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VACUUM-ASSISTED WOUND CLOSURE THERAPY (V.A.C.®)

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Invitation.

This document was developed to assist decision-making in the McGill University Health Centre. All are welcome to make use of it. However, to help us estimate its impact, it would be deeply appreciated if potential users could inform us whether it has influenced policy decisions in any way.

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EXECUTIVE SUMMARY

Extensive and chronic wounds can take weeks or months to heal. The different types of wound treatments include dressings, compression bandages, debridement, topical antimicrobials, skin grafting and negative pressure. V.A.C.® is an adjunctive wound treatment that utilizes subatmospheric pressure and consists of a vacuum pump, a collection canister, connection tubings and specialized topical dressings.

Efficacy. Five technology assessment reports and one systematic review on V.A.C.® therapy have consistently concluded that there is insufficient evidence to justify recommending routine use of V.A.C.® therapy. After performing a systematic review of the most recent literature and reviewing the earlier original studies, the TAU Committee concurs with the conclusions of these previous publications.

Costs. The average estimated amortized capital costs and the costs of materials and nursing of in-hospital wound treatment with V.A.C.® may be approximately $360 per patient for one week of treatment, with higher and lower estimates depending on the nature of the wound and the extent of discharge, ranging from $303-$445. Estimated treatment costs of moist wound dressing carried out once per day would be $333 per week, ranging from $222 to $444. No cost-effectiveness analyses have been performed due to the lack of good quality efficacy data.

Recommendation 1. No additional V.A.C.® pumps should be purchased or rented until clear evidence of efficacy becomes available.

Recommendation 2. In view of the conviction of users of V.A.C.® therapy at the MUHC that this therapy is effective, the recent purchase of V.A.C.® equipment by the institution, and the absence of compelling published evidence of efficacy of V.A.C.®, the MUHC should urgently consider undertaking studies designed to establish the value of this treatment in the different clinical situations in which it is employed.

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FOREWORD

In December 2004, the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC) received a request from Ms. Marie-France Noel, Chair, MUHC Nursing Equipment Committee to evaluate the current clinical evidence for the use of vacuum-assisted closure (V.A.C.®) therapy in wound closure.

In the past four years, approximately 16 vacuum-assisted closure (V.A.C.®) pumps have been used at the MUHC at any given time on a rental basis. Based on this recent utilization rate, 15 V.A.C.® pumps were purchased in February 2005 in order to meet the needs of the patients treated at the MUHC (T. Alam, personal communication).

INTRODUCTION

Most wounds heal fairly rapidly. However, more extensive and chronic wounds can take weeks or months to heal, a process that may be further delayed by infection, vascular insufficiency, sustained pressure or other reasons[1].

The presence of difficult-to-treat wounds is a common problem[2]. Numerous treatment modalities are available, such as dressings, compression bandages, debridement, topical antimicrobials, skin grafting[3] and negative pressure[4]. In the MUHC, difficult-to-treat wounds are a frequent cause of increased hospital costs and prolongation of hospital stay. Since its approval by Health Canada in 2001[5], V.A.C.® therapy has been increasingly used.

Purported theoretical mechanisms of action of V.A.C.® therapy are improved circulation, decreased bacterial load, decreased edema, and increased tissue granulation, which are achieved through fluid control and mechanical stimulation[1]. V.A.C.® is normally used to decrease the wound dimensions to a size that allows the treatment to be continued with traditional moist dressings (T. Alam, personal communication). However, the evidence relating to the clinical efficacy of this treatment is sparse and mostly of poor quality. Moreover V.A.C.® technology has never been compared with other new competing technologies (eg artificial skin for venous stasis

ulcers). V.A.C.® has been the subject of numerous reviews of which six have appeared in the last 18 months. These have come to the following conclusions:

CCOHTA (Canadian Coordinating Office for Health Technology Assessment). March 2003. Based on the currently available evidence the clinical effectiveness of VAC therapy to heal chronic wounds is unclear[5].

ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures-Surgical). Dec 2003. In a review of six randomized controlled trials, no difference could be found between VAC and use of traditional gauze dressings for management of pressure sores and ulcers. However, foot ulcers managed with VAC therapy decreased by 28.4% surface area as opposed to those managed with saline-moistened gauze which increased by 9.5% (P. = 0.004) [6].

Center for Clinical Excellence. Monash. December 2003. "whilst VAC may offer advantages over other forms of wound dressings, these findings are currently not confirmed in any controlled studies identified in this report"[7].

Blue Cross Blue Shield Association. For AHRQ (Agency for Healthcare Research and Quality). December 2004. "Vacuum-assisted trials did not find a significant advantage for the intervention on the primary endpoint, complete healing, and did not consistently find significant differences on secondary endpoints and may have been insufficiently powered to detect differences"[8].

Evans and Land. Cochrane review. 2004. Reviewers conclusions. "The two small trials provided weak evidence suggesting that TNP may be superior to saline gauze dressings in healing chronic human wounds. However, due to the small sample sizes and methodological limitations of these trials, the findings must be interpreted with extreme caution"[9].

OHTAC (Ontario Health Technology Advisory Committee). December, 2004. "The clinical utility for VAC therapy in the context of chronic wound healing is unclear". It is recommended that the Ministry of Health "do not provide additional preferential funding for VAC therapy, based on the dearth of existing evidence of effectiveness"[10].

In striking contrast to the absence of convincing evidence of therapeutic efficacy, there is increasing clinical adoption of this treatment. According to a report from the Ontario Ministry of Health and Long-Term Care from 2004, about 800 V.A.C.® pumps are currently being rented in Canada[11], and the MUHC has recently purchased 15 VAC apparatuses after renting them for the past four years. Users of this technology whom we have consulted in the MUHC are very convinced of its value for assisting in closing many wounds, e.g. "Through VAC therapy we are now able to frequently achieve closure in wounds that would have previously necessitated full thickness grafts" (Dr T. Zadeh. Plastic Surgeon. Personal communication). The Ontario Health Technology Advisory Committee (OHTAC) in its recent recommendation predicted that, "Because V.A.C. therapy is readily available, easy to administer and potentially cost-saving, it may be used inappropriately, thus denying patients access to more effective interventions"[10]. Is the increasing use of this technology justifiable or is it the result of extensive and aggressive marketing?

METHODS

To estimate the clinical effectiveness of this intervention, the literature was reviewed to identify clinical comparative studies in humans concerning either the effectiveness or costs of V.A.C.® therapy. The methodology is described in Appendix 1. We included controlled studies with 9 or more subjects in either arm, and one crossover study involving seven subjects (see appendix 1).

To estimate the costs of the V.A.C.® therapy and the costs of the current "standard treatment" using advanced moist wound dressings, we estimated the in-hospital costs including nursing fees, materials costs, and capital equipment amortized over 5 years, based on present cost at the MUHC (see Appendix 3). Physicians' fees and all costs

incurred after discharge from the hospital were not included. It was assumed that the length of stay for patients undergoing either treatment would be the same.

STUDY RESULTS

We have identified 13 clinical studies[1 12 13 14 15 16 17 18 19 20 21 22 23] and one systematic review[9] that compared V.A.C.® to other treatment alternatives. The clinical studies included four randomized controlled trials (RCTs) [1 14 15 17], two non-randomized prospective studies[12 19] , one cross over study in which subjects received a randomly selected alternate two week treatments[18], one study in which different halves of wounds received V.A.C.® and moist dressing treatment[13], and five retrospective reviews[16 20 21 22 23]. These trials are summarized in Table one.

Table 1 – Study Characteristics and Results

Author (Year) Age.VAC/Control	**N VAC/C**	**Trial Type**	**Blind**	**Wound type**	**Outcome variable**	**Result§** VAC vs Control	**Significance**
Ford [15](2002) V42y / C 54y	20/15 wounds	RCT	Yes	Decubitus ulcers	Wound volume* Complete healing	-52% vs. -42% Diff.: -10% (95% CI: -43 , +23) 10% vs. 13%	NS. NS.**§**
Eginton[18](2003) Patients' age not provided	7 wounds	Crossover First treatment selected randomly	Yes	Diabetic foot	Wound area * Wound volume *	-16.4cm^2 vs +5.9cm^2 -59cm^3 vs –0.1cm^3	NS. p<0.005
Moisidis**[13](2004) 64y	20 patients	Split wound Treatment *	Yes	Large (25 Cm$^{2)}$) Awaiting Skin Graft	Epithelialization Graft appearance	No difference Better with VAC	NS. p<0.05
Moues[17](2004) 48y	29/25 wounds	RCT	Yes	Acute and chronic wounds	Time to surgery Wound area *	No difference -3.8%/day vs-1.7%/day Diff.: -2.1% (95% CI: (-11 , +6.5)	NS. NS.
Joseph[1](2000) V56y / C49y	12/12 patients	RCT	Yes	Chronic wounds	Wound volume * Wound depth	-78% vs -30% Diff. : -48% (-83 , -13) -66% vs -20% Diff. : -46 (-85 , -7)	p<.00001 p<0.00001
Wanner[14](2003) V49y / C53y	11/11 patients	RCT	No	Pelvic region pressure sores	Time to 50% wound volume *	No difference	NS.
Page[22](2003) V66y / C 60y	22/25 patients	Retrospective Consecutive	No	Foot wounds	Wound filling Wound closure Hospital stay	38days vs 80days No difference 20.1 days vs. 15.5days	p=0.04 NS. NS.
Scherer[21](2004) V33y / C 41y	34/27 patients	Retrospective Consecutive	No	Securing skin grafts	N repeat graft % Graft take Hospital stay	1 vs 5 No difference No difference	p=0.04 NS. NS.
Shilt[23](2004) V4y / C9y	16/15 patients	Retrospective Historical controls	No	Lawnmower injuries	N req. free flap Hospital stay	3 vs 8 17days vs 10days	p=0.04 NS.
Doss[20](2002) 66y	20/22 patients	Retrospective Not randomized	No	Post-sternotomy osteomyelitis	Treatment duration Hospital stay	17 days vs 23 days 27 days vs 33 days	p=0.009 p=0.03
Song[16] (2003) 63 y	18/17 patients	Retrospective Consecutive	No	Sternal wounds	Time to close	6 days vs 8 days	NS
Genecov[12](1998) 39-81 y	10 patients	2 sites on each patient..Prospectiv e Not randomized	Yes	Donor site of Split-thickness graft	Epithelialization rate	"Faster with VAC"	p=0.003
Catarino[19] (2000) V68y. / C66y	9/11 patients	Prospective Not randomized	No	Poststernotomy mediastinitis	Treatment failure Hospital stay after start of treatment	0 vs. 5 15 days vs. 41days	p=0.03 p=0.02

N= Number of subjects or wounds in subjects who completed the study. V= VAC therapy. C= Control therapy. RCT= randomized controlled trial. CI=confidence interval

* = Objective Measurement / **In this study of 22 subjects the wound area was divided into two parts, one receiving VAC therapy and the other moist dressings, with the allocation of area randomly selected.

*** In this study of 10 subjects, there were two graft donor sites on each patient. One was treated with VAC, the other served as control. Epithelialization on day seven was judged by examining (blinded) biopsies microscopically.

§ The 95% confidence interval or p-value of the difference in the outcomes shown as proportions was calculated by us if not provided in the studies.

Study defects

These studies have many defects, such as:

- The studies were very small, i.e., 7 to 34 patients in the V.A.C.® group[1 12 13 14 15 16 17 18 19 20 21 22 23].
- Possibly heterogeneous patient populations among the studies [1 12 13 14 15 16 17 18 19 20 21 22 23].
- Possible non-comparability of study groups in non-randomized studies[12 19 20 21 16,23 22].
- Inadequate description of baseline characteristics that may influence the outcome measure [13 15] , including baseline wound dimensions[12 15,16 14,17 19 20 23] .
- Outcome evaluation was not always performed by a blinded observer[14 16 19 20 21 22 23 17].
- In five [12 13 15 18 19] out of eight prospective studies[1 12 13 14 15 17 18 19] , 5%-40% of the patients did not complete the treatment for various reasons. Exclusion of patients not completing the treatment jeopardizes the internal validity of the studies.

As can be seen in table 1 these studies not only concern different types of wound, but V.A.C.® therapy is used with different objectives. For example, it may be used to prepare the wound surface for skin grafting[23], or to secure the skin graft in place[21], or even to accelerate epithelialization of the donor site[12]. Furthermore, the effect of its use is assessed in different ways. Thus, meta-analysis is not possible.

While the weight of the more credible evidence suggests that there is no benefit from V.A.C.® therapy, the results are inconsistent and the numbers of subjects involved in even the largest study are far too small to establish the absence of benefit in relation to the outcome measures that have been studied.

Of the five studies that reported length of hospital stay, two found hospital stay was shorter with VAC treatment[19 20] two found that it was longer[22 23], and one found that there was no difference[21].

Thus, while numerous and important methodological issues severely jeopardize both the internal and external validity of the identified studies(Appendix 2), their heterogeneity prevents combining the results into a meta-analysis. Consequently, we agree with the conclusions of the previous technology assessment reports and systematic review[5 6 7 8-11] that there is insufficient evidence to recommend the routine use of this technology. These conclusions are consistent with a Canadian consensus report published by wound care opinion leaders on the use of V.A.C.® who note, "because the costs of using adjunctive treatments, including V.A.C.®, are high, their use as first line therapy is usually inappropriate"[4]. The remarkable discrepancy between the lack of evidence in reported studies and the conviction of users that VAC therapy is beneficial remains unexplained.

Appendix 4 lists the complications reported in the different studies.

Economic Studies

We have identified six publications[11 24 25 26 27 28] and one review[29] that compared the costs of V.A.C.® to other alternatives. In these, V.A.C.® is estimated to cost: 40%, 18% and 17% less than the control therapy[24 25 26], the same or similar to control therapy[28 11], and 8.5% more than control therapy[27]. The review reported a cost saving of $1,623/patient/year[29]. However, none of these studies supply details about how the costs were calculated and how the efficacy measures included in the analyses were obtained (for more details see Appendix 3).

V.A.C.® USE AT THE MUHC

The MUHC previously rented V.A.C.® pumps and have recently purchased 15 V.A.C.® pumps. According to the draft of the MUHC Policy and Procedures on V.A.C.® therapy, it is used for the indications listed in table 2. Usage of V.A.C.® at the MUHC has increased from 2,075 days ($122,430) in the year 2002 to 3,485 days ($289,255) in 2005 (KCI Canada, Inc.). The expected length of in-hospital wound treatment with V.A.C.® varies between one and six weeks, and is reported to be comparable whether V.A.C.® or moist dressing treatment is used (Mr. T. Alam, personal communication).

Table 2 – Indications for V.A.C.® at the MUHC (source: V.A.C.® Therapy Policy and Procedures MUHC)

- Surgical open/dehisced wounds	- Enteric fistulas
- Diabetic ulcers	- Pilonidal sinuses
- Pressure Ulcers stage III-IV	- Radiation ulcers
- Chronic-static/non healing wounds	- Burns
- Arterial and venous insufficiency ulcers	- Traumatic wounds
- Adjunct to plastic surgery (skin graft/flap procedures)	- Incisions to decrease edema and prevent dehiscence

COSTS

The estimated costs of the V.A.C.® pump and other material are given in table 3. Normally, during V.A.C.® therapy, dressings are changed 3 times/week. For wounds treated by advanced moist dressings, the dressing changes are normally done every 24 hours unless the wound is infected, in which case dressings are changed every 12-hours[30]. Only the treatment costs incurred in the hospital were included in the calculations. Hospital overhead costs and the costs of physicians' fees are excluded.

We have estimated that the pumps, materials and nursing costs with V.A.C.® therapy would average around $360, ranging from $302 to $445, depending on wound type. By comparison the cost of advanced moist wound dressings changed once/day was estimated to be $333, ranging from $222 to 444 depending on wound type. These results should be interpreted with caution since costs of other procedures that may be required as a result of complications or lack of response to either treatment were not taken into account in our cost calculations.

The capital cost of each VAC instrument is $19,900. As V.A.C.® is a relatively new technology, it is not clear for how long each pump lasts. For example the classic V.A.C.® model had been in use for at least 5 years at the MUHC and the pumps were still in good conditions when they were replaced by a new model, V.A.C.® A.T.S. (T. Alam, personal communication).

Although V.A.C.® may decrease dressing changes, it may still be more costly than traditional dressings due to materials, and a longer time for dressing changes (table 3).

A cost-effectiveness analysis was not carried-out due to a lack of evidence of a difference in response between V.A.C.® and the control group. For the same reason, costs incurred by treatment of complications were not included in the cost analysis.

Table 3 – V.A.C.® ATS equipment cost (in Canadian dollars)

	V.A.C.®		Advanced moist wound dressing	
Equipment	**Unit cost**	**Cost per patient (1 week)**	**Unit cost**	**Cost per patient (1 week)**
V.A.C.® ATS pump	$19,900* (purchase) $81 / day (rental)*	**$80**§§	-	0
V.A.C.® ATS pump maintenance	$ 1,575†	**$31.5‡‡**	-	0
Dressings (includes tubing†)	Packages with 10**: C$380 (small) C$475 (medium) C$570 (large)	(using medium size dressing: $47.5/unit) **$142.5** ($47.5 x 3 (changes every 48 hours) (Extremes: $114 (small) , $171 (large)	C$ 15‡	Average use (average of 1.5 dressing changes/day)†: **157.5 ($15 x 1.5 x 7 days)** (Extremes: $105 (1x/day) - $210 (2x/day)
Other material¶	$3.5 per dressing change	**$10.5** (3 changes/week)	$3.5 per dressing change	Average use: **$36.8 ($3.5 x 1.5 changes x 7 days)** (Extremes: $24.5 (1change/day) - $49 (2 changes/day)
Canister	C$360 (with 10)** (changed 1/week or sooner)	Average use: 1 canister **$36** (Extreme: 2 canisters/week: $72)	-	0
Nursing fees	$39.59/hour§	Assuming 3 dressing changes/week Average time: 30 minutes†: **$59.4 (30 min, 3 times/week)** Extremes (15 minutes¶¶: $30 , 40 minutes†: $79.2)	$39.59/hour§	Average use: **$138.6 (1.5 dressing changes/day, 20 minutes each change†)** Extremes: $92.4 (1/day, 20 min.) - $185 (2/day, 20 min.)
Total cost (materials and nursing)	-	**Average: $359.9** (Extremes: $302 , $444.2)	-	**Average: S332.9** (Extremes:$221.9 - $444)

*Finance department, MUHC

** General stores, MUHC

‡‡ - Assuming 50 weeks of use per year

¶ Other material: $3.5 =$1.771 (1 dressing set) +$ 0.208 (8 4x4 inches pieces of gauze) + $1.10 (500ml saline solution) + $0.107 (1 abdominal pad) + $0.251 (1x 30cc syringe) + 0.027 (1x 18g needle)

Information provided by T. Alam (personal communication

† - Information provided by T. Alam (personal communication)

§ - Finance department, Mr. P. Tan

§§ - Amortizing the V.A.C. ® pump cost over 5 years, i.e., $19,900 / 5=$3980/year, $80/week (based on 50 weeks of use/year)

‡ - Source: Ontario Ministry of Long-Term Care[11] – According to T. Alam (personal communication), the cost of advanced topical dressings normally used varies between $10 and $20.

¶¶ Information provided by Ms. Nevart Hotakorzian (personal communication).

DISCUSSION

The published comparative studies did not show a consistent statistical or clinical difference in meaningful health outcomes between patients with complex wounds treated with V.A.C.® and other therapies. The quality of the evidence is poor, with small studies and inconsistent study methodology[1 12 13 14 15 16 17 18 19 20 21 22 23]. Therefore, we are lead to concur with the 5 other recent technology assessments[5 6 7 8 10,11] and one systematic review[9] that the available evidence does not support the routine use of V.A.C.®. While V.A.C.® may, under certain circumstances, require less nursing time due to less frequent dressing changes, any saving in nursing time may be offset by the increased material costs associated with V.A.C. treatments.

The strong opinion of users that this therapy is beneficial cannot be discounted. However, in the past TAU has consistently adhered to the policy that the introduction of an institutional policy that involves the use of public funds demands stronger evidence than would be necessary for an individual physician or patient deciding to undergo the same intervention. For this reason, any extension of V.A.C.® therapy should not be undertaken in the absence of new evidence. At the same time it would be consistent with the role of academic leadership appropriate for the MUHC to undertake a study to resolve the discrepancy between local expert opinion and the available evidence.

Recommendation 1. **No additional V.A.C.® pumps should be purchased or rented until clear evidence of efficacy becomes available.**

Recommendation 2. In view of the conviction of users of V.A.C.® therapy at the MUHC that this therapy is effective, the recent purchase of V.A.C.® equipment by the institution, and the absence of compelling published evidence of efficacy of V.A.C.®, the MUHC should urgently consider undertaking studies designed to establish the value of this treatment modality in the different clinical situations in which it is employed.

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APPENDIX 1 – SYSTEMATIC REVIEW METHODOLOGY

Literature Review

The literature search was performed by using the Pubmed and EMBASE databases, and the Cochrane Database of Systematic Reviews. The search terms used were:

- "vacuum" **or** "vacuum-assisted" **or** "VAC" or "negative pressure" **or** "suction dressing" **or** "subatmospheric" **or** "sub-atmospheric" **or** "subatmospheric pressure" **or** "NPWT" **and** "wound healing"

There were no restrictions for dates of publication (last search on March 27th 2005), however, only articles published in English and French were reviewed for relevance. The studies selected had to meet the following criteria:

- Studies in humans
- Comparative clinical studies, or economic studies, or systematic reviews

We included controlled studies with 9 or more subjects in either arm, and one crossover study involving seven subjects

Health technology agencies databases were also searched for technology assessment reports, systematic reviews and economic studies with the keywords "vacuum", "subatmospheric pressure", and "sub-atmospheric pressure" used individually. A list of the technology assessment agencies included in the search is given below.

The reference lists of the clinical studies, systematic reviews, and technology assessment reports selected were also searched in an attempt to find additional clinical studies that might have been missed during the literature search.

List of health technology assessment databases used in the literature search

Health Technology Assessment Agencies:

- CHSPR – Centre for Health Services and Policy Research (UBC) British Columbia
- ICES – Institute for Clinical Evaluative Sciences
- MCHP – Manitoba Centre for Health Policy
- INAHTA database – International Network of Agencies for Health Technology Assessment (list of members below)

Members of INAHTA (agencies included in the INAHTA database):

AÉTMIS - Agence d'évaluation des technologies et des modes d'intervention en santé

AHFMR - Alberta Heritage Foundation for Medical Research

ANAES - L'agence nationale d'accréditation et d'évaluation en santé

ASERNIP-S– Australian Safety & Efficacy Register of New Interventional Procedures - Surgery

CAHTA - Catalan Agency for Health Technology Assessment and Research

CCOHTA – Canadian Coordinating Office for Health Technology Assessment

CÉDIT – Comité d'évaluation et de diffusion des innovation technologiques

CMS – Center for Medicare and Medicaid Services

CMT – Center for Medical Technology Assessment (Sweden)

CVZ - College voor zorgverzekeringen

DACEHTA – Danish Centre for Evaluation and Health Technology Assessment

DIMDI – German Institute of Medical Documentation and Information

DSI – Danish Institute for Health Services Research

FinOHTA – Finnish Office for Health Care Technology Assessment

GR - Gezondheidsraad

ITA – Institute of Technology Assessment (Austria)

MSAC – Medical Services Advisory Committee (Australia)

NCCHTA - National Coordinating Centre for Health Technology Assessment

NHS QIS - NHS Quality Improvement Scotland

NHS – National Horizon Scanning Centre

NICE – National Institute for Clinical Excellence

NZHTA – New Zealand Health Technology Assessment

Ontario Ministry of Health and Long-Term Care

SBU – The Swedish Council on Technology Assessment in Health Care

SNHTA – Swiss Network for Health Technology Assessment

APPENDIX 2 - DESCRIPTION OF THE STUDIES INCLUDED IN THE REPORT

Studies	Sample size	Prospective / Retrospective	Randomized Method	Comparability between groups	Comparability in baseline wound size	Blinded (Y/N) Assessment	Patients not completing the study
Eginton[18]	N=10 (VAC=10)	Prospective Crossover design (2 weeks in each group)	Randomized (random numbers)	Each patient is their own control	Possibility of carry-over effect ?	Blinded assessment of wound dimensions	4 (did not complete procedures)
Ford[15]	N=28 (41 wounds) (VAC=20)	Prospective	Randomized (random letters)	Difference in age (1 parameter shown)	No information	Blinded wound evaluation	6 (did not complete treatment)
Moues[17]	N= 54 (VAC=29)	Prospective	Randomized (closed envelope)	Differences in underlying diseases	No information	Not clear	Not clear if all patients were included in the analyses
Joseph[1]	N= 24 (VAC=12)	Prospective	Randomized (closed envelope)	Differences in age, gender	Differences at baseline	Blinded wound evaluation	0
Wanner [14]	N=22 (VAC=11)	Prospective	Randomized	Diff. in underlying conditions	No information	Not clear	0
Genecov[12]	N= 15 (patients received VAC and Opsite in diff. sites	Prospective	Not randomized	Patients serve as their own control.	Information not available	Blinded biopsy evaluation	5 (did not complete the study)
Moisidis[13]	N=22 (each wound was divided in 2, half= VAC half =C	Prospective	Randomized	Each patient served as its own control	Each wound half received 1 treatment	Blinded wound evaluations	2 (lost to follow-up)
Catarino[19]	N=20 (VAC=9)	Prospective	Not randomized Treatment in diff. Period	No large diff. in parameters shown	Information not available	No	1 (did not complete study)
Doss[20]	N=42 (VAC=20)	Retrospective	Not randomized Treatment assigned by surgeon	No large diff. in parameters shown	Information not available	No	Only patients with complete treatment
Scherer[21]	N=61 (VAC=34)	Retrospective	Not randomized	No large diff. in parameters shown	Different graft size	No	Only patients with complete treatment
Song[16]	N=35 (VAC=18)	Retrospective	Not randomized	No large diff. in parameters shown	Information not available	No	Only patients with complete treatment
Page[22]	N=47 (VAC=22)	Retrospective	Not randomized	Some differences	VAC > large wounds	No	Only patients with complete treatment
Shilt[23]	N=31 (VAC=16)	Retrospective	Not randomised	Differences in age and presence of fractures	NA	No	NA

C=control / NA=not available

* patients who completed the treatment

APPENDIX 3 – COST STUDIES SUMMARY

Equipment costs reported

Author (year) Country	CCOHTA[5] Canada	ASERNIP-S[6] Australia	Ontario Ministry of Health and Long-term Care[11]
VAC pump rental fee	C$65/day	-	C$100* (pump & disposables)
VAC ATS pump rental fee	C$83/day	AU$ 65 / day	-
Mini-VAC pump rental fee	-	AU$ 58 / day	-
VAC unit cost	C$11,500 (includes battery	-	-
VAC ATS unit cost	C$19,900	-	-
VAC dressings cost	C$380-C$570 (pkge with 10)	-	-
VAC ATS dressings	C$425-C$635 (pkge with 10)	-	-
VAC canister (changed weekly)	C$260 (with 5) C$360 (with 10)	-	-
VAC ATS canister	C$290 (with 5) C$400 (with 10)	-	-

*Pump model not specified
VAC: vacuum-assisted closure

Treatment costs reported in the literature

Author (year) Country	Mendez-Eastman[30] US	Philbeck[25] US Diabetic foot ulcers	Philbeck[24] US Trunk or trochanteric wounds	Herscovici[28] US High-energy soft tissue injuries	Luckaz[26] UK Infected sternal wounds	Phillips and Rao[27]	Ontario Ministry of Health and Long-Term Care[11]	Milliman US Information from Neubauer et al. [29]
Treatment cost / day **Includes materials/pump and nursing fees**	US$ 100 (VAC)	-	Trunk or trochanteric wound US$149.96 (VAC)	US$ 103/day (VAC)‡ US$100/day (wet-to-dry dressings)‡	-	C$107.7/day (VAC) C$99.3/day (saline dressing)	With VAC pump rental C$124-129/day With VAC pump purchase C$94-$99 (C$60-$146 /day - traditional dressing)	-
Total treatment cost	-	US$ 23,066 (VAC) (US$ 27,899 for saline dressing*)	Area: 22cm^2 US$ 14,546** (VAC) (US$23,465 for saline gauze and pressure release)	-	$16,400 (VAC) ($20,000 sternal rewiring and closed irrigation)	-	-	Overall cost savings (VAC):† $1,623/pt/yr

* No details were given about the comparability of the patient populations used in each treatment group. Cost based on $100/day estimate by Mendez-Eastman[30], source for the cure rate estimates not provided. ‡ VAC: Nursing time assuming that sponges are changed 3 times per week. Wet-to-dry dressing: Nursing time assuming dressing are changed 3 times/day[28]. Excludes surgical fees and hospitalization costs in both cases[28]. Plus US$ 6,000 if a free tissue transfer is required[28]. † Original data not found in the peer-reviewed literature. Additional information on comparators and other information used in the cost calculation not provided.
Overall treatment cost savings of $1,623/pt/yr ($921 – inpatient / $3699 – home care / $324 long-term care). No information about how the result was obtained, i.e., the costs and efficacy in each group.
** Based on daily cost and 0.23 cm^2 wound closure rate observed in 43 patients
VAC: vacuum-assisted closure

APPENDIX 4 - COMPLICATIONS WITH V.A.C.®

The use of V.A.C.® therapy is associated with pain caused by pressure on the wound margins, and manipulation of the wound[4]. The pain may be associated with the amount of pressure applied, and in these cases the pressure can be controlled[11]. Other expected complications include possible pressure necrosis of the skin under the evacuation tubing and minor bleeding when the dressing is changed[31].

The table below summarizes the complications reported in the studies identified.

	Joseph[1] N=24	Song[16] N=35	Genecov[12] N=15	Argenta**[32] N=300
Pain	-	-	No difference betwee VAC and control groups	Pain associated with negative pressure was reported§ Pain requiring narcotics occurred in traumatic wounds
Granulation tissue growth into the pores of the tissue (bleeding)	-	-	-	Excessive ingrowth particularly if dressing kept > 48 hours
Difficulty achieving/maintaining negative pressure	-	-	-	-
Maceration of peri-wound tissue	-	-	-	-
Erosion of adjacent tissue	-	-	-	When positioned directly over bone or if patient lies on the tube
Fistulas	VAC=0 C=2 (11%)	-	-	1 case¶
Wound infection	VAC=0 C=6 (33%)	-	-	2 (5.4%) – due to overgrowth of granulation tissue
Osteomyelitis	VAC=1 (6%) C=2 (11%)	-	-	
Calcaneal fractures*	VAC=2 (11%) C=0	-	-	
Chronically draining wound	-	VAC=1 (7%) C: 1 (6%)	-	
Mediastinitis	-	VAC=1 (7%) C: 1 (6%)	-	
Omental flap losses	-	VAC=0 C: 2 (12%)	-	
Intestinal evisceration	-	VAC=0 C: 1 (6%)	-	
Hernia	-	VAC=0 C: 1 (6%)	-	

*Not considered as related to the wound treatment by the investigator
** Not a comparative study
§ The pain diminished within approximately 20 minutes. More discomofort was seen with stasis ulcers and chronic vasculitis lesions of lower extremity
¶ Foam was placed over compromised intestine in a debilitated patient who had eviscerated.