis was not performed, with two patients being excluded from the final analysis. It was not clear to which group these patients were initially allocated.

Ford et al (2000) employed an appropriate method of sequence generation to randomise patients, although it was not stated whether allocation to groups was concealed from investigators. The different mean age of the groups (41.7 versus 54.4 years) may be evidence of failure of the randomisation process or due to chance, and may have contributed to differences in the behaviour of the groups in addition to the impact of the intervention. It was not stated whether patients or clinicians were blinded to treatment allocation. Wound volumes and dimensions were appropriately assessed effectiveness, and were measured by staff blinded to treatment allocation. Osteomyelitis was also reported as an outcome, although the authors did not discuss the validity of bone biopsy and MRI for assessment of osteomyelitis. This appeared to be relevant as different numbers were obtained from the different measures. It was unclear what order the three

patients who received both therapies received them in, or if there were any treatment order effects. Also, it was unclear if the results of these three patients were included in the summary result for all patients. If included, this would be inappropriate as it would require a combination of between subjects and within subjects results. Of 28 patients enrolled, 22 completed the trial (three lost to follow up, two deaths and one non compliant). Intention to treat analysis was not undertaken, as only the 22 trial completers were included in the analysis.

Overall, included primary studies had serious methodological flaws that limit the validity of their conclusions. This parallels the conclusion of Evans & Land (2003) in their Cochrane systematic review. The addition of two further primary studies (comprising 44 patients) in this report that were not included in the systematic review does not change this conclusion. Therefore, whilst VAC may offer advantages over other forms of wound dressings, these findings are presently not confirmed in controlled studies identified by this report. There remains a need for well designed, adequately powered, multi-centre randomised trials to evaluate the contribution of VAC in the management of wounds. Patient relevant outcomes such as mobility and quality of life associated with different treatments should also be collected to further inform clinicians in the management of patients with wounds.

<p style="text-align: center;"><b>EVIDENCE SUMMARY</b></p>	<p>Evans D &amp; Land L. Topical negative pressure for treating chronic wounds (Cochrane Review). In: The Cochrane Library, Issue 4, 2003. Chichester, UK: John Wiley &amp; Sons, Ltd.</p>	<p>Wanner MB, Schwarzl F, Strub B, Zaech GA &amp; Pierer G (2003). Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scandinavian Journal of Plastic &amp; Reconstructive Surgery &amp; Hand Surgery. 37(1): 28-33.</p>
<p><b>STUDY DESIGN &amp; NHMRC LEVELS OF EVIDENCE</b></p>	<p>Systematic review Level 1 Evidence</p>	<p>Randomised controlled trial Level II Evidence</p>
<p><b>DESCRIPTION:</b></p>	<p><b>Patients (Subjects):</b> Any person in any health care setting with a chronic wound.  <b>Intervention:</b> Any type of topical negative pressure treatment.  <b>Comparisons:</b> Any form of standard care, no treatment, sham or other experimental therapy.  <b>Outcomes:</b> Primary – time to complete healing, rate of change in wound area, proportion of wounds completely healed within trial period. Secondary – cost, quality of life, pain, comfort.  <b>Inclusion criteria:</b> All randomised controlled trials that evaluated the effectiveness of topical negative pressure in treating chronic wounds.  <b>Exclusion criteria:</b> None stated.</p>	<p><b>Patients (Subjects):</b> 34 consecutive paraplegic or tetraplegic patients with pressure sores admitted to the Swiss Paraplegic Centre. Of these, 22 were randomised. Mean age was 53 in the traditional treatment group and 49 in the vacuum assisted group. Of 11 patients in each group, 8 and 7 were male in the traditional and vacuum assisted groups, respectively. Both patient groups underwent standard treatment of surgical debridement, followed by wound preparation (intervention versus control) before wound closure with a 'flap'.  <b>Intervention:</b> The intervention consisted of vacuum assisted therapy. Continuous sub atmospheric pressure of 125 mmHg was applied, using equipment obtained from KCI Mediscus. Dressings were changed after 2 to 7 days, depending on the amount of fluid produced by the wound.  <b>Comparisons:</b> The control group underwent traditional care, which involved wet-to-dry/wet-to-wet dressings. These were gauze soaked with Ringer's solution. These were changed 3 times/day until clean granulation tissue was observed, after which the wound was kept wet with Ringers solution and dressings changed one to three times/day to keep the wound moist.  <b>Outcomes:</b> Reduction in wound size was used as an outcome, as a proportion of the initial volume.  <b>Inclusion criteria:</b> Consecutive patients admitted with pelvic pressure sores, with the ulcer deeper than Grade 2 (penetrating subcutaneous fat).  <b>Exclusion criteria:</b> Non-pelvic pressure sores, sores with depth less than Grade 3.</p>
<p><b>VALIDITY:</b></p>	<p><b>Focussed question:</b> Yes. Two clear questions stated around effectiveness in improving outcomes considered, and in terms of an optimum regimen.  <b>Search strategy:</b> Adequate. A thorough and reproducible search strategy was detailed.  <b>Assessed validity:</b> Yes. A list of ten items of study quality was used, addressing key validity criteria.  <b>Consistent results:</b> No. Different outcomes reported made consistent results impossible.  <b>Appropriate analysis of results:</b> Yes. A narrative synthesis of results was undertaken due to only two small trials being included, with different outcomes reported.</p>	<p><b>Randomisation:</b> Patients were randomly allocated to groups though the method of sequence generation was not detailed.  <b>Concealment of allocation:</b> Not stated.  <b>Blinding:</b> Not stated. It was unlikely patients were blinded due to the markedly different treatment regimens. One person made all measurements of wound volume. It was not stated that this was blind to group allocation.  <b>Loss to follow up:</b> No patients were lost to follow up.  <b>Intention to treat analysis:</b> Not undertaken. Two patients were not included in the final analysis (one had inadequate data (although it was unclear why) and one developed diarrhoea which made it impossible to adequately fix the vacuum dressing).</p>

<p><b>RESULTS:</b></p>	<p><b>EFFECTIVENESS</b>  One study (Joseph et al (2000) reported a greater reduction in wound volume at six weeks in favour of topical negative pressure (78% versus 30% of initial volume, p=0.038). Duration to complete wound closure was not stated. Two patients suffered calcaneal fractures whilst ambulating on the negative pressure dressing (both leading to amputation). There was a greater number of adverse events in the control group 44% versus 17%, p=0.0028).  The McCallon et al (2000) study reported a decrease in number of days to healing in favour of negative pressure therapy (22 days versus 43 days) although it was not stated whether these were means or medians. No statistical analysis was reported. Wound surface at two weeks showed a 28% decrease with VAC and 10% increase with saline moistened gauze dressings. Again it was unclear if the data were means or medians, and no statistical analysis was reported.  <b>OPTIMAL REGIMEN</b>  There were no trials included evaluating the effectiveness of different regimens of topical negative pressure.</p>	<p>The initial wound size in the vacuum assisted group was 50 ml (SD 33ml) compared to 42ml (SD 16ml) in the control group (p=NS). The mean (SD) time to reach 50% of the initial wound volume was 27 (10) days in the vacuum assisted group and 28 (7) days in the traditional group (p=0.NS).</p>
<p><b>AUTHORS COMMENTS:</b></p>	<p>Only two trials with very small sample sizes and methodological limitations were identified. Whilst these trials suggest topical negative pressure may increase healing rates of chronic wounds compared to saline gauze dressings, the findings must be interpreted with extreme caution.  There is a need for well designed, adequately powered, multi-centred randomised trials to evaluate the contribution of topical negative pressure in the management of chronic wounds.</p>	<p>The authors noted the non-significance of the result, and also that statistically, equivalence could not be proven either. However, they conclude:  “Our findings do not support our impression of much faster wound healing with the vacuum assisted than the traditional treatment. They show, however, that the vacuum method is no less effective” (page 32).</p>
<p><b>OUR COMMENTS:</b></p>	<p><b>Potential for bias:</b> There was minimal potential for bias as key criteria for validity in systematic reviews were met by the authors.  <b>Strength:</b> Overall, the review was well conducted, and made conclusions that would be reproducible due to the explicit outline of the methodology.</p>	<p><b>Potential for bias:</b> It was not possible to assess for a potential selection bias as there was limited detail regarding the randomisation process, and concealment of allocation form investigators. There was some potential for performance and detection bias as patients were not blinded to treatment, and it was unlikely there was blinded assessment of outcome (though this was not made explicit by the authors). Failure to undertake intention to treat analysis may have affected results as two patients were excluded from the analysis. It was unclear which group these two patients were from.  <b>Weakness:</b> The sources of bias noted above affect the validity of the trial. The small sample size limited the power of the study to detect a difference if one existed. Also, the nature of the setting may limit the generalisability of results if the centre is more proficient in managing pressure sores. The para/tetraplegic population may also limit generalisability to ambulatory patients with pressure sores.</p>

<p style="text-align: center;"><b>EVIDENCE SUMMARY</b></p>	<p>Ford CN, Reinhard ER, Yeh D, Syrek D, De Las Morenas A, Bergman SB, Williams S &amp; Hamori CA (2002). Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers. <i>Annals of Plastic Surgery</i> 49(1): 55-61.</p>
<p><b>STUDY DESIGN &amp; NHMRC LEVELS OF EVIDENCE</b></p>	<p>Randomised controlled trial (interim analysis) Level II Evidence</p>
<p><b>DESCRIPTION:</b></p>	<p><b>Patient (subjects):</b> 28 patients with 41 wounds were recruited from the plastic surgery clinic and inpatient physician referral, at Boston Medical Centre. Distribution of wound site for each group was not stated, although overall there were 9 ischial, 17 sacral, 4 lateral malleolar, 1 trochanteric and 4 calcaneal wounds. The average age of patients in the vacuum assisted closure (VAC) group was 41.7 years, and 54.4 years in the Healthpoint System (HP) of wound dressings.</p> <p><b>Interventions:</b> VAC was administered (pressure not stated) with dressings changed Mondays, Wednesdays and Fridays.</p> <p><b>Comparisons:</b> The HP system consisted of three gel products (Accuzyme, Iodosorb and Panafil). Accuzyme was not used at all as all wounds were surgically debrided, and patients received Iodosorb or Panafil depending on the amount of exudates in the wound. HP dressings were changed once or twice daily, depending on the degree of wound drainage.</p> <p><b>Outcomes:</b> All patients were reviewed at 3 and 6 weeks. Outcomes assessed were wound volume (with plaster cast), wound dimensions, number of PMNs (abbreviation unclear), lymphocytes and capillaries in soft tissue biopsies, inflammation and osteomyelitis in bone biopsies and with magnetic resonance imaging. (3 patients also completed one 6 week trial of one therapy, followed by a 6 week trial of the opposing treatment).</p> <p><b>Inclusion criteria:</b> Presence of stage III or IV ulcer for 4 or more weeks; albumin levels <math>\geq</math> 2.0 g/dL; ulcer volume (after debridement) between 10 and 150 ml.</p> <p><b>Exclusion criteria:</b> A list of 18 was detailed (Table 1) and included fistulas to organs or body cavities, malignancy in wound, pregnancy, systemic sepsis.</p>
<p><b>VALIDITY:</b></p>	<p><b>Randomisation:</b> Adequate. Randomisation was based on a table of random letters, generated before the trial.</p> <p><b>Concealment of allocation:</b> Not stated.</p> <p><b>Blinding:</b> It would not have been possible to blind patients to treatment allocation. Outcome assessment was conducted by staff blinded to treatment allocation.</p> <p><b>Loss to follow up:</b> of 28 patients enrolled, 22 patients completed the trial. Three patients were lost to follow up, 1 was deemed non compliant, and 2 died.</p>

	<p><b>Intention to treat analysis:</b> Not undertaken. Patients enrolled but lost to follow up were not included in the analysis. Further, it was unclear which group they had been allocated to.</p>
<p><b>RESULTS:</b></p>	<p>Two ulcers in each group (10% and 13% for VAC and HP, respectively) healed completely (p=NS).  One wound in the VAC group was complicated by sepsis and required amputation of the foot.  Six wounds in each group (30% and 40% for VAC and HP, respectively) underwent flap surgery.  The three patients who underwent both therapies experienced wound volume reductions of 57% and 25% (for VAC and HP, respectively), although it was unclear what order the patients underwent the procedures, or if there were any order effects. It was also unclear how No statistical test was reported, or standard deviations to repeat any tests. Overall, the mean reduction in ulcer volume was 51.8% with VAC and 42.1 % with HP (p=0.NS). Mean reductions in ulcer dimensions were not significant. The mean changes in PMNs, lymphocytes and capillaries were not significant.  15 of 35 wounds were suspicious for osteomyelitis (3 were positive on bone biopsy and 10 on MRI). Three in the VAC group showed improved osteomyelitis (2 by biopsy and 1 by MRI), with none in the HP group showing any improvement.  (Two individual reports of single patients were also presented, though the results are not presented here as they represent level IV Evidence.</p>
<p><b>AUTHORS COMMENTS:</b>  Limitations, implications for practice and research</p>	<p>The authors concluded, "VAC promotes an increased rate of wound healing" (page 60). Also, that "VAC may prove useful in the management of osteomyelitis underlying complicated pressure ulcers" (page 60).</p>
<p><b>OUR COMMENTS:</b> Opportunity for bias, weakness and strength</p>	<p><b>Potential for bias:</b> Whilst there was adequate description of generation of the randomisation sequence, it was not possible to assess for selection bias as no details of concealment of allocation were provided. There was some potential for a performance bias as patients were not blinded to treatment allocation, though the practicalities of this are doubtful. There was minimal potential for detection bias as there was adequate blinding of outcome assessors. There was potential for an attrition bias, as not all patients randomised were included in the analysis.  <b>Weaknesses:</b> There was some potential for the different ages of the groups to confound results, as younger subjects may be expected to heal differently to older subjects. Limited details about the baseline characteristics of subjects, especially in terms of wound severity, limits the ability to draw conclusions about the effectiveness of the interventions. The validity of diagnostic tests for osteomyelitis was not discussed, though appears to be relevant as there were different numbers assessed as positive on each test. The implications of this were not discussed. Also, the distribution of osteomyelitis between groups (15 of 35 wounds) was not stated, making any statistical test between groups impossible. The author's conclusions did not appear to be supported based on the results reported.</p>

## EXPLANATION OF TERMINOLOGY USED IN SPREADSHEET

**Level of evidence:** A hierarchy of study evidence that indicates the degree to which bias has been eliminated in the study design.

**Focussed question:** The review should address a clearly focused issue, in terms of the population studies, the intervention given and the outcomes considered.

**Search strategy:** A description of methods used to identify relevant studies from various computer databases and other sources.

**Systematic review:** The process of systematically locating, appraising and synthesising evidence from scientific studies in order to obtain a reliable overview.

**Validity:** The degree to which reviewers assessed the quality of the studies they included  
Of measurement: an expression of the degree to which a measurement measures what it purports to measure; it includes construct and content validity.

Of study: the degree to which the inferences drawn from the study are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn (internal and external validity, applicability, generalisability).

**Consistent results:** The similarity of results from the included studies. Often called heterogeneity which refers to the differences in treatment effect between studies contributing to a meta-analysis (systematic review). If there is significant heterogeneity, this suggests that the trials are not estimating a single common treatment effect.

**Appropriate analysis of results:** When study results are pooled in a meta-analysis it is important that the results are combined in appropriate manner. The studies should be sufficiently similar in study design, the results of included studies should be clearly displayed and reasons for any variation in results should be discussed.

**Potential for bias:** Bias is a systematic deviation of a measurement from the 'true' value leading to either an over or underestimation of the treatment effect. Bias can originate from many different sources, such as allocation of patients, measurement, interpretation, publication and review of data.

**Intervention:** A therapeutic procedure such as treatment with a pharmaceutical agent, surgery, a dietary supplement, a dietary change or psychotherapy.

**Randomisation:** A process of allocating participants to treatment or control group within a controlled trial by using a random mechanism, such as coin toss, random number table or computer-generated random numbers. Study subjects have an equal chance of being allocated to an intervention or control group; thus, the two groups are comparable. Randomisation ensures that the results are not biased by the selection of particular types of patients to receive a specific therapy.

**Blinding:** Blinding or masking is a process used in epidemiological studies and clinical trials in which the observers and the subjects have no knowledge as to which treatment groups subjects are assigned. It is undertaken in order to minimise bias occurring in patient response and outcome measurement.

**All patients accounted for:** Once patients are randomly allocated to a specific group and withdraw before study conclusion, they have to be accounted for in order to ensure that patients withdrawing from the study are not significantly different from those continuing in the study. The final analysis should be conducted on an intention-to-treat basis, which includes the results of withdrawn patients in the analysis.

**Patients treated equally:** To be able to attribute any difference in the observed outcome to the intervention, study patients need to be treated equally in every way except for the intervention being evaluated.

**Similar groups:** Baseline characteristics of patients that are also likely to affect results should be evenly distributed between the intervention and control groups. Following proper randomisation, patients' attributes would be expected to be equally distributed between groups.

## ARTICLES CRITICALLY APPRAISED FOR THIS REPORT

Evans D & Land L. Topical negative pressure for treating chronic wounds (Cochrane Review). In: The Cochrane Library, Issue 4, 2003. Chichester, UK: John Wiley & Sons, Ltd.

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

Ford CN, Reinhard ER, Yeh D, Syrek D, De Las Morenas A, Bergman SB, Williams S & Hamori CA (2002). 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* 49(1): 55-61.

## ARTICLES NOT INCLUDED IN THE APPRAISAL

Fisher A & B. B (2003). Vacuum assisted wound closure therapy. Canadian Coordinating Office for Health Technology Assessment (CCOHTA). Ottawa: Cochrane HTA. Available at: <http://www.ccohta.ca/>.

Luckraz H, Murphy F, Bryant S, Charman SC & Ritchie AJ (2003). Vacuum-assisted closure as a treatment modality for infections after cardiac surgery. *Journal of Thoracic & Cardiovascular Surgery*. 125(2): 301-305.

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

Scherer LA, Shiver S, Chang M, Meredith JW & Owings JT (2002). The vacuum assisted closure device: a method of securing skin grafts and improving graft survival. *Archives of Surgery*. 137(8): 930-933.

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# APPENDIX 1

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## Levels Of Evidence

Based on "How to use the evidence: assessment and application of scientific evidence" (National Health & Medical Research Council, Canberra, 2000):

Level I		Evidence obtained from a systematic review (or meta-analysis) of all relevant randomised controlled trials.
Level II		Evidence obtained from at least one randomised controlled trial.
Level III	-1	Evidence obtained from pseudo-randomised controlled trials(alternate allocation or some other method).
	-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group.
	-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.
Level IV		Evidence obtained from case series, either post-test or pretest/post-test.

## APPENDIX 2

### Search strategy

	<b>Search strategy for MEDLINE</b>
1	Topical negative pressure.mp
2	Sub-atmospheric pressure AND (therapy OR dressing).mp
3	Vacuum AND (sealing OR compression OR pack).mp
4	Vacuum assisted wound closure.mp
5	Vacuum assisted closure OR VAC OR "V.A.C".mp
6	Negative pressure AND (therapy OR dressing).mp
7	Foam suction dressing.mp
8	Sealed surface wound suction.mp
9	Sealing aspirative therapy.mp
10	OR/ 1-9
11	Exp Wounds and Injuries/
12	Wound\$.mp
13	11 OR 12
14	10 AND 13

Similar terms, appropriately translated, were used in the other databases searched.