

Vacuum assisted closure for chronic wounds: a review of the evidence

INTRODUCTION

Wounds with tissue loss usually heal by secondary intention; new tissue fills any deficit before epithelium covers the gap. The majority of wounds heal with simple dressings but a significant minority fail to heal and require additional therapies. Vacuum assisted closure (also called topical negative pressure, negative pressure wound therapy and sub-atmospheric pressure wound therapy) has been used in many acute and chronic wounds and this summaries the effectiveness and cost-effectiveness of this treatment.

BACKGROUND

Wounds that fail to heal may be accompanied by local oedema thought to prevent effective oxygen and nutrient exchange, and act as a substrate for infection. The application of a negative pressure dressing increases perfusion (Argenta and Morykwas 1997) and this may be important for tissue repair. Suction may also remove bacteria and factors that impede healing in chronic wounds such as matrix metalloproteinases. In addition, researchers have identified relationships between mechanical stress applied to cells and cellular proliferation and protein synthesis (Morykwas and Argenta 1997), suggesting that applying forces may kick start healing.

The technique involves placing a dressing made of an open-pored foam into the wound, inserting a tube between the foam and a source of negative pressure, and sealing the system with an adhesive film. Suction is applied at between 50 and 125 mmHg, and wound fluid is drawn into a disposable collection receptacle. Dressings are usually changed every 48 hours. The treatment options can be modified by varying pressure, applying it intermittently or continuously, choosing one of two foams, a portable and standard method of applying negative pressure, or an instillation version for use with fluids such as topical antiseptics. The majority of studies have used a commercial vacuum assisted closure device (VAC™, KCI) and this has been available since 1995.

EVIDENCE OF EFFICACY AND SAFETY

A number of reviews (e.g. Evans et al 2001, Samson et al 2004, Ontario Ministry of Health and Long-Term Care 2004; Mendonca et al 2006, Pham et al 2006, Pilatakis and Molnar 2006) have summarised the evidence for vacuum assisted closure. Searching the Cochrane Library in November 2006 using the search terms 'vacuum assisted closure' or 'negative pressure therapy' or 'topical negative pressure' yielded 54 citations to potential randomised controlled trials. In order to identify unpublished work, the KCI website and bibliographies of studies retrieved from electronic searching were also inspected. These searches identified eleven randomised controlled trials (RCTs) in open wounds published between 2000 and 2006 (16 citations). A further 11 trials are only described in conference abstracts (Orgill and Bayer 2004, Stannard 2004, Niezgodza 2004, Molnar 2004, Greer 2004, Bayer and Orgill 2004, John Lantis 2004, Stremitzer 2006, Foo et al 2004, Obdeijn et al 2004, Payne 2004) and insufficient information was available within these to appraise study quality or obtain full results. Other studies were excluded as they were not trials: commentaries (5), investigated acute wounds (8), not about vacuum assisted closure (4), controlled clinical trials without randomisation (10), retrospective analyses (1), or reported a study investigating physiological effects of vacuum closure (1).

Description of studies (see table 1)

Pressure ulcers

Two RCTs (n=50) reported on the effect of vacuum closure on pressure ulcers (Ford 2002, Wanner 2003).

Ford (2002) reported on 22 people with 35 full thickness pressure ulcers. The proportion of ulcers healing with vacuum assisted therapy was 10% (2/20), similar to that healing moist wound products (13%, 2/15). There was no significant difference in reductions in reduction in volume (51.8% with vacuum therapy and 42.1% with dressings). Problems with this trial included lack



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Table 1. Characteristics of studies

Study identifier	Type of wound	Participants	TNP therapy
Ford	Pressure ulcers, grade 3 or 4	28 people with 41 ulcers	TNP changed 3 times a week
Wanner	Pressure ulcers, grade 3 or 4	34 people	TNP changed every 2-7 days
McCallon 2000	DFU	10 people	vacuum therapy
Eginton 2003	DFU	Ten patients with 11 wounds: cross-over trial	with two weeks of vacuum assisted therapy (125 mmHg continuous)
Armstrong 2005	DFU	162 people with partial foot amputation wounds	16 weeks of vacuum therapy (regimen not reported)
Verstaek 2006	Patients with ulcers of at least 6 months duration	n=60	Vacuum assisted therapy (125 mmHg continuous pressure)
Joseph 2000	Mixed wound population: 78% due to pressure, rest due to venous insufficiency, surgical wound dehiscence, radiation, trauma)	24 people with 36 wounds	or vacuum closure changed every 48 hours.
Moues 2004	Wounds requiring open wound management before surgical closure. Thirty seven percent of the wounds were secondary to pressure; the others were caused by infection, dehiscence or 'miscellaneous' aetiologies.	54 people	vacuum therapy (continuous 125 mmHg) changed every 48 hours.
Jeschke 2004	Large defects requiring grafting with an artificial skin replacement. Fifty percent of the wounds were traumatic, the rest were due to melanoma, burn, healing delay, decollement and fibroleimyosarcoma.	12 people	or fixation with fibrin glue and vacuum therapy (continuous 150 mmHg)
Moisisdis 2004,	Acute and chronic wounds requiring grafting (5 trauma, 4 burns, pressure ulcer, sternal dehiscence, wound infection, extravasation, necrotising fasciitis, degloving, venous insufficiency and cellulitis). Randomised	22 people. Wounds were grafted and then each half (proximal/ distal) was treated with TNP or control	(100 mmHg continuous).
Braakenburg 2006	People with acute or chronic wounds secondary to surgery (48%), pressure (29%), diabetes (9%), trauma (8%), and venous insufficiency (6%)	included 65 people (66 wounds)	vacuum (125 mmHg continuous) changed three times a week

of information on randomisation, the assumption that multiple ulcers were independent, lack of baseline characteristics, and attrition rate.

Wanner (2003) reported on 22 people (from an initial study population of 34) with grade 3 or 4 pressure ulcers. The primary outcome was time to ulcer reduction of 50%. There was no significant difference in the mean time to achieve a 50% reduction in area: 27 (SD 10) days in the vacuum group and 28 (SD 7) days in the gauze group. Problems with this trial included a high rate of attrition, lack of information on method of randomisation, and the assumption that multiple ulcers were independent. In two small, poorly reported trials, therefore, there was no significant difference in reduction in area/ volume, nor in the number of ulcers healing between vacuum therapy and either moist wound healing products or gauze dressings.

Foot wounds in people with diabetes

Three RCTs (182 participants) evaluated vacuum closure in people with diabetic foot ulcers, or post amputation wounds (McCallon 2000, Eginton 2003, Armstrong 2005).

The first study (McCallon 2000) studied 10 people allocated (initially by a coin flip and then alternately) to vacuum therapy or saline gauze changed twice daily. Patients were non-weight bearing throughout. Patients were 'healed or ready for surgical closure/ grafting' in 22.8 days with vacuum closure and 42.8 days in the gauze group. They also reported the change in wound area at 2 weeks; vacuum group had a 28% decrease (+/-24) and standard care had a 10% increase (+/-17). They do not indicate whether values are means or medians, and standard errors or standard deviations, therefore determining statistical significant is not possible. Problems with this trial include

Control therapy	Results	Comment
Moist wound healing products from Healtpoint system	1. Wounds healed: 2/20 vs 2/15 (NSD). 2. Reuction in wound volume, 51.8% vs 42.1% (NSD)	No data on 65 people with 6 ulcers
Wet to dry or wet to wet gauze	Time to achieve 50% reduction in volume: 27 days vs 28 days (NSD)	Data on 22 people
saline gauze changed twice daily	1. 'healed or ready for surgical closure/grafting': 22.8 days vs 42.8 days 2. change in wound area at 2 weeks; 28% decrease vs 10% increase	
hydrocolloid gel/gauze dressing	1. reduction in wound volume: 59% +/- 9.7 versus increase of 0.1% +/-14.7; p < 0.005).	Data was reported on six patients (7 wounds).
moist wound therapy	1. complete wound closure (either primary intention or surgical closure): 56% versus 39%;p=0.04 2. wounds healing time: 56 days (median) vs. 77 days (p = 0.005).	More chronic ulcers in the control group
Modern dressings (alginates or hydrogels)	1. Time to complete healing: 29 days vs 45 days (p=0.0001) 2. Time to grafting: 7 days vs 17 days; p = 0.005. 3. Wound care costs were higher in the dressings group, mainly due to higher bandage and dressings costs (5452 vs 3881; p = 0.001).	Differences in healing time were robust to imbalances in the groups at baseline (TNP median area 33 cm ² , dressings group 43 cm ²). Quality of life was lower in the TNP group in the first week of therapy. Complication rate was higher for the TNP group: not significant (p = 0.17).
wet-to-moist gauze dressings covered by a film (changed three times a day)	1. Reduction in wound volume: 78% vs 30%. 2. Time to 90% reduction in volume said to be shorter for the TNP group. Data not presented, authors p=0.04 log rank).	
moist gauze (changed twice a day)	1. Time to a clean, red, granulating wound, 6 days vs 7 days (NSD). 2. Reduction in area: 3.8% per day vs 1.7% per day; p<0.05).	
standard graft fixation (compression dressings and daily dressing changes for 14 days)	The time to skin transplantation was shorter with fibrin and vacuum closure than compression alone (10 days compared with 24 days; p<0.002). Graft take was higher with fibrin and vacuum closure (78% compared with 98%; p <0.003).	The method of randomisation was not reported and the people in the vacuum group were older and had larger ulcers than the dressings group.
A hydrocolloid dressing	1. Degree of graft take at two weeks: 86% vs 87%. 2. A qualitative appraisal of graft take by a clinician found this to be equivalent in 7 cases, worse with vacuum in 3 and better with vacuum in 10.	No outcomes on 2 people
conventional care using dressings from the formulary (hydrocolloids, alginates, acetic acid, Eusol).	1. Time to complete granulation or being ready for grafting: 16 days vs 20 days hazard ratio 1.33, 95% CI 0.74 to 2.4: log rank p = 0.32). NSD	

an open method of allocation and lack of baseline wound measurements.

Ten patients with 11 wounds had their wounds randomised (Eginton 2003) into a cross-over trial with two weeks of vacuum assisted therapy (125 mmHg continuous) and two weeks of hydrocolloid gel/gauze dressing. Data was reported on six patients (7 wounds). There was a greater reduction in wound volume with vacuum closure than moist dressings (59% +/- 9.7 reduction versus increase of 0.1% +/- 14.7; p < 0.005). Problems in this trial included the analysis did not take into account the cross-over design, there may have been selection bias, baseline characteristics were not reported, and multiple ulcers were considered as independent.

The largest study (Armstrong 2005) randomized 162 people with partial foot amputation wounds to 16 weeks of vacuum therapy (regimen not reported) or moist wound therapy. Allocation was concealed and patients received

off-loading therapy with a pressure relief walker or sandal. The control group had ulcers of longer duration (1.8 months compared with 1.2 months) than the vacuum closure group. After 16 weeks more people with had complete wound closure (either healing by primary intention or surgical wound closure) in the vacuum closure group (56% versus 39%; p=0.04) than the dressings group. The vacuum closure wounds healed in a median of 56 days compared with 77 days in the standard care group (authors' p = 0.005). Problems with this trial included the lack of an adjusted analysis to control for the more chronic ulcers in the control group.

Vacuum closure was associated with more rapid healing of post-amputation wounds in people with diabetic foot ulcers in one trial. In two small, poorly reported trials, vacuum assisted closure was associated with higher rates of area or volume reduction but insufficient information

is presented on baseline risk in these two small studies to determine any potential biases.

Venous leg ulcers

One RCT (n=60) randomised patients with ulcers of at least 6 months duration to vacuum assisted therapy (125 mmHg continuous pressure) or modern dressings (alginates or hydrogels) (Verstaek 2006). Once the wounds were completely granulated full thickness punch skin grafts were applied. After grafting the vacuum assisted closure group had 4 days of vacuum treatment then compression therapy; the control group had compression therapy. Patients were on almost complete bed rest throughout. The time to complete healing was 29 days in the vacuum assisted closure group and 45 days in the dressings group (p=0.0001) The trial also reported shorter time to grafting with vacuum assisted therapy (7 days to 17 days; p = 0.005). The differences in healing time were robust to imbalances in the groups at baseline (vacuum group median area 33 cm², dressings group 43 cm²). Quality of life was lower in the vacuum group in the first week of therapy, and this difference disappeared during therapy. The complication rate was higher for the vacuum assisted closure group but this was not significant (p = 0.17). Wound care costs were higher in the dressings group, mainly due to higher bandage and dressings costs (5452 vs 3881; p = 0.001) and this did not include the lower costs of hospital care as it is not usual to keep people in hospital until complete healing.

In one trial, vacuum closure accelerated the healing of recalcitrant venous ulcers for in-patients on bed-rest treated with punch skin grafting. It was also associated with lower treatment costs. This trial is relevant to a small proportion of the leg ulcer population as few are offered skin grafting and long term hospitalisation.

Mixed wound populations

Five RCTs recruited a mixed population (Joseph 2000, Moues 2004, Jeschke 2004, Moisisdis 2004, Braakenburg 2006). Two studied the effect of vacuum therapy on fixation rates of grafts (Moisisdis 2004, Jeschke 2004), the others studied the effect of vacuum closure on wound healing. The studies included 190 wounds (in 177 people) due to, pressure (36%), trauma, infection, dehiscence, radiation, burns and venous insufficiency, and other unique causes such as melanoma.

Joseph (2000) randomised 24 people with 36 wounds (78% due to pressure, rest due to venous insufficiency, surgical wound dehiscence, radiation, trauma) to wet-to-moist gauze dressings covered by a film (changed three times a day) or vacuum closure changed every 48 hours. It is not clear if allocation was concealed and ulcers were larger in the vacuum assisted closure group; 38cc compared with 24cc. Assessment was supposed to be by personnel

unaware of allocation to the treatment groups at 3 and 6 weeks, but other investigators indicated that assessment could not be blinded (Braakenburg 2006). Ten patients were cared for at home, the remainder were in residential care or hospital in-patients. There was a greater reduction in wound volume in the vacuum group than the dressings group (78% compared with 30%) and the time to 90% reduction in volume was shorter for the vacuum group, even when adjusted for imbalances in the baseline characteristics (data not presented, authors p=0.04 log rank). Problems with this trial included the assumption that multiple ulcers were independent, and the imbalance in areas at baseline may be evidence of selection bias.

In a second study (Mouës et al 2004), 54 people who needed open wound management before surgical closure were randomised to moist gauze (changed twice a day) or vacuum therapy (continuous 125 mmHg) changed every 48 hours. Thirty seven percent of the wounds were secondary to pressure; the others were caused by infection, dehiscence or 'miscellaneous' aetiologies. The endpoint was time to a clean, red, granulating wound, and there was no difference between vacuum therapy (median 6 days) and moist gauze (median 7 days). The study reported a greater reduction in area in the vacuum group than conventional therapy (3.8% per day vs 1.7% per day; p<0.05). Problems with this trial include the lack of baseline data which means the difference in outcomes may be due to differences in baseline areas.

The third study included 65 people (66 wounds) with acute or chronic wounds secondary to surgery (48%), pressure (29%), diabetes (9%), trauma (8%), and venous insufficiency (6%)(Braakenburg et al 2006). They were randomised to vacuum (125 mmHg continuous) changed three times a week or conventional care using dressings from the formulary (hydrocolloids, alginates, acetic acid, Eusol). The outcome was time to complete granulation or being ready for grafting healing and Cox regression analysis showed no difference between groups (16 days with vacuum, 20 days with dressings; hazard ratio 1.33, 95% CI 0.74 to 2.4; log rank p = 0.32). Problems with this trial include the modest sample size.

Two small studies with methodological weaknesses reported a higher healing rate in people treated with vacuum than those treated with wet-to-moist gauze. One study (Braakenburg et al 2006) found no difference in time to achieve a granulated wound ready for grafting between various wound dressings and vacuum therapy.

Skin graft fixation

Two studies (n=34), evaluated vacuum therapy in fixing skin grafts (Jeschke et al 2004, Moisisdis et al 2004). In the first study, twelve people with large defects requiring grafting with an artificial skin replacement (Integra™, Johnson and Johnson, Hamburg, Germany) were ran-

domised to either standard graft fixation (compression dressings and daily dressing changes for 14 days) or fixation with fibrin glue and vacuum therapy (continuous 150 mmHg) (Jeschke et al 2004). Fifty percent of the wounds were traumatic, the rest were due to melanoma, burn, healing delay, decollement and fibroleimyosarcoma. The method of randomisation was not reported and the people in the vacuum group were older and had larger ulcers than the dressings group. The time to skin transplantation was shorter with fibrin and vacuum closure than compression alone (10 days compared with 24 days; $p < 0.002$). Graft take was higher with fibrin and vacuum closure (78% compared with 98%; $p < 0.003$). Problems with this trial include the lack of information on randomisation, the ulcers in the control group were smaller and the people were younger. In addition, it is not possible to determine whether this difference is due to the fibrin glue, vacuum therapy or a combination of both.

The second study (Moisisidis et al 2004) evaluated vacuum therapy in a study including 22 people with acute and chronic wounds requiring grafting (5 trauma, 4 burns, pressure ulcer, sternal dehiscence, wound infection, extravasation, necrotising fasciitis, degloving, venous insufficiency and cellulitis). Wounds were grafted and then each half (proximal/distal) was randomised to compression dressings or vacuum therapy (100 mmHg continuous). A hydrocolloid dressing at the junction of the two areas prevented transmission of pressure and dressings were left intact for five days. Outcomes were reported on 20 people. There was no significant difference in the degree of graft take at two weeks: 86% with vacuum and 87% with compression dressings. A qualitative appraisal of graft take by a clinician found this to be equivalent in 7 cases, worse with vacuum in 3 and better with vacuum in 10. Problems with this trial included the use of an unvalidated assessment scale used, blinded outcome assessment may not be possible, and the suction dressing may have also exerted a vacuum effect on the control dressing.

One very small study reported that vacuum therapy and fibrin fixation of Integra was associated with accelerated skin transplantation and graft take compared with compression dressing alone. One small study in which divided wounds were treated with vacuum therapy and dressings found no difference in degree of graft take.

COSTS

Two studies included formal analyses of costs (Moues 2004, Braakenburg 2006).

Moues (2004) found that vacuum therapy was associated with lower labour costs (233 minutes compared with 283; $p < 0.0001$) and higher material costs 2414 versus 215; $p < 0.0001$). As people treated with vacuum therapy were ready for grafting sooner, they had lower hospitalisation costs and this partly offset the higher treatment costs.

Overall, there was no difference in the costs of treatment (material, staff and hospitalisation) with vacuum and moist gauze. Moist gauze is not standard care in many settings, therefore the relevance of this finding is unclear.

Braakenburg (2006) reported that total costs per day were higher in the vacuum therapy group compared with the conventional group (material costs 259 euro cf 94 euro: labour 81 euro cf 176 euro). Because the vacuum therapy was used for fewer days, then the increased material costs were offset by lower labour costs, therefore the overall costs were not significantly different (353 euro with vacuum therapy and 273 euro with conventional dressings; $p = 0.09$).

In a hospital the reduced labour costs are unlikely to be realised by the organisation, and therefore the use of vacuum therapy may result in higher material costs with only a *potential* saving of nursing time, and similar or improved outcomes.

Modern wound dressings require changing less often than gauze and comparison of vacuum therapy costs using gauze as a comparison may be biased in favour of vacuum therapy. This is particularly of importance in countries where twice daily wet-to-dry gauze is no longer used to heal wounds. Future studies examining cost-effectiveness should use modern dressings as a comparator. None of the studies included the depreciation or repair costs of the machines, nor the cost of training nurses to apply, monitor and renew the vacuum dressings.

ADVERSE EFFECTS

A number of studies reported adverse effects associated with vacuum therapy. These include pain at the initiation of the vacuum (Braakenburg 2006), foam being left in the wound cavity, removal of foam leading to wound bed trauma (McCallon 2000), maceration of skin around the wound (McCallon 2000) and immobilisation of the patients as it requires connection to a pump for 22 hours per day. In one RCT (Vuerstaek 2006) people in the vacuum group had a lower quality of life than the control group in the first week of therapy, which rapidly increased after this time. The effect of vacuum therapy on quality of life was studied in a cohort study of 26 people (Mendonca et al 2007) where it was also reported that the use of vacuum closure was associated with a deterioration in health related quality of life (11/26 people). The authors surmised that this might be due to the limitations on undertaking activities of daily living (Mendonca 2007). One RCT also reported more adverse effects, particularly skin damage caused by the treatment in the vacuum group compared with the control group (7/30 vs 2/30) (Vuerstaek 2006). Some trials (e.g. McCallon 2000) mentioned the difficulties in maintaining the seal around the wounds, and the RNAO guidelines point out that nurses need high levels of training and skill to be able to use the vacuum therapy ►

effectively (RNAO 2002). In one trial the learning curve with the technology was specifically referred to (Braakenburg 2006) and nurses needed an average of two demonstrations of the system to be able to apply it with eroding the skin around the ulcer or the ulcer bed.

RECOMMENDATIONS IN GUIDELINES

Some clinical practice guidelines for the management of pressure ulcers, venous ulcers, and pressure ulcers have considered vacuum assisted closure within the search for effective interventions, usually as adjuvant to care after healing has not progressed. One guideline on diabetic foot disorders (Frykberg et al 2006) recommend it for use in initial foot ulcer treatment (page 19) for simple foot ulcers, for infected foot ulcers (page 29) as well as over exposed bone, tendons, and hardware (page 26) to promote granulation tissue. This is based on professional consensus; it does not grade the recommendations or link recommendations and evidence.

Two clinical practice guidelines for venous ulcers mention vacuum closure. The first guideline recommends it as a treatment to be used if conservative therapy does not work in 30 days (Grade B evidence: result of two or more trials (not RCTs), or a single RCT) (AAWC 2005). A later guideline (RCN 2006) concluded there was no research evidence that vacuum assisted closure speeds the healing of any wounds. Both Guidelines were completed before the single study in venous ulcers (Verstaek 2006) was published. In venous ulcers, therefore, the guidelines differ – one recommending vacuum closure for recalcitrant ulcers and the other not recommending it at all.

Four clinical guidelines in the management of pressure ulcers refer to vacuum closure. The 2002 Canadian guideline included a recommendation (grade B) that vacuum therapy could be recommended for chronic pressure ulcers, but no definition of chronicity was given. Grade B evidence required well conducted studies but no RCTs (RNAO 2002). A second guideline stated that vacuum therapy could be considered '*on an individual basis for those wounds that do not respond to more traditional therapies and osteomyelitis has been ruled out*' (Evidence grade C: observational studies or controlled trials with inconsistent results)(Folkedahl et al 2002). Topical negative pressure was recommended for recalcitrant stage III and IV wounds in a third guideline (WOCN 2003) (level of evidence = A: two or more supporting RCTs or a systematic review). The fourth guideline states that that using vacuum therapy should be based on a full patient assessment, previous positive effects of the therapy, patient preference, and practitioner's competence (evidence Grade D, i.e. based on consensus or cohort studies) (RCN 2005).

In pressure ulcers, therefore, guidelines recommend the use of vacuum assisted closure with levels of evidence from all points on the hierarchy of evidence for effectiveness,

even accounting for the fact that different evidence grading systems were used, from multiple RCTs/systematic review to consensus.

OUTCOMES USED IN VACUUM THERAPY TRIALS

There are a number of outcomes used in these trials. Accelerating time to complete ulcer healing, whether by grafting or by secondary intention, is the primary objective but as this may require months of follow-up many investigators report surrogate outcomes such as reduction in area or volume, or time to attainment of a clean ulcer bed. It is assumed that earlier debridement or surgery will lead to earlier closure but this is not clear from clinical studies how valid these surrogate outcomes are. One study used a qualitative measure of graft take using a simple scale, and the validity of this tool is not known. Assessing wound area / volume and wound bed outcomes in this area is complicated by the fact that vacuum therapy usually leaves marks on the wound or skin and hence the person assessing the wound is inevitably aware of the allocation (Moues 2004, Braakenburg 2006).

The use of wound volume as an outcome is problematic as in some wounds there are undermined wound edges, and changes in volume with patient position.

Wound area is not a sensitive indicator of healing in large wounds with considerable tissue loss as in the initial stages of healing there may be considerable reduction in wound depth and hence volume, but no change in area.

Bradley et al (1999) reported that imbalances in size of wound at baseline may lead to biased reporting if authors only present relative or absolute reduction in size (area or volume).

As there is no clear evidence of the validity of surrogate outcome measures, then complete wound closure should be used as the primary outcome, even if the vacuum therapy is only used for one part of care, and future studies should collect information on the validity of reduction in volume (both relative and absolute) and the time to surgery in predicting healing.

STUDIES IN PROGRESS

A number of studies of vacuum assisted closure have been mentioned in the literature. There were conference abstracts identified in this search describing another 8 trials (Orgill and Bayer 2004, Stannard 2004, Niezgoda 2004, Molnar 2004, Greer 2004, Bayer and Orgill 2004, John Lantis 2004, Stremitzer 2006). Two reviews (Samson 2004; Pham 2005) list 2 completed but unpublished RCTs, and three more ongoing RCTs in wounds healing by secondary intention. It is not possible, however, to determine whether there is any overlap in these reports as only one of the trials reported (Armstrong 2006) had a trial registration number.

CONCLUSION

There is no good quality evidence that vacuum therapy helps the healing of pressure ulcers or mixed populations of wounds. In people with diabetes and post-amputation foot wounds, there is some evidence that vacuum therapy leads to more rapid healing; whereas in simple diabetic foot ulcers there is no high quality evidence of an effect on healing. In chronic venous ulcers, vacuum therapy accelerated healing in people treated with bed rest and punch grafts, but few patients are likely to be offered hospitalization and bed rest due to the costs. Vacuum therapy appeared to help graft take when used in conjunction with fibrin glue.

Analysis of costs in two studies found that vacuum therapy is associated with lower staff costs and higher material costs if compared against traditional or regular formulary dressings. Local decision makers should determine if any reduction in staff time is likely given their pattern of care, as one of these studies used moist gauze needing changed 2-3 times a day. They may also consider the potential for

realizing the savings due to lower nursing time as it is unlikely to lead to lower staff costs as the nurses will be deployed elsewhere.

There are some adverse effects associated with vacuum therapy, such as pain, damage to skin around the ulcer, and for some, poorer quality of life initially as mobility is impaired. Care must be taken in application and renewal to ensure no damage is done to the wound bed, the seal is maintained and an appropriate treatment (foam/suction device/pressure) is selected. There have been no studies comparing outcomes in different treatment regimens and this seems to be determined from clinical experience.

Many trials are in progress or completed and it is important that their results are made available so that future summaries of effectiveness are based upon the full set of clinical trials rather than a selected sub-set which may lead to publication bias. ■

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