The accompanying article (The V.A.C. Veraflo Therapy system for infected wounds) published by National Institute of Health and Clinical Excellence (NICE) is a Medical Innovation Briefing (MIB), which provides advice on the use of the V.A.C.ULTA™ Negative Pressure Wound Therapy System with V.A.C. VERAFLO™ Therapy.

V.A.C. VERAFLO™ Therapy is designed for patients with a variety of open wounds who would benefit from vacuum-assisted drainage and controlled delivery of topical cleansing solutions over the wound bed.

The V.A.C.ULTA™ Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts. V.A.C. VERAFLO™ Therapy is not specifically indicated for the treatment of infection but can be used in the management of infected wounds along with good clinical practice such as antibiotic therapy and debridement.

Note: This article lists the classification of the device as Class II. For clarification, the V.A.C. VERAFLO™ Dressings are Class IIb and the V.A.C.ULTA™ Therapy Unit is Class IIa in the European Community.

11 Nimrod Way, Ferndown Industrial Estate, Wimborne, Dorset, UK, BH21 7SH
t: 0800 980 8880 | e: info@acelity.com | w: www.acelity.com

NICE advice

The V.A.C. Veraflo Therapy system for infected wounds

Medtech innovation briefing
Published: 2 September 2019
www.nice.org.uk/guidance/mib189

Summary

- The **technology** described in this briefing is the V.A.C. Veraflo Therapy system. It is used to promote healing in chronic and acutely infected wounds.
- The **innovative aspects** are that V.A.C. Veraflo Therapy system combines the use of negative pressure wound therapy (NPWT) and wound cleaning with topical solutions. Treatment is delivered in automated treatment cycles allowing wounds to be repetitively cleansed without the need for dressing removal.
- The intended **place in therapy** would be to replace normal NPWT in standard care in people with open infected wounds or chronic wounds that do not respond to standard care.
- The **main points from the evidence** summarised in this briefing are from 5 studies: a randomised control trial, 3 cohort studies with historic cohort control and a retrospective data analysis, including a total of 357 adults with acutely infected or chronic wounds in a secondary care setting. They show that the V.A.C. Veraflo Therapy system is more effective than standard care, including moist wound care and normal NPWT, in treating acutely infected or chronic non-healing wounds.
- **Key uncertainties** around the evidence are the lack of studies comparing the V.A.C. Veraflo Therapy system with the UK standard care for treating complex wounds.
- The **cost** of V.A.C. Veraflo Therapy system is £82.06 per wound per day. The **resource impact** would be greater than standard care because of the incurred costs of the device rental. The

- technology may offset these costs with potential savings related to decreases in dressing changes and nursing time, number of sharp debridements and shorter hospital stays.

The technology

The V.A.C. Veraflo Therapy system (KCI a subsidiary of Acelity LP Inc) combines negative pressure wound therapy (NPWT) and wound instillation with topical solutions for wound healing. The therapy system delivers automated cycles of wound cleansing, removal of infectious material and exudate and NPWT depending on the wound.

Before using the V.A.C. Veraflo Therapy system, the V.A.C. Veraflo dressing foam is applied to the wound bed, available in a variety of sizes. A V.A.C.Advance drape is then placed over the wound with a 3-cm margin to make sure there is full adhesion, with a small hole cut into the drape surface. The V.A.C. VERAT.R.A.C. pad can then be attached to the drape, using a stabilisation layer to ensure complete contact. The pad is then connected to the Veraflo Therapy system. This collects fluid and substances produced by the body in response to tissue damage from the wound into a single-use 500-ml or 1,000-ml canister. The V.A.C.system fill assist tool is used to determine and ensure an appropriate instillation volume has been applied and the SEAL CHECK leak detector is designed to minimise potential leaks.

The Veraflo Therapy system is primarily used for patients with open, infected wounds or chronic wounds, which are failing to heal.

Innovations

The Veraflo Therapy system differs from other NPWT therapies because it is designed to both apply and wash out a cleansing solution, as well as giving automated cycles of NPWT. The technology allows for repeated cleansing without needing dressing removal. This means potential reductions in nursing time, dressing changes and risk of contamination. The company claims it is the first device in the UK to allow combined instillation of fluids and removal of exudate at the same time as the delivery of NPWT.

Current care pathway

There are a number of indications that have the potential to result in acutely infected or chronic non-healing wounds, such as surgical site infections, diabetic foot problems and pressure ulcers, for which NICE has published recommendations and advice.

Care of acutely infected or chronic non-healing wounds is targeted towards promoting healing and

minimising risk of further complications. If infection of the wound is suspected, a microbiological sample is taken and an antibiotic prescribed to treat the causative organisms. The wound is treated with regular cleansing and debridement followed by the application of a dressing. Hospital staff choose a dressing that will promote healing and manage exudate on a case-by-case basis. Some wounds are treated with topical negative pressure therapy. Chronic non-healing wounds typically need more advanced dressings. Tissue viability nurses assess wounds with serious infections. Occasionally patients will be referred to a specialist for multidisciplinary care.

NICE has also issued guidance on the use of negative pressure wound therapy for the open abdomen, which recommends the use of NPWT in patients at risk of developing surgical site infections.

Population, setting and intended user

The V.A.C. Veraflo Therapy system would be used to treat open wound infections or wounds that do not respond to standard care and need additional therapy to promote healing and wound closure. The company claims wounds with high levels of exudate are likely to benefit from this treatment.

The V.A.C. Veraflo Therapy system is applied by healthcare professionals in a hospital setting. Healthcare staff using the technology will need training provided by the company. The company provides online resources to reinforce the training.

Costs

Technology costs

The V.A.C. Veraflo Therapy system is rented from the company and costs on average £82.06 per wound per day, including device and consumables (calculated using the total cost of dressing changes, consumables and device rental throughout the treatment). All information relating to the cost of the technology has been supplied by the company.

Table 1 Cost of V.A.C. Veraflo Therapy system per wound per day

Description	Cost per day	Additional information

Device rental	£16.00	–
Average dressing cost	£46.75	Available in different sizes. Dressing changes estimated to be once every 2 days. The per day cost is calculated as an average of the total dressings used throughout the treatment.
Canister	£15.02	–
Cassette	£2.98	–
Saline	£1.31	–
Sum of above components	£82.06	–

Costs of standard care

No standard list of dressings for acutely infected or chronic wounds has been identified. The costs described below are for a selection of dressings in the BNF. A full list of products, including secondary dressings and accessories, can be found at BNF wound management.

Table 2 Cost of dressings used in standard care

Dressing	Size range	Cost range
Absorbent cellulose dressing	10 cm×10 cm to 60 cm×70 cm	£0.19 to £13.88
Soft polymer dressing (cellulose dressing)	5 cm×5 cm to 30 cm×20 cm	£1.49 to £10.26
Soft polymer dressing (with absorbent pad)	7.5 cm×7.5 cm to 20 cm×50 cm	£0.90 to £27.39
Soft polymer dressing (without absorbent pad)	5 cm×7 cm to 35 cm×60 cm	£1.12 to £39.83
Hydrocolloid fibrous dressing	5 cm×5 cm to 25 cm×30 cm	£0.97 to £10.37
Polyethane foam dressing	5 cm×5 cm to 20 cm×20 cm	£0.71 to £3.20

Antimicrobial dressing	5 cm×5 cm to 20 cm×50 cm	£0.18 to £64.13
Super absorbent dressing	5 cm×5 cm to 20 cm×20 cm	£0.83 to £25.00

Resource consequences

Currently, the technology is being used in 85 NHS trusts across the UK. Adopting The V.A.C. Veraflo Therapy system would involve a regular extra cost of, on average, £82.06 per wound per day. The company claims these incurred costs will be offset by later reductions in healthcare resources.

The company claims, based on findings published in a clinical and cost-effectiveness outcomes study (Gabriel et al. 2014), that the use of the V.A.C. Veraflo Therapy system could reduce patients' length of hospital stay by 39%, and reduces the number of debridements from 4.2 to 2 in cases of acutely infected or chronic non-healing wounds.

The cost of the device includes all necessary training to NHS staff and online training resources.

Regulatory information

V.A.C. Veraflo Therapy system is a CE-marked class II medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics and others.

Some people are more likely to have poor wound healing because of their age, ethnicity or medical condition for example diabetes or renal disease. Age, disability and race are protected characteristics under the 2010 Equality Act.

Case series have reported the use of the V.A.C. Veraflo Therapy system in the treatment of infections after mastectomy for women with breast cancer. Cancer is considered a disability under the 2010 Equality Act. Sex also is a protected characteristic under the 2010 Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 5 studies including 357 patients in total.

This evidence base consists of 1 randomised control trial and 3 cohort studies with retrospective controls and a retrospective analysis. Overall, the evidence base is supportive of the technology.

Table 3 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The studies in table 3 highlight the use of the V.A.C. Veraflo Therapy system for managing chronic and acutely infected wounds. In general, the outcome measures reported in the evidence base are appropriate indicators of clinical effectiveness such as days until wound closure and length of hospital stay. The evidence base lacks randomised controlled trials comparing the technology with standard care or an equivalent alternative. None of the studies were blinded because of the physical differences between the technology and the comparators. The cohort studies with retrospective controls are limited because of the potential for results being confounded by variables, which were not controlled for such as changes in hospital procedure or selection bias. Also, the way the technology is used and the procedures it is compared with are not consistent across the evidence base, making it difficult to draw clear conclusions. Finally, none of the studies were done in the UK and may not be generalisable to the NHS.

Table 3 Summary of selected studies

Omar et al. (2016)	
Study size, design and location	Prospective treatment of infected wounds with V.A.C. Veraflo Therapy system compared with retrospective matched pairs treated with NPWT in 20 patients. Germany.

Intervention and comparator(s)	Intervention: V.A.C. Veraflo Therapy system with saline. Comparator: NPWT.
Key outcomes	The study identified a trend which indicated that V.A.C. Veraflo Therapy system with saline resulted in fewer days in hospital and faster wound healing compared with NPWT but this was not statistically significant (p=0.43 and p=0.36).
Strengths and limitations	The study's outcome measures are relevant to clinical effectiveness. Between-group variances were controlled for using matched pairs and tested statistically. The study is limited by a small sample size and retrospective cohort comparison. The study had support from the company for the surgical materials.
Kim et al. (2015)	
Study size, design and location	Randomised control trial (n=100 ITT, n=83 per protocol) comparing clinical effectiveness of V.A.C. Veraflo Therapy with saline and V.A.C. Veraflo Therapy with PHMH in 83 people with infected wounds. US.
Intervention and comparator(s)	Intervention: V.A.C. Veraflo Therapy system with PHBM. Comparator: V.A.C. Veraflo Therapy. System with normal saline.
Key outcomes	Patients who had normal saline had their final surgical procedure in significantly fewer days than the group treated with PHMB (5.7±3.6 and 7.5±4.4; respectively; p=0.04). There was no significant difference in length of hospital stay between the 2 groups.
Strengths and limitations	This was a well-designed randomised, comparative study with a relatively large sample size. The study compares various uses of the technology but does not compare the technology against standard care or equivalent treatments, limiting its relevance. The first author has previously had research and consulting funding from the company; however, this study was not financially supported by the company.
Gabriel et al. (2014)	

Study size, design and location	Retrospective analysis of the use of V.A.C. Veraflo Therapy system in 82 patients with the treatment of trunk and thoracic wounds. US.
Intervention and comparator(s)	Intervention: V.A.C. Veraflo Therapy system. Comparator: NPWT.
Key outcomes	Statistically, patients who had the V.A.C. Veraflo Therapy experienced significantly fewer days in hospital compared with the NPWT cohort (average of 8.1 days and 27.4 days, respectively; $p<0.0001$). The V.A.C. Veraflo Therapy system cohort's wounds took significantly fewer days to close than the NPWT cohort (average of 4.1 days and 20.9 days, respectively; $p<0.0001$) as well as significantly fewer debridements (average of 2 and 4.4, respectively; $p<0.0001$). A hypothetical economic model estimated V.A.C. Veraflo Therapy system to be a more cost-effective treatment than NPWT.
Strengths and limitations	This is a reasonably sized comparator study. The outcome measures appropriately address clinical effectiveness and resource impact. The study is limited by a change in facility protocol in relation to treating infected wounds which occurred during the data collection period, this will likely confound the results of the study. Cohort demographics were reported to be similar but were not tested for statistical difference and wound size data were not included. Named authors contributing to statistical and economics analysis work for the manufacturer.
Kim et al. (2014)	
Study size, design and location	Retrospective cohort control study comparing NPWT with various uses of V.A.C. Veraflo Therapy system in 142 patients with acutely or chronically infected wounds. US.
Intervention and comparator(s)	Intervention: V.A.C. Veraflo Therapy System with instillation and dwell time of 20 minutes. Intervention: V.A.C. Veraflo Therapy System with instillation and dwell time of 6 minutes. Comparator: NPWT.

Key outcomes	Significantly fewer operative visits were reported in both V.A.C. Veraflo Therapy system groups (VAC6, 2.4±0.9 and VAC20, 2.6±0.9) compared with NPWT (3.0±0.9; p≤0.05). Similarly, time to final procedure was significantly reduced in both V.A.C. Veraflo Therapy system groups (VAC6, 7.8 days±5.2 and VAC20, 7.5 days±3.1) compared with the NPWT group (9.23 days±5.2; p≤0.05) and patients in the VAC20 group (11.4 days±5.1) had a significantly shorter stay in hospital compared with the NPWT group (14.92 days±9.23; p≤0.05).
Strengths and limitations	This study was a relatively large comparator study accounting for various uses of the technology. Relevant multivariate statistics and a confidence level of 95% were applied to compare cohorts. MANOVA tests assume normal distribution and equal variance, the study does not report outcomes of normality or equal variance tests. Significant differences in cohort demographics, including a higher percentage of people of African family origin in the V.A.C. Veraflo Therapy System arms and variance in the wound locations included in the VAC20 group compared with the other 2 cohorts. The retrospective nature of the study prevents the control of selection bias. Volume of topical solution and duration of NPWT were not controlled for. The first author is a consultant for the company.
Gabriel et al. (2008)	
Study size, design and location	Comparison of prospective use of V.A.C. Veraflo Therapy system with retrospective use of moist wound care in 30 patients with trunk and extremity wounds. US.
Intervention and comparator(s)	Intervention: V.A.C. Veraflo Therapy system with silver nitrate. Comparator: Standard care, moist standard wound care.

Key outcomes	Patients who had the V.A.C. Veraflo Therapy with silver nitrate had significantly fewer days of treatment compared with patients who had moist standard wound care (9.9±4.3 and 36.5±13.1, respectively; p<0.001) and spent fewer days in hospital (14.7±9.2 and 39.2±12.1, respectively; p<0.001). In all patients who had the V.A.C. Veraflo Therapy, the infection cleared compared with 66.7% of patients who had moist standard care (p≤0.04). The V.A.C. Veraflo Therapy system group experienced significantly fewer days before the wound was free from clinical infection (6.00±1.46 days and 25.40±6.57, respectively; p<0.001) and until the wound closed (13.20±6.75 and 29.60±6.54 respectively; p<0.001).
Strengths and limitations	There was no significant between-group variance in patient demographic information and wound characteristics. The study compared the technology with standard care and outcome measures addressed clinical effectiveness. The study is limited by the retrospective cohort comparison. The use of silver nitrate antimicrobial solution in the V.A.C. Veraflo Therapy system arm makes it difficult to attribute the findings to the technology alone. The first author is a member of the company's speakers bureau and clinical advisory panel. The authors received editorial assistance from the company.
Abbreviations: ITT, intention to treat; NPWT, negative pressure wound therapy; PHBM, polyhexanide plus 0.1% betaine; VAC6, V.A.C. Veraflo Therapy System with 6-minute instillation and dwell time; VAC20, V.A.C. Veraflo Therapy System with 20-minute instillation and dwell time.	

Recent and ongoing studies

- Negative pressure wound therapy with instillation of saline solution versus collagenase ointment in grade 3 or higher pressure ulcers. ClinicalTrials.gov identifier: NCT03722485. Status: ongoing. No results published. Indication: Pressure ulcer. Devices: V.A.C.Ulta Therapy Unit, KCI.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Four specialists were familiar with the technology, 3 of whom have used the technology.

Level of innovation

Three specialists consider the technology to be innovative compared with usual care in the NHS, while 1 feels it is a more advanced version of technology used in current care. Two commented that the instillation aspect of the technology is innovative. One acknowledged that the technology has been available commercially outside of the UK since 1996.

Potential patient impact

Three specialists commented that the technology has the potential to reduce a patient's length of stay in hospital and all 4 agreed it is likely to reduce wound infection. Two commented that the technology improved wound healing. All believe the technology has the potential to improve patient care and outcome.

Potential system impact

Two specialists felt the technology would allow for an earlier transition from secondary care to primary care. One felt the technology would reduce staff time spent on wound care. One commented that the technology is likely to be cost incurring, the remaining 3 were unclear about the cost saving potential of the technology. Three commented that the technology is limited to an inpatient setting unlike normal NPWT which is also used in outpatient and community run care pathways.

General comments

Two specialists considered the technology would be used as well as standard care. One believes the technology will replace current practise and 1 feels the technology will replace current care in the first stage of complex wound treatment. One specialist commented that the evidence base primarily investigates the effect of the technology in acute infected wounds and does not fully address the technology's efficacy in chronic wounds.

Specialist commentators

The following clinicians contributed to this briefing:

- Professor Michael Clark, commercial director, Welsh Wound Innovation Centre. Conducted funded research in medical devices within the Welsh Wound Innovation Centre.

- Mr Haitham Khalil, consultant oncoplasty and reconstructive surgeon, Division of Plastic and Reconstructive Surgery, University Hospitals Birmingham. Invited as a speaker to the Veraflo Innovation Council Frankfurt 2018 and Veraflo meeting Cambridge 2019 for which he received an honorarium payment.
- Mr David Russell, consultant vascular surgeon and honorary clinical associate professor, Leeds General Infirmary. Involved in various research trials within wound care for which he has received consultancy fees. Organisations supporting these trials included URGO, Integra Lifesciences and the NIHR HTA.
- Dr Fania Pagnamenta, clinical academic nurse consultant (tissue viability), Newcastle upon Tyne Hospitals NHS Foundation Trust. Declared no interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-3523-9