



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

Vacuum-assisted closure for enterocutaneous fistula

May 2007



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



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID: S000034

NAME OF TECHNOLOGY: VACUUM-ASSISTED CLOSURE

PURPOSE AND TARGET GROUP: FOR THE MANAGEMENT OF ENTEROCUTANEOUS FISTULAS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input checked="" type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Argentina	✓		
Brazil	✓		
New Zealand	✓		
Northern Ireland	✓		
United States	✓		

IMPACT SUMMARY:

Vacuum-assisted closure therapy has been previously used to treat open or infected wounds. The use of this technology to treat enterocutaneous fistulas has only recently been reported in the literature. The V.A.C.[®] Therapy[™] system is manufactured by Kinetic Concepts, Incorporated (Texas, United States).

BACKGROUND

A fistula is an abnormal connection between two epithelialised surfaces (Gunn et al. 2006). An enterocutaneous fistula (also called gastrointestinal fistula) communicates between the gut (stomach, small or large bowel) and skin with the loss of gut content (Gunn et al. 2006). The majority of enterocutaneous fistulas (75% to 85%) are associated with previous operations. These may include operations for inflammatory bowel disease (e.g. Crohn's disease), division of adhesions, cancer, pancreatitis and emergency procedures on patients who have been poorly prepared for emergency surgery or who are malnourished (Berry and Fischer 1996, Falconi and Pederzoli 2002). A minority of patients (15% to 25%) may develop an enterocutaneous fistula without a preceding operation. This may occur following trauma (e.g. after penetrating wounds) or in association with radiation enteritis, diverticular disease, pancreatic or gynaecologic malignancies, perforated duodenal ulcers or inflammatory processes (e.g. infection or inflammatory bowel disease) (Falconi and Pederzoli 2002).

An enterocutaneous fistula may be classified according to the output level of the fistula (Gunn et al. 2006). This refers to the amount of fluid lost from the fistula over a 24 hour period (Medeiros et al. 2004). If the effluent from the fistula is digestive in nature, the skin will become excoriated and this will cause significant pain (Gunn et al. 2006). This loss of fluid and associated electrolytes, trace elements and proteins, may result in dehydration and finally malnutrition (Berry and Fischer 1996). In more extreme situations, sepsis, multi-organ failure and bleeding may occur (Falconi and Pederzoli 2002).

Because the spontaneous closure rate for an enterocutaneous fistula is low (between 30% and 40%), patients can expect to be in hospital for up to three months (Li et al. 2003).

The treatment of an enterocutaneous fistula remains challenging and is focused on correcting fluid and electrolyte imbalances, minimising malnutrition and controlling sepsis (Dudrick et al. 1999). Management of these fistulas usually consists of delineation of the anatomy of the fistula, restricted oral intake and total parenteral nutrition (Chang et al. 2000). His approach may allow the fistula to close. If not successful, an operation may be required to remove the segment of the intestine involved (Chang et al. 2000).

The use of vacuum-assisted closure (VAC) therapy was first reported in 1993 for the treatment of open or infected wounds (Fleischmann et al. 1993). Since then, VAC therapy has proved to be effective in improving healing rates in acute and chronic open wounds (Argenta and Morykwas 1997; Joseph et al. 2000). An enterocutaneous fistula was initially considered a contra-indication to the use of VAC therapy but recently this has been re-considered (Argenta et al. 2006).

Kinetic Concepts, Incorporated (Texas, United States) manufactures the V.A.C.[®] Therapy[™] system. An open-cell polyurethane foam (pore size 500 to 600 µm) is placed into the wound and the site is sealed with an adhesive dressing. The vacuum system is then applied to create a continuous sub-atmospheric (also known as negative) pressure environment at the fistula site. This allows fluid to be removed from the wound and efficiently collected in a purpose-designed canister, promoting healing.

CLINICAL NEED AND BURDEN OF DISEASE

Estimating the frequency of enterocutaneous fistulas is difficult. It is affected by numerous surgeon and patient related factors (Falconi et al. 1999). A literature search did not provide information on the incidence and prevalence of enterocutaneous fistulas in Australia or in any other country.

Mortality rates for patients with enterocutaneous fistulas have ranged between 5.5% to as high as 30% (Kaur and Minocha 2000; Li et al. 2003).

DIFFUSION

The use of VAC therapy for enterocutaneous fistulas has not yet gained widespread acceptance (Gunn et al. 2006). There have been no comparative studies published.

COMPARATORS

Other treatment options for enterocutaneous fistulas include (Draus et al. 2006):

- biologic fibrin glue injection;
- somatostatin analogs;
- fistulotomy

SAFETY AND EFFECTIVENESS ISSUES

A case series study by Medeiros et al. (2004) reported the use of VAC therapy in combination with a normal diet in 74 patients with postoperative enterocutaneous fistulas. The patients in this study were likely to have a favourable outcome because they did not require total parenteral nutrition and were not seriously ill. The fistulas had been present for at least 7 to 10 days and were at least 10 cm long. Fifteen patients were classified as having high¹ output fistulas, while 35 were classified as moderate² and 24 as low³ output.

Although the V.A.C. Therapy system was not used, the sub-atmospheric pressure treatment described was similar. Briefly, after drain removal (if present), a Foley catheter was positioned in the fistulous opening so that the tip of the catheter was in the tract but outside the fistulated viscera. The catheter balloon was then inflated to seal the fistula tract. Sub-atmospheric pressure was applied using a negative pressure flask that was changed daily for five days, after which the Foley catheter was withdrawn. If the fistula persisted, the catheter was re-inserted and the sub-atmospheric pressure resumed for a second five-day period. If necessary, a third five-day treatment was performed.

No deaths were reported. The fistulas closed in 92% (68/74) of patients. The remaining six patients underwent surgical closure supplemented with enteral nutrition by jejunostomy (Table 1). Treatment failure was significantly higher in high output fistulas, compared to moderate and low output fistulas ($p < 0.05$). Patients with higher levels of serum albumin (≥ 3.5 g/dl) were also more likely to achieve fistula closure ($p < 0.05$).

Table 1: Number of patients achieving fistula closure according to output classification and intervention

Fistula Output Classification	Vacuum Closure	Surgical Closure
High output	11	4
Moderate output	34	1
Low output	23	1
Total number of patients	68	6

¹ High output fistula: defined as fluid loss greater than 500 mL over a 24-hour period.

² Moderate output fistula: defined as fluid loss between 200 and 500 mL over a 24-hour period.

³ Low output fistula: defined as fluid loss less than 200 mL over a 24-hour period.

Of the fistulas that healed, 48 (65%) closed after five days of treatment; 16 (22%) closed after 10 days; and four (5%) closed after 15 days. The difference between these rates was statistically significant ($p < 0.0001$). The single patient with a low output fistula that did not close had a caecal post-appendectomy fistula. While most of the patients were treated in hospital, seven with low output fistulas were treated as outpatients. In each of these cases closure was achieved after five days (Medeiros et al. 2004).

Another case series study by Gunn et al. (2006) described their experience with the V.A.C. Therapy system in patients with enterocutaneous fistula that had not resolved after surgical treatment. Nine patients with low output and six patients with high output postoperative fistulas were included. The fistulas were located in the colon and small bowel ($n = 1$), small bowel ($n = 11$) and colon ($n = 3$).

Unlike the previous study of Medeiros et al. (2004), dressings were changed three times per week. Patients were allowed enteral feeds as tolerated. If the fistula output thickened and affected the negative pressure the patient was placed on restricted oral intake.

During the mean follow-up period of 3 months (range 2 to 5 months), no deaths or other significant adverse events were reported. Successful closure was achieved in 73.3% (11/15) of patients using the V.A.C. Therapy system, with no recurrences. The mean time to fistula closure was 14 days (range 9 to 22 days). The authors noted that within several days of initiating treatment the fistula output decreased. This trend continued until output ceased completely, at which time the therapy was discontinued. The fistulas failed to close in four (26.7%) patients, all of whom had bowel mucosa visible in the abdominal wound. The authors determined that absence of visible mucosa and older age were both associated with increased fistula closure rates ($p = 0.0007$ and $p = 0.0271$, respectively) (Gunn et al. 2006).

COST IMPACT

The direct cost of the V.A.C. Therapy system is as follows (Woodfield et al. 2006).

- Pump: approximate cost of AU\$7970, but can be hired for AU\$62 per day.
- 500 mL canister: AU\$67.
- Large and medium foam dressings: AU\$85 and AU\$72, respectively.

It has been suggested that for certain clinical applications the V.A.C. Therapy system may potentially reduce the number of days patients spend in hospital (Woodfield et al. 2006).

Table 2: Medical Benefits Schedule of fees for procedures related to the treatment of enterocutaneous fistulas (Department of Health and Ageing 2007)

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Enterocutaneous fistula: Radical repair of (involving extensive dissection and resection of bowel)	30382	\$1,154.85	70

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

No issues were identified from the retrieved material.

RECOMMENDATION:

The current evidence on using VAC therapy to treat enterocutaneous fistulas is limited. Only two case series studies were identified, although several case reports have also been published. Despite the positive results presented by these two studies, comparative studies with larger patient numbers and longer follow-up periods are required. Due to the potential benefits of this procedure within the healthcare system, VAC therapy for enterocutaneous fistulas will be monitored for future developments.

SOURCES OF FURTHER INFORMATION:

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Goverman J, Yelon J, Platz J, Singson R, Turcinovic M. The "fistula VAC," a technique for management of enterocutaneous fistulae arising within the open abdomen: Report of 5 cases. *The Journal of Trauma Injury, Infection, and Critical Care* 2006; 60(2): 428-431.

Hyon S, Martinez-Garbino J, Benati M, Lopez-Avellaneda M, Brozzi N, Argibay P. Management of a high-output postoperative enterocutaneous fistula with a vacuum sealing method and continuous enteral nutrition. *American Society for Artificial Internal Organs Journal* 2000; 46(4): 511-514.

Nienhuijs S, Manupassa R, Strobbe L, Rosman C. Can topical negative pressure be used to control complex enterocutaneous fistulae? *Journal of Wound Care* 2003; 12(9): 343-345.

LIST OF STUDIES INCLUDED

Total number of studies 2
Level IV intervention evidence

SEARCH CRITERIA TO BE USED:

Vacuum assisted closure
VAC
Negative pressure
Sub-atmospheric pressure
Fistula
Enterocutaneous fistula
Gastrointestinal fistula

REFERENCES:

Argenta L, Morykwas M. Vacuum-assisted closure: a new method of wound closure and clinical treatment: clinical experience. *Annals of Plastic Surgery* 1997; 38(6): 563-577.

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Berry S and Fischer J. Classification and pathophysiology of enterocutaneous fistulas. *Surgical Clinics of North America* 1996; 76(5): 1009-1018.

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Department of Health and Ageing. Medicare Benefits Schedule. Last updated 2007. <http://www9.health.gov.au/mbs/> [Accessed March 2007].

Draus J, Huss S, Harty N, Cheadle W, Larson G. Enterocutaneous fistula: Are treatments improving? *Surgery* 2006; 140(4): 570-578.

Dudrick S, Maharaj A, McKelvey A. Artificial nutritional support in patients with gastrointestinal fistulas. *World Journal of Surgery* 1999; 23(6): 570-576.

Falconi M, Pederzoli P. The relevance of gastrointestinal fistulae in clinical practice: A review. *Gut* 2002; 49(Suppl 4): iv2-iv10.

Falconi M, Sartori N, Caldiron E, Salvia R, Bassi C, Pederzoli P. Management of digestive tract fistulas. *Digestion* 1999; 60(Suppl 3): 51-58.

Fleischmann W, Strecker W, Bombelli M, Kinzl L. Vacuum sealing as a treatment of soft tissue damage in open fractures [German]. *Unfallchirurg* 1993; 96(9): 488-492.

Gunn L, Follmar K, Wong M, Lettieri S, Levin L, Erdmann D. Management of enterocutaneous fistulas using negative-pressure dressings. *Annals of Plastic Surgery* 2006; 57(6): 621-625.

Joseph E, Hamori C, Bergman S, Roaf E, Swann N, Anastasi G. A prospective, randomized trial of vacuum-assisted closure versus standard therapy of chronic non-healing wounds. *Wounds* 2000; 12(3): 60-67.

Kaur N and Minocha V. Review of a hospital experience of enterocutaneous fistula. *Tropical Gastroenterology* 2000; 21(4): 197-200.

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Medeiros A, Aires-Neto T, Marchini J, Brandao-Neto J, Valenca D, Egito E. Treatment of postoperative enterocutaneous fistulas by high-pressure vacuum with a normal oral diet. *Digestive Surgery* 2004; 21(5-6): 401-405.

Woodfield J, Parry B, Bissett I, McKee M. Experience with the use of vacuum dressings in the management of acute enterocutaneous fistulas. *ANZ Journal of Surgery* 2006; 76(12): 1085-1087.

PRIORITISING SUMMARY UPDATE (2008)

REGISTER ID:	S000034
NAME OF TECHNOLOGY:	VACUUM-ASSISTED CLOSURE
PURPOSE AND TARGET GROUP:	FOR THE MANAGEMENT OF ENTEROCUTANEOUS FISTULAS

A search of relevant databases was conducted in April 2008, following the recommendation in May 2007 that Vacuum-assisted closure for enterocutaneous fistula be monitored for 12 months. Nine studies including three case series and five case reports were retrieved. Two case series studies were included in this update.

2008 SAFETY AND EFFECTIVENESS ISSUES

Draus et al. 2006 studied the aetiology, treatment and outcome of enterocutaneous fistulas in 106 patients (58 male and 48 female, median age 52 years). The study aimed to assess the authors' current treatment methods and outcomes of enterocutaneous fistulas, with newer therapies including octreotide, fibrin glue and vacuum-assisted closure (VAC).

Measurements assessed were fistula origin, fistula output, etiology, length of hospital stay, type of therapy selected and mortality. The fistula origin was the small bowel (n = 67), colon (n = 26), stomach (n = 8) and duodenum (n = 5). The fistulas were characterised as being high output (n = 31) (greater than 200 mL/day), low output (n = 44), and or of unknown output with no record of volume (n = 31). Twenty four patients received Octreotide as therapy. In eight patients the fistula output declined significantly (> 50%) and the authors deemed this therapy to be beneficial. Thirteen patients received therapy with the VAC system. The VAC system protected the skin and improved the condition of the wound in these patients. In several patients VAC therapy promoted wound contracture and healing. Use of the VAC did not lead to any septic complications and did not lead to an increase in the output volume. One case of healed fistula was reported, however in 12 patients there was no improvement in the fistula and required definitive operative repair. The fibrin glue was used in eight patients (including seven with low output fistulas), which led to a response in only one patient.

In a case series by Heller et al. (2006), 21 patients (10 female, 11 male, mean age 48 years) with postoperative abdominal wound dehiscences that could not be closed immediately underwent VAC therapy. Thirteen patients had fascial dehiscence, and nine had frank bowel exposure. The aim of the study was to restore the abdominal wall integrity. The VAC device was used simultaneously with other sharp debridement. VAC therapy was utilised until the abdominal wall was re-established.

In nine of 13 patients with fascial dehiscence, definitive fascial closure was performed. In all patients, stable cutaneous coverage was achieved through various methods including local abdominal skin flap advancement (n = 6), skin grafting (n = 9), or secondary intention healing (n = 6). Complications noted were a low-output small bowel enterocutaneous fistula in two patients and partial skin graft loss in one patient.

2008 HEALTHPACT ACTION

Given the lack of comparative studies for the VAC, it is recommended that this technology be archived. There is insufficient evidence for vacuum assisted closure to be used in the setting of enterocutaneous fistulas.

NUMBER OF INCLUDED STUDIES

Total number of studies	2
Level IV Case series	2

REFERENCES

Draus J, Huss S, Harty N, Cheadle W, Larson G. Enterocutaneous fistula: are treatments improving? *Surgery*. 2006; 140(4): 570 - 576.

Heller L, Levin S, Butler C. Management of abdominal wound dehiscence using vacuum assisted closure in patients with compromised healing. *American Journal of Surgery*. 2006; 191(2): 165 - 172.

SOURCES OF FURTHER INFORMATION

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