NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of negative pressure wound therapy for the open abdomen

Negative pressure (vacuum) therapy for abdomens left open to help healing

Trauma or surgery to the abdomen can result in a wound that cannot be closed by traditional techniques. Such wounds can take many months to heal. In negative pressure (vacuum) wound therapy, a foam dressing with a drainage tube is put into the wound. The tube is attached to a small vacuum unit that applies suction to the wound, removing excess blood and fluid. This may allow the wound to heal faster. Negative pressure wound therapy can be used for periods of a few days to a few weeks.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2013.

Procedure name

- Negative pressure wound therapy for the open abdomen.

Specialist societies

- Association of Coloproctology of Great Britain and Ireland
- Association of Surgeons of Great Britain and Ireland
- Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
- Intensive Care Society.

Description

Indications and current treatment

Negative pressure wound therapy (NPWT) for the open abdomen may be used in the management of patients with an open abdominal wound (laparostomy) when the gut and other intraperitoneal organs are exposed. The abdomen is left open as part of the surgical treatment of complex intra-abdominal problems that make closure difficult, such as severe sepsis, abdominal trauma and after grafting of ruptured aortic aneurysms.

First-line management of the open abdomen may include use of dressings or impermeable devices (e.g. Bogota bag) to protect the exposed organs and limit leakage of fluid. The abdomen may be left to heal by secondary intention or delayed closure may be done using sutures, mesh repair, skin grafts, muscle flaps or a combination of these. The choice of closure technique depends on the size of the wound and other clinical considerations.

What the procedure involves

The aims of NPWT for the open abdomen include removing infected material and helping nursing care by reducing escape of fluid: its use may also influence the possibility of delayed primary closure.

NPWT involves the use of a sealed suction system to remove exudate and infected material from the open wound in the abdominal cavity. There is wide variation in the systems and techniques used, but the underlying principle is that the abdominal contents are covered with a foam sponge or other porous dressing (for example, gauze), usually with a membrane between the sponge/dressing and the abdominal contents. The entire wound and surrounding skin are covered with an adhesive transparent membrane, which is perforated by a drainage tube attached to the suction system. This facilitates the provision of negative pressure and prevents escape of fluid, because the membrane adheres to the skin all the way around the wound. Fluid within the wound is absorbed by the foam sponge and removed via the drainage tube into a container attached to the suction unit. A sensing device (a pad placed on top of the foam dressing) may be used to ensure that the prescribed amount of negative pressure is being applied to the wound.

A number of different commercial systems are available, each of which requires specific training for safe and effective use. A number of non-commercial systems have also been described.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to negative pressure wound therapy for the open abdomen. Searches were

conducted of the following databases, covering the period from their commencement to 26 September 2012: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with an open abdomen
Intervention/test	Negative pressure wound therapy
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on approximately 5263 patients from 1 systematic review, 2 randomised controlled trials (1 of which is also included in the systematic review), 2 non-randomised comparative studies, and 2 case series[1–7].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table2 Summary of key efficacy and safety findings on negative pressure wound therapy for the open abdomen

Abbreviations used: ASA, American Society of Anesthesiology; CI, confidence interval; DRS, dynamic retention sutures; NPWT, negative pressure wound therapy; RSSFC, retention sutured sequential fascial closure; SOFA, sequential organ failure assessment; VAC, vacuum-assisted closure

Study details	Key efficacy findings	Key safety findings	Comments
Quyn AJ (2012)[1] **Systematic review** UK Search date: December 2009 Study population: patients with an open abdomen **n=4303 patients (106 papers including 2 RCTs)** Age: not reported; Sex: not reported Study selection criteria: all studies on temporary abdominal closure techniques that mentioned the indication for the open abdomen, the closure rate and/or mortality were included. Exclusion criteria: editorials, reviews, series of <5 patients, non-peer-reviewed publications and paediatric series. Main aetiologies: peritonitis (73 series), trauma (55 series), pancreatitis (40 series), abdominal compartment syndrome (29 series) vascular (18 series). Technique: vacuum-assisted closure (38 series), mesh (30 series), Wittmann patch (8 series), packing (15 series), zipper (15 series), Bogota bag (6 series), locking device (1 series), dynamic retention sutures (3 series), skin only (1 series). **Follow-up: not reported** Conflict of interest/source of funding: not reported	Number of patients analysed: **4303 (1634 VAC, 1366 mesh, 334 Wittmann patch, 312 packing, 283 zipper, 264 Bogota bag, 55 locking device, 47 dynamic retention sutures, 8 skin only)** **Primary delayed fascial closure (weighted percentages)** • VAC=57.8% (95% CI: 50.8 to 64.7) • Mesh=35.7% (95% CI: 25.6 to 46.4) • Wittmann patch=77.8% (95% CI: 56.2 to 93.5) • Packing=13.1% (95% CI: 3.3 to 28.1) • Zipper=44.0% (95% CI: 27.4 to 61.3) • Bogota bag=28.1% (95% CI: 7.9 to 54.8) • Locking device=48.0% (95% CI: 34.5 to 60.3) • DRS=72.0% (95% CI: 57.1 to 85.5) • Skin sutures only, n=6 The authors noted that patients with an open abdomen secondary to peritonitis had a worse outcome with higher mortality, increased complications and a lower delayed primary closure rate compared with trauma patients.	**Mortality (weighted percentages)** • VAC=22.3% (95% CI: 17.5 to 27.5) • Mesh=29.8% (95% CI: 23.6 to 36.5) • Wittmann patch=15.7% (95% CI: 5.4 to 30.0) • Packing=33.4% (95% CI 25.3 to 42.1) • Zipper=29.6% (95% CI: 23.4 to 36.3) • Bogota bag=28.0% (95% CI: 20.2 to 36.6) • Locking device=36.0% (95% CI: 24.6 to 49.5) • DRS=18.0% (95% CI: 0.34 to 54.9) **Fistula (weighted percentages)** • VAC=7.0% (95% CI: 5.0 to 9.3) • Mesh=7.5% (95% CI: 5.0 to 10.4) • Wittmann patch=2.8% (95% CI: 1.1 to 5.2) • Packing=10.6% (95% CI 6.1 to 16.1) • Zipper=12.5% (95% CI: 5.1 to 22.5) • Bogota bag=7.9% (95% CI: 2.3 to 16.4) • Locking device=8.0% (95% CI: 2.4 to 16.5) • DRS=10.0% (95% CI: 1.8 to 21.4) **Abscess (weighted percentages)** • VAC=4.2% (95% CI: 2.3 to 6.9) • Mesh=8.7% (95% CI: 5.2 to 13.1) • Wittmann patch=2.4% (95% CI: 0.1 to 7.7) • Packing=7.3% (95% CI 2.0 to 15.5) • Zipper=16.1% (95% CI: 3.7 to 19.2) • Bogota bag=12.0% (95% CI: 1.4 to 31.2) • Locking device=10.0% (95% CI: 3.5 to 18.9) • DRS=2.0% (95% CI: 0.0 to 6.7)	**Study design issues**: • The studies included were generally retrospective reviews. The authors of the systematic review stated that the methodology of inclusion was not clear, severity of illness was rarely quantified and many studies suffered from bias in patient and treatment selection. **Other issues**: • During the last decade, most published series used VAC systems. • The authors noted that advances in intensive care support may be responsible for the improved survival in patients treated in the last decade.

Abbreviations used: ASA, American Society of Anesthesiology; CI, confidence interval; DRS, dynamic retention sutures; NPWT, negative pressure wound therapy; RSSFC, retention sutured sequential fascial closure; SOFA, sequential organ failure assessment; VAC, vacuum-assisted closure

Study details	Key efficacy findings	Key safety findings	Comments
Bee TK (2008)[2] **Randomised controlled trial** USA Recruitment period: 2003–7 Study population: all trauma patients and emergency general surgery patients having exploratory laparotomy requiring temporary abdominal closure indicated for 'damage-control' laparotomy, massive visceral oedema or planned re-exploration. All patients severely injured and in haemorrhagic shock. **n=51 (31 NPWT versus 20 mesh)** Age: mean 41 years; Sex: 82% male 90% (46/51) trauma patients. Patient selection criteria: patients not expected to survive for 7 days and pregnant women excluded from the study. Technique: NPWT with one of two methods – either a traditional method or a KCI device after placement of a gastric or jejunal feeding tube – versus polyglactin 910 mesh secured to the fascia with a running suture after placement of a gastric or jejunal feeding tube. **Follow-up: not reported** Conflict of interest/source of funding: not reported	Number of patients analysed: **51 (31 versus 20)** **Closure success** There was no statistically significant difference in the rate of delayed fascial closure achieved in the NPWT group (31%) and the mesh repair group (26%) (absolute figures not stated). 2 patients in the NPWT group and 1 in the mesh repair group were excluded from analysis. NPWT failed in 2 patients, both of whom had evisceration around the device on multiple occasions and underwent mesh placement.	**Complications** Overall 15% (7/48) of patients developed a small-bowel fistula, 6 patients in the NPWT group and 1 in the mesh repair group. This excludes 3 patients who died within 7-day follow-up (cause of death not reported). 1 patient in the mesh group had a pancreatic fistula. **Enterocutaneous fistula** • NPWT=21% (6/29) • Mesh=5% (1/19) p=0.14 **Abdominal abscess** • NPWT=44% (n=12) • Mesh=47% (n=9) p=not significant (denominator not reported)	This study is included in the Quyn et al, 2012 systematic review and was also in the original overview for IPG322. **Study design issues**: • Randomisation by shuffled envelopes. • Two different methods were used to produce NPWT in the active treatment arm of the study. **Study population issues**: • No difference between the groups in baseline demographic characteristics, mechanism of injury, severity of shock or injury severity.

Abbreviations used: ASA, American Society of Anesthesiology; CI, confidence interval; DRS, dynamic retention sutures; NPWT, negative pressure wound therapy; RSSFC, retention sutured sequential fascial closure; SOFA, sequential organ failure assessment; VAC, vacuum-assisted closure

Study details	Key efficacy findings	Key safety findings	Comments
Carlson GL (2013)[3] **Non-randomised comparative study (prospective)** UK Recruitment period: 2010– 11 Study population: hospital inpatients with an open abdomen **n=578 (355 NPWT versus 223 no NPWT)** Age: mean 59 years; Sex: 59% (341/578) male Patient selection criteria: patients in whom the abdomen had been left open, with exposure of intestines and other intraperitoneal organs, irrespective of whether initial management included placement of prosthetic material over the exposed organs. The only exclusion criterion was superficial wound dehiscence, without exposure of viscera. Most patients had their abdomen left open for the management of sepsis. Technique: negative pressure wound therapy was used in 355 (61%) patients (a commercially available system was used for 314 patients and an 'in-house' system was used for the remainder). A Bogota bag was used in 127 (57%), a prosthetic mesh in 39 (18%) and dynamic retention sutures were used in 8 (4%). Simple packing or a stoma bag were used in 19 (9%) and no data were available for 27 (12%). **Follow-up: discharge from hospital** Conflict of interest/source of funding: none	Number of patients analysed: **578 (355 versus 223)** **Delayed primary closure of the open abdomen:** • NPWT=41.1% (146/355) • No NPWT=60.1% (134/223) **Prosthetic replacement of the abdominal wall needed:** • NPWT=12.1%(43/355) • No NPWT=9.9%(22/223) ***Propensity score pair-matched cohort analysis*** **Delayed primary closure of the open abdomen:** • NPWT=44.9% (84/187) • No NPWT=61.0% (114/187) p=0.002 Risk ratio=0.74 (95%CI 0.60 to 0.90) Risk difference=-16.0% (95%CI -26.2% to -5.9%) **Prosthetic replacement of the abdominal wall needed:** • NPWT=14.4%(27/187) • No NPWT=10.7%(20/187) p=0.28 Risk ratio=1.35 (95%CI 0.78 to 2.35) Risk difference=3.7 (95%CI -3.1 to 10.6)	**Intestinal fistula**: • NPWT=13.8% (49/355) • No NPWT=8.5% (19/223) **Mortality:** • NPWT=27.3% (97/355) • No NPWT=29.6% (66/223) **Intervention to control bleeding**: • NPWT=11.3% (40/355) • No NPWT=15.7% (35/223) **Intestinal failure (defined as the need for parenteral nutrition for >28 days)**: • NPWT=18.3% (65/355) • No NPWT=16.6% (37/223) ***Propensity score pair-matched cohort analysis*** **Intestinal fistula**: • NPWT=8.0% (15/187) • No NPWT=9.6% (18/187) p=0.58 **Mortality:** • NPWT=25.7% (48/187) • No NPWT=29.4% (55/187) p=0.40 **Intervention to control bleeding**: • NPWT=12.3% (23/187) • No NPWT=16.6% (31/187) p=0.25 **Intestinal failure (defined as the need for parenteral nutrition for >28 days)**: • NPWT=15.0% (28/187) • No NPWT=15.0% (28/187) p=1.00	**Study design issues**: • Data were submitted from 105 hospitals. • Propensity scores were used to create a matched pairs sample. Predictor variables for the propensity score were age, gender, emergency surgery, ASA score, number of previous abdominal procedures in current admission, procedure done in a high volume centre (>10 cases in the audit database), open abdomen initiated at another hospital, and indication for open abdomen therapy. **Study population issues**: • NPWT was more likely to be used in patients who were younger, male, had any surgical tube enterostomy or who were managed in a hospital treating >10 cases during the study period. **Other issues**: • There was a lack of data on illness severity, which may have differed between the groups. • There was heterogeneity of the patient populations.

Abbreviations used: ASA, American Society of Anesthesiology; CI, confidence interval; DRS, dynamic retention sutures; NPWT, negative pressure wound therapy; RSSFC, retention sutured sequential fascial closure; SOFA, sequential organ failure assessment; VAC, vacuum-assisted closure

Study details	Key efficacy findings	Key safety findings	Comments
Pliakos I (2012)[4] **Non-randomised comparative study** Greece Recruitment period: 2000–9 Study population: patients undergoing laparostomy for a septic intra-abdominal condition **n=58** (27 VAC versus 31 other techniques of temporary abdominal closure [control]) Age: median 59 years (VAC), 68 years (control) Sex: 65% male (VAC), 71% male (control) Patient selection criteria: not reported. Technique: the techniques used for temporary abdominal closure in the control group included Bogota bag, zipper fasteners, mesh, and occlusive dressing under suction. **Follow-up: not reported** Conflict of interest/source of funding: not reported	Number of patients analysed: **58 (27 versus 31)** **Complete fascia closure** • VAC=81.5% (22/27) (4 with a mesh implant) • Controls=29.0% (9/31) (4 with a mesh implant) p<0.001 Among the 22 patients in the control group who did not have fascial closure, 8 died before closure was attempted and 14 had a planned ventral hernia because of extensive fascia retraction (all 14 had only a skin closure). Of the 5 patients in the VAC group who did not have fascial closure, 3 died before abdominal closure and 2 had extensive fascia retraction, which did not permit a mesh implant (1 of these patients had a skin closure and the other had a skin graft). **Patients needing re-exploration** • VAC=40.7% (11/27) • Controls=48.4% (15/31) p<0.002 (as reported in the paper)	**Enteroatmospheric fistula** • VAC=0% (0/27) • Controls=54.8% (17/31) p<0.00001 **In-hospital mortality rates** • VAC=37.0% (10/27) (5 multiple organ failure, 5 cardiorespiratory insufficiency) • Controls=45.2% (14/31) (12 multiple organ failure, 2 cardiorespiratory insufficiency) p=not significant	**Study design issues**: • Consecutive patients. • Retrospective analysis of a prospectively formed database. **Study population issues**: • No significant differences were reported in baseline characteristics with regard to age, sex and APACHE II score. **Other issues**: • The authors stated that the decision to manage an open abdomen became easier with the introduction of the VAC device. They noted that VAC has been the method of choice since 2005.

Abbreviations used: ASA, American Society of Anesthesiology; CI, confidence interval; DRS, dynamic retention sutures; NPWT, negative pressure wound therapy; RSSFC, retention sutured sequential fascial closure; SOFA, sequential organ failure assessment; VAC, vacuum-assisted closure

Study details	Key efficacy findings	Key safety findings	Comments
Pliakos I (2010)[5] **Randomised controlled trial** Greece Recruitment period: 2007–9 Study population: patients with severe abdominal sepsis **n=53** (26 VAC only versus 27 VAC and retention sutured sequential fascial closure (RSSFC) Age: median 58 years (range 39–87) for VAC group and 75 years (range 30–83) for RSSFC group. Sex: 70% (21/30) male Patient selection criteria: age >18 years and laparostomy with VAC system application. Exclusion criteria were a SOFA score >5 at first dressing change; death prior to abdominal closure; an abdominal gap after the first dressing change <15 cm. Technique: V.A.C. system used (KCI, Texas, USA). RSSFC procedure was started after 2-day application of VAC – the existing dressing was then removed and replaced with a perforated plastic barrier covered with a sponge. Over this sponge, the fascia was placed under moderate tension with sutures along the wound length. A second sponge was placed and sealed with an airtight plastic sheet and NPWT applied. Sequential fascial closure and replacement of the sponge and sutures was done every 2 days. **Follow-up: not reported** Conflict of interest/source of funding: not reported	Number of patients analysed: **30 (15 versus 15)** **Primary fascial closure** • VAC only=40.0% (6/15) • VAC and RSSFC=93.3% (14/15) p=0.005 5 patients in the VAC only group had a planned hernia. 4 patients in the VAC only group and 1 patient in the RSSFC group had a mesh implant. **Open abdomen duration (days)** • VAC only=12 (range 9–19) • VAC and RSSFC=8 (range 6–11) p=0.0001 **Dressing changes (mean±standard deviation)** • VAC only=4.4±1.4 • VAC and RSSFC=2.9±0.7 p=0.001 **Hospital stay (days)** • VAC only=17.5±4.6 • VAC and RSSFC=11.9±2.1 p=0.0001	No safety outcomes were reported.	**Follow-up issues**: • The paper states that 24 patients were excluded after randomisation (12 in each group): 9 patients had SOFA >5 at first dressing change, 11 patients died and 4 had an abdominal gap <15 cm after the first dressing change. **Study design issues**: • Patients were randomised by computer-generated tables. • The aim of the study was to compare the outcome of the VAC technique with or without RSSFC. **Study population issues**: • The 2 groups were similar with regard to initial diagnosis and SOFA scores.

Abbreviations used: ASA, American Society of Anesthesiology; CI, confidence interval; DRS, dynamic retention sutures; NPWT, negative pressure wound therapy; RSSFC, retention sutured sequential fascial closure; SOFA, sequential organ failure assessment; VAC, vacuum-assisted closure

Study details	Key efficacy findings	Key safety findings	Comments
Kafka-Ritsch R (2012)[6] **Case series** Austria Recruitment period: 2005–10 Study population: patients with an open abdomen (abdominal sepsis 78%, ischaemia 16%, other 6%) **n=160** Age: median 66 years (range 21–88) Sex: 64% male Patient selection criteria: advanced peritonitis in more than 1 quadrant, critically ill patients requiring wound closure after laparotomy, need for a second look, abdominal compartment syndrome, or the impossibility to close the abdomen without the risk of abdominal compartment syndrome. Exclusion criteria were haemorrhage, localised peritonitis, or the ability to perform sufficient source control during the initial procedure in patients in a stable condition. Technique: negative pressure therapy (using V.A.C. vacuum dressing, KCI, Texas, USA) was combined with dynamic sutures to the fascia. Negative pressure was applied continuously. **Follow-up: to hospital discharge** Conflict of interest/source of funding: not reported	Number of patients analysed: **160** **Primary delayed fascia closure=76% of the intention-to-treat population, 87% of surviving patients (n=121)** In 16 of these patients the abdomen was closed with the aid of a patch. Planned ventral hernia=1.3% (2/160) In 5% (6/121) of patients with primary closure, a dehiscence had to be revised. Multivariate analysis demonstrated a significant correlation between primary fascial closure and female sex, limited surgery, and generalised peritonitis.	• Mortality=21% (33/160) (28 from prolonged sepsis and/or multiple organ dysfunction syndrome, 4 from cardiac complications, and 1 from withdrawal of therapy with poor oncologic prognosis. Among these patients, 21 died before termination of the open abdomen treatment.) • Abdominal abscess after closure of the abdominal wall=8.1% (13/160) (7 patients were treated successfully by percutaneous drainage and 6 patients underwent reoperation) • Superficial wound infection=19.4% (31/160) • Deep wound infection=3.8% (6/160) • Enteric fistula during open abdomen treatment=3.1% (5/160) (2 patients died with a persistent intestinal fistula; the fistula resolved in 2 patients and 1 patient was discharged with a chronic enteric fistula that was closed 6 months later) • Pancreatic fistula=2.5% (4/160) (in patients with pancreatic complications) • Anastomotic insufficiency needing relaparotomy=3.1% (5/160) (open abdomen treatment was repeated in 3 of these patients)	**Study design issues**: • Consecutive patients. • Retrospective study of patients enrolled prospectively.

Abbreviations used: ASA, American Society of Anesthesiology; CI, confidence interval; DRS, dynamic retention sutures; NPWT, negative pressure wound therapy; RSSFC, retention sutured sequential fascial closure; SOFA, sequential organ failure assessment; VAC, vacuum-assisted closure

Study details	Key efficacy findings	Key safety findings	Comments
Acosta S (2011)[7] **Case series (prospective)** Sweden Recruitment period: 2006–9 Study population: patients with an open abdomen (the 3 main aetiologies were vascular disease [41%], visceral surgical disease [51%] and trauma [8%]) **n=111** Age: median 68 years (range 20–91) Sex: 73% (81/111) male Patient selection criteria: exclusion criteria were age <18 years, abdominal wall hernia before open abdomen treatment, anticipated open abdomen treatment lasting fewer than 5 days and midline incisions. Technique: vacuum-assisted wound closure with mesh-mediated fascial traction. V.A.C. system was used (KCI, Texas, USA). Continuous or intermittent topical negative pressure was applied according to the surgeon's preference. The VAC system was changed and the mesh tightened under general anaesthesia every 2–3 days. **Follow-up: not reported** Conflict of interest/source of funding: none	Number of patients analysed: **111** **Complete delayed primary fascial closure=76.6% (85/111) (intention-to-treat analysis)** 16 patients died before fascial closure was possible. Abdominal wall reconstruction with a polypropylene mesh=7.2% (8/111) No patient was left with a large planned ventral hernia. **Fascial closure rate among the 95 patients alive at the time of closure=89% (85/95)** Vacuum-assisted wound closure treatment lasting for at least 14 days was independently associated with failure of fascial closure (odds ratio 5.47, 1.01 to 29.55; p=0.048).	**Complications during treatment** • Possible treatment-induced intestinal fistula=6.3% (7/111) • Leakage of stool from colostomy to abdomen=1.8% (2/111) • Leakage of stool from rectal stump=1.8% (2/111) • Dehiscence of colostomy=0.9% (1/111) • Intra-abdominal abscess=0.9% (1/111) • Vascular prosthesis infection=0.9% (1/111) • Bleeding from rectus muscle=1.8% (2/111) • Bleeding from liver fracture=1.8% (2/111) • Cartilage-bone formation in abdominal incision=2.7% (3/111) • Cardiac arrest during initiation of anaesthesia=0.9% (1/111) **Complications after treatment** • Possible treatment-induced intestinal fistula=0.9% (1/111) • Intra-abdominal abscess=3.6% (4/111) • Mesh infection after abdominal wall reconstruction=0.9% (1/111) • Vascular prosthesis infection=0.9% (1/111) • Aortoenteric fistula=0.9% (1/111) • Superficial wound infection=9.0% (10/111) • Deep wound infection=0.9% (1/111) • Wound dehiscence needing resuture=0.9% (1/111) Total number of complications=42 (29 patients) **In-hospital mortality rate=29.7% (33/111)**	**Study design issues**: • Consecutive patients treated at 4 different centres. **Other issues**: • Complications were mainly attributed to the underlying pathology and the subsequent development of infectious complications. • The authors noted there was a learning curve in wound care and dressing changes.

Efficacy

Achievement of delayed primary closure

A meta-analysis of 4303 patients reported closure rates of 58% (95% CI 51 to 65) for vacuum assisted closure (VAC), 36% (95% CI 26 to 46) for mesh, 78% (95% CI 56 to 94) for Wittmann patch, 13% (95% CI 3 to 28) for packing, 44% (95% CI 27 to 61) for zipper, and 28% (95% CI 8 to 55) for Bogota bag[1].

A randomised controlled trial of 53 patients treated by VAC alone or VAC combined with retention sutured sequential fascial closure reported closure rates of 40% (6/15) and 93% (14/15) respectively (p=0.005)[5].

A non-randomised comparative study of 578 patients treated by negative pressure wound therapy or other temporary abdominal closure techniques reported closure rates of 45% (84/187) and 61% (114/187) respectively (p=0.002, matched pair analysis)[3].

A case series of 160 patients treated by negative pressure wound therapy combined with dynamic sutures reported delayed primary closure in 76% of the intention-to-treat population and 87% of surviving patients (n=121)[6]. A case series of 111 patients treated by VAC with mesh-mediated fascial traction reported delayed primary closure in 77% (85/111) of the intention-to-treat population and 89% (85/95) of surviving patients[7].

Need for prosthetic replacement of the abdominal wall

The non-randomised comparative study of 578 patients treated by negative pressure wound therapy or other temporary abdominal closure techniques reported that 14% (27/187) and 11% (20/187) of patients respectively needed prosthetic replacement of the abdominal wall (p=0.28, matched pair analysis)[3].

The case series of 111 patients reported that 7% (8/111) of patients needed abdominal wall reconstruction with a polypropylene mesh[7].

Safety

Mortality

Mortality rates of 22% (95% CI 18 to 28) for VAC, 30% (95% CI 24 to 37) for mesh, 16% (95% CI 5 to 30) for Wittmann patch, 33% (95% CI 25 to 42) for packing, 30% (95% CI 23 to 36) for zipper, and 28% (95% CI 20 to 37) for Bogota bag were reported in a meta-analysis of 4303 patients[1].

Mortality rates of 26% (48/187) for patients treated by negative pressure wound therapy and 29% (55/187) for patients treated by other temporary abdominal closure techniques (p=0.40, matched pair analysis) were reported in a non-randomised comparative study of 578 patients[3].

Mortality rates of 21% (33/160) and 30% (33/111) were reported in the 2 case series of 160 and 111 respectively[6,7].

Fistulae

Fistulae were reported in 7% (95% CI 5 to 9) of patients treated by VAC compared to 8% (95% CI 5 to 10) for mesh, 3% (95% CI 1 to 5) for Wittmann patch, 11% (95% CI 6 to 16) for packing, 13% (95% CI 5 to 23) for zipper, and 9% (95% CI 2 to 16) for Bogota bag in a meta-analysis of 4303 patients[1].

Intestinal fistulae were reported in 8% (15/187) of patients treated by negative pressure wound therapy and in 10% (18/187) of patients treated by other techniques (p=0.58, matched pair analysis) in a non-randomised comparative study of 578 patients[3].

Intestinal fistulae that were considered to be possibly related to negative pressure wound therapy were reported in 7% (8/111) of patients in the case series of 111 patients[7].

Abscess

Abscess was reported in 4% (95% CI 2 to 7) of patients treated by VAC compared to 9% (95% CI 5 to 13) for mesh, 2% (95% CI 0.1 to 8) for Wittmann patch, 7% (95% CI 2 to 16) for packing, 16% (95% CI 4 to 19) for zipper, and 12% (95% CI 1 to 31) for Bogota bag in a meta-analysis of 4303 patients[1].

Abdominal abscess after closure of the abdominal wall was reported in 8% (13/160) of patients in the case series of 160 patients; 7 patients were treated successfully by percutaneous drainage and the other 6 patients underwent reoperation[7]. Abdominal abscess was reported in 5% (5/111) of patients in the case series of 111 patients (1 occurred during treatment and 4 occurred after treatment)[7].

Intervention to control bleeding

Intervention to control bleeding was reported in 12% (23/187) of patients treated by negative pressure wound therapy and in 17% (31/187) of patients treated by other techniques (p=0.25, matched pair analysis) in a non-randomised comparative study of 578 patients[3].

Intestinal failure

Intestinal failure (defined as the need for parenteral nutrition for less than 28 days) was reported in 15% (28/187) of patients treated by negative pressure wound therapy and in 15% (28/187) of patients treated by other techniques (p=1.00, matched pair analysis) in a non-randomised comparative study of 578 patients[3].

Validity and generalisability of the studies

- The patient populations are heterogeneous. Authors of the systematic review note that only limited conclusions can be drawn from the analysis because of data heterogenity[1].
- There are technical variations in systems used for negative pressure wound therapy – some studies used a commercially available system and other used 'in-house' systems. There were differences in the level of negative pressure used and in whether the pressure was applied continuously or intermittently.
- It is likely that advances in intensive care support may have improved survival in patients treated more recently.
- One non-randomised comparative study noted that there was a lack of data on illness severity between the 2 groups[3]; some of the difference in outcomes may have been due to baseline differences in disease severity.
- Mortality may relate largely to the success of the surgery itself rather than to the method of closure.
- The follow-up period in most studies did not extend beyond wound closure and discharge.
- None of the studies summarised in table 2 include data from children.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Negative pressure wound therapy for the open abdomen. NICE interventional procedures guidance 322 (2009). This guidance is currently under review and is expected to be updated in 2013. Available from www.nice.org.uk/guidance/IPG322

Medical technology

- The MIST Therapy system for the promotion of wound healing. NICE medical technology guidance 5 (2011). Available from www.nice.org.uk/guidance/mtg5

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr A Acheson, Mr J Hartley (Association of Coloproctology of Great Britain & Ireland), Mr I Anderson (Association of Surgeons of Great Britain & Ireland), Ms R Clegg, Mr S Palfreyman (Royal College of Nursing).

- Three Specialist Advisers have performed the procedure at least once and 2 Advisers perform the procedure regularly.
- Three Advisers described the procedure as established practice and no longer new and 2 described it as definitely novel and of uncertain safety and efficacy.
- Standard practice would involve dressing the open abdomen using a variety of techniques. These include a plastic bag (usually attached to the edges of the abdominal wound) - the so-called "Bogota bag", standard abdominal packs, or some form of synthetic mesh.
- Theoretical adverse events include bowel fistulation or perforation, infection, haemorrhage, large ventral hernia, and pain.
- Anecdotal adverse events include difficulty with removing foam due to granulation tissue in the foam, and an increased risk of cancerous cell regeneration.
- Adverse events reported in the literature include enterocutaneous fistulae, bleeding and pain.
- The key efficacy outcomes are exudate reduction, early fascial closure, length of hospital stay, lower mortality, improvement in patient quality of life, and lower rate of secondary procedures to reconstruct the abdominal wall.
- There are uncertainties about efficacy, particularly with regard to patient selection. One Adviser noted that it is unclear whether efficacy in terms of the ability to achieve abdominal closure is an index of the pathology which

necessitated the abdomen being left open in the first instance or the use of negative pressure technology.

- Four Specialist Advisers consider the potential impact of this procedure on the NHS to be moderate, in terms of patients eligible for treatment and use of resources; 1 Adviser considered the potential impact to be minor.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

None other than those described above.

References

1. Quyn AJ, Johnston C, Hall D et al. (2012) The open abdomen and temporary abdominal closure systems - historical evolution and systematic review. Colorectal Disease 14: e429–38

2. Bee TK, Croce MA, Magnotti LJ et al. (2008) Temporary abdominal closure techniques: a prospective randomized trial comparing polyglactin 910 mesh and vacuum-assisted closure. Journal of Trauma-Injury Infection & Critical Care 65: 337–42

3. Carlson GL, Patrick H, Amin AI et al. (2013) Management of the open abdomen. A national study of clinical outcome and safety of negative pressure wound therapy. Annals of Surgery doi: 10.1097/SLA.0b013e31828b8bc8

4. Pliakos I, Papavramidis TS, Michalopoulos N et al. (2012) The value of vacuum-assisted closure in septic patients treated with laparostomy. American Surgeon 78: 957–61

5. Pliakos I, Papavramidis TS, Mihalopoulos N et al. (2010) Vacuum-assisted closure in severe abdominal sepsis with or without retention sutured sequential fascial closure: a clinical trial. Surgery 148: 947–53

6. Kafka-Ritsch R, Zitt M, Schorn N et al. (2012) Open abdomen treatment with dynamic sutures and topical negative pressure resulting in a high primary fascia closure rate. World Journal of Surgery 36: 1765–71

7. Acosta S, Bjarnason T, Petersson U et al. (2011) Multicentre prospective study of fascial closure rate after open abdomen with vacuum and mesh-mediated fascial traction. British Journal of Surgery 98: 735–43

Appendix A: Additional papers on negative pressure wound therapy for the open abdomen

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies. Case series with fewer than 10 patients have not been included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Amin AI, Shaikh IA (2009) Topical negative pressure in managing severe peritonitis: a positive contribution? World Journal of Gastroenterology 15: 3394–7	Case series n=20	Abdominal closure=75% (15/20) within 4.5 days.	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Barker DE, Green JM, Maxwell RA et al. (2007) Experience with vacuum-pack temporary abdominal wound closure in 258 trauma and general and vascular surgical patients. Journal of the American College of Surgeons 204 (5): 784–92	Case series n=258	68% (154/226) of patients underwent fascial wound closure at a mean of 4 days after the initial procedure. 32% (72/226) required delayed closure with skin grafting and planned ventral hernia.	Included in systematic review by Quyn AJ, 2012. More recent case series are included.
Batacchi S, Matano S, Nella A et al. (2009) Vacuum-assisted closure device enhances recovery of critically ill patients following emergency surgical procedures. Critical Care 13: R194	Non-randomised comparative study n=66	Patients with abdominal compartment syndrome who were treated with VAC had a faster abdominal closure rate and earlier discharge from ICU compared to patients treated with the Bogota bag.	Included in systematic review by Quyn AJ, 2012.
Boele van Hensbroek P, Wind J, Dijkgraaf MG et al. (2009) Temporary closure of the open abdomen: a systematic review on delayed primary fascial closure in patients with an open abdomen. World Journal of Surgery 33: 199-207	Systematic review n=3169	Artificial burr and VAC are associated with the highest fascial closure rates and the lowest mortality rates.	A more recent systematic review is included.
Brock WB, Barker DE, Burns RP (1995) Temporary closure of open abdominal wounds: the vacuum pack. American Surgeon 61 (1) : 30–5	Case series n= 28	All closures remained intact until removed; there were no eviscerations or abdominal wall injuries	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Burlew CC, Moore EE, Biffl WL et al. (2012) One hundred percent fascial approximation can be achieved in the postinjury open abdomen with a sequential closure protocol. The Journal of Trauma and Acute Care Surgery 72: 235–41	Case series n=51	Sequential fascial closure reduces the morbidity of the open abdomen.	Larger studies are included in table 2.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Caro A, Olona C, Jimenez A et al. (2011) Treatment of the open abdomen with topical negative pressure therapy: a retrospective study of 46 cases. International Wound Journal 8: 274–9	Case series n=46	Closure was possible in 52% (24/46) of patients. Mean treatment time=26 days.	Larger studies are included in table 2.
DeFranzo AJ, Pitzer K, Molnar JA et al. (2008) Vacuum-assisted closure for defects of the abdominal wall. Plastic & Reconstructive Surgery 121 (3): 832–9	Case series n=100	Mean NPWT closure time was 13 days (range 11–14 days) in the 67 patients in the partial-thickness deficit group. The size of the wound did not correlate with closure time.	Larger and more recent case series are included.
Dietz UA, Wichelmann C, Wunder C et al. (2012) Early repair of open abdomen with a tailored two-component mesh and conditioning vacuum packing: a safe alternative to the planned giant ventral hernia. Hernia 16: 451–60	Case series n=19	A 4-stage procedure achieved abdominal wall closure in patients treated with open abdomen and allowed mobilisation of patients before final skin closure.	Larger studies are included in table 2.
Franklin ME, Alvarez A, Russek, K (2012) Negative pressure therapy: a viable option for general surgical management of the open abdomen. Surgical Innovation 19: 353–63	Case series n=19	Fascial closure was achieved in 90% (17/19) of patients, with a Kaplan-Meier (KM) median time to closure of 6 days.	Larger studies are included in table 2.
Garner GB, Ware DN, Cocanour CS et al. (2001) Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. American Journal of Surgery 182 (6) : 630–8	Case series n= 14 Follow-up = 10 days	Use of NPWT can safely achieve early fascial closure in more than 90% of trauma patients with open abdomens	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Gutierrez IM, Gollin G (2012) Negative pressure wound therapy for children with an open abdomen. Langenbecks Archives of Surgery 397: 1353–7	Case series n=25	NPWT is a reliable tool for infants and children with an open abdomen. Wound management was facilitated and abdominal wall closure was ultimately achieved in all survivors.	Larger studies are included in table 2.
Hatch QM, Osterhout LM, Ashraf A et al. (2011) Current use of damage-control laparotomy, closure rates, and predictors of early fascial closure at the first take-back. Journal of Trauma-Injury Infection & Critical Care 70: 1429–36	Case series n=242	Use of the vacuum-assisted closure was associated with increased likelihood of early fascial closure.	Paper focuses in predictors of early fascial closure at first take-back.
Heller L, Levin SL, Butler CE (2006) Management of abdominal wound dehiscence using vacuum assisted closure in patients with compromised healing. American Journal of Surgery 191 (2) : 165–72	Case series n = 21 Follow-up = 6 months	NPWT system appears to be successful and should be considered in patients to provide a stable healed wound	Larger studies are included in table 2.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Horwood J, Akbar F, Maw A (2009) Initial experience of laparostomy with immediate vacuum therapy in patients with severe peritonitis. Annals of the Royal College of Surgeons of England 91: 681–7	Case series n=27	Laparostomy with immediate intraperitoneal VAC therapy is a robust and effective system to manage patients with intra-abdominal catastrophes. There were significantly improved outcomes compared to the mortality predicted by P-POSSUM scores.	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Kleif J, Fabricius R, Bertelsen CA et al. (2012) Promising results after vacuum-assisted wound closure and mesh-mediated fascial traction. Danish Medical Journal 59: A4495	Case series n=16	It seems that VAWCM can improve the rate of complete fascial closure after treatment with OA without increasing the mortality or the occurrence of enteric fistula compared with other kinds of temporary abdominal closure.	Larger studies are included in table 2.
Koss W, Ho HC, Yu M et al. (2009) Preventing loss of domain: a management strategy for closure of the "open abdomen" during the initial hospitalization. Journal of Surgical Education 66 (2): 89–95.	Case report n=18	A technique of managing the open abdomen that prevents fascial retraction results in a high primary closure rate with an acceptable rate of short-term complications	Larger studies are included in table 2.
Labler L, Zwingmann J, Mayer D et al. (2005) V.A.C. abdominal dressing system: a temporary closure for open abdomen European Journal of Trauma 31 (5) : 488–94	Case series n=18 Follow-up= 5 to 33 months	NPWT for open abdomen in critically ill patients makes late closure up to 2 months after laparotomy possible	Larger studies are included in table 2.
Mayer D, Rancic Z, Meier, C et al (2009) Open abdomen treatment following endovascular repair of ruptured abdominal aortic aneurysms. Journal of Vascular Surgery 50 (1): 1–7.	Case report n=20 (with open abdomen)	The use of standardised novel techniques and a treatment protocol and algorithm for open abdomen treatment after eEVAR for RAAA was feasible and safe	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
McCord SS, Naik-Mathuria BJ, Murphy KM et al. (2007) Negative pressure therapy is effective to manage a variety of wounds in infants and children. Wound Repair & Regeneration 15 (3) : 296–301	Case series n=68	NPWT can be effectively used to manage a variety of wounds in children and neonates. No major complications were identified	Larger studies are included in table 2.
Miller MS, McDaniel C (2006) Postsurgical post-hysterectomy abdominal wound dehiscence treated with negative pressure wound therapy. International Journal of Gynaecology & Obstetrics 93 (3) : 264–6	Case series n=53 Follow-up = 185 days	NPWT resulted in significantly higher fascial closure rates obviating the need for subsequent hernia repair in most patients	Larger studies are included in table 2.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Navsaria PH, Bunting M, Omoshoro-Jones J et al. (2003) Temporary closure of open abdominal wounds by the modified sandwich-vacuum pack technique.[see comment] British Journal of Surgery 90 (6) : 718–22	Case series n=55 Follow-up =1 month	A modified NPWT technique is easy and provides an effective means of containing abdominal wall contents	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Olejnik J, Vokurka J, Vician M. (2008) Acute necrotizing pancreatitis: intra-abdominal vacuum sealing after necrosectomy. Hepato-Gastroenterology 55: 315–8	Non-randomised comparative study n=109	The median surgical treatment period was significantly shorter in the NPWT group (16 days; range 9–29 days) than in the foil group (21 days; range 10–33 days) ($p<0.05$).	Limited patient outcomes were reported.
Patel NY, Cogbill TH, Kallies KJ et al. (2011) Temporary abdominal closure: long-term outcomes. Journal of Trauma-Injury Infection & Critical Care 70: 769–74	Case series n=108 (15 VAC) Follow-up=34.5 months	Successful definitive fascial closure was achieved in 91% of patients. No associations with indications, temporary closure techniques, or definitive closure methods were demonstrated	Larger studies are included in table 2.
Perez D, Wildi S, Demartines N et al. (2007) Prospective evaluation of vacuum-assisted closure in abdominal compartment syndrome and severe abdominal sepsis. Journal of the American College of Surgeons 205 (4): 586–92	Non-randomised comparative study n=72 Follow-up=339 days	Complete fascia closure was achieved in 70% (26/37) of patients in the NPWT group. A high-output enterocutaneous fistula developed in 3% (1/37) of patients in the NPWT group; this was treated surgically but recurred 9 days later. VAC caused hypertrophic and large scars but patient satisfaction was similar to controls (standard laparotomy).	Included in systematic review by Quyn AJ, 2012.
Plaudis H, Rudzats A, Melberga L et al. (2012) Abdominal negative-pressure therapy: a new method in countering abdominal compartment and peritonitis - prospective study and critical review of literature. Annals of Intensive Care 2 (Suppl 1): S23	Case series n=22	Application of abdominal NPT could be a very promising technique for the control of sustained intra-abdominal hypertension and management of severe sepsis due to purulent peritonitis.	Larger studies are included in table 2.
Prichayudh S, Sriussadaporn S, Samorn P et al. (2011) Management of open abdomen with an absorbable mesh closure. Surgery Today 41: 72–8	Case series n=73	33% (24/73) of patients had delayed primary fascial closure after initial vacuum pack closure. The closure rate was significantly lower in patients with an associated infection or contamination.	Larger studies are included in table 2.
Rao M, Burke D, Finan PJ et al. (2007) The use of vacuum-assisted closure of abdominal wounds: a word of caution. Colorectal Disease 9 (3): 266–8	Case series n=29	20% (6/29) of patients developed intestinal fistulae during NPWT at a median of 20-day (range 2–50 days) follow-up.	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Rasilainen SK, Mentula PJ, Leppaniemi A K (2012) Vacuum and mesh-mediated fascial traction for primary closure of the open abdomen in critically ill surgical patients. British Journal of Surgery 99: 1725–32	Non-randomised comparative study n=104	50 VAC with mesh-mediated fascial traction versus 54 other techniques (historical control group) VAC and mesh-mediated fascial traction resulted in a higher fascial closure rate and lower planned hernia rate than methods that did not provide fascial traction.	VAC was combined with mesh-mediated fascial traction.
Roberts DJ, Zygun DA, Grendar J et al. (2012) Negative-pressure wound therapy for critically ill adults with open abdominal wounds: A systematic review. Journal of Trauma and Acute Care Surgery 73: 629–39	Systematic review n=11 studies	Limited prospective comparative data suggests that NPWT versus alternate closure techniques may be linked with improved outcomes. However, the clinical heterogeneity and quality of available studies preclude definitive conclusions.	A systematic review with meta-analysis is included in table 2.
Schmelzle M, Alldinger I, Matthaei H et al. (2010) Long-term vacuum-assisted closure in open abdomen due to secondary peritonitis: a retrospective evaluation of a selected group of patients. Digestive Surgery 27: 272–8	Case series n=49	Fascial closure=22% (11/49) Complications=88% (43/49) Re-explorations were associated with the occurrence of enterocutaneous fistula and were also of prognostic value regarding the rate of fascial closure.	Larger studies are included in table 2.
Schimp VL, Worley C, Brunello S et al. (2004) Vacuum-assisted closure in the treatment of gynecologic oncology wound failures. Gynecologic Oncology 92: 586–91	Case series n=27 Follow-up = 52 days	Experience indicates that this is a safe method for the treatment of wound failures in gynaecologic oncology patients.	Larger studies are included in table 2.
Shaikh I, Ballard-Wilson A, Yalamarthi S, et al. (2010) Use of topical negative pressure in assisted abdominal closure does not lead to high incidence of enteric fistulae. Colorectal Disease 12: 931–4	Case series n=42	This study does not support the reports suggesting a higher fistulae rate with topical negative pressure.	Included in systematic review by Quyn AJ, 2012.
Stone PA, Hass SM, Flaherty SK et al. (2004) Vacuum-assisted fascial closure for patients with abdominal trauma. Journal of Trauma-Injury Infection & Critical Care 57: 1082–6	Case series n=48	Delayed closure with NPWT was achieved in 72% of surviving patients	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Stonerock CE, Bynoe RP, Yost MJ et al. (2003) Use of a vacuum-assisted device to facilitate abdominal closure. American Surgeon 69: 1030–4	Case series n=15 Follow-up = 6 months	Although not successful in every case, in most the abdominal wall could be closed primarily	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Subramonia S, Pankhurst S, Rowlands BJ et al. (2009) Vacuum-assisted closure of postoperative abdominal wounds: a prospective study. World Journal of Surgery 33: 931–7	Case series n=51 Follow-up= 8 months	Enteric fistulae=4% (2/51). At a median follow-up of 8 months, 24% (12/51) patients developed an incisional hernia. VAC therapy is a useful adjunct in the management of the open abdomen and should be considered in the treatment of this problem.	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Suliburk JW, Ware DN, Balogh Z et al. (2003) Vacuum-assisted wound closure achieves early fascial closure of open abdomens after severe trauma. Journal of Trauma-Injury Infection & Critical Care 55 (6) : 1155–60	Case series n=35	NPWT achieved early fascial closure in a high percentage of open abdomens with an acceptable rate of complications	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.
Wondberg D, Larusson HJ, Metzger U et al. (2008) Treatment of the open abdomen with the commercially available vacuum-assisted closure system in patients with abdominal sepsis: low primary closure rate. World Journal of Surgery 32: 2724–9	Case series n=30	Patients with abdominal sepsis. Primary fascial closure=33% (10/30) Fistula=7% (2/30) Fascial edge necrosis=10% (3/30) Skin blister=3% (1/33) Prolapse of small bowel between fascia and foam=13% (4/30)	Included in systematic review by Quyn AJ, 2012. Larger studies are included in table 2.

Appendix B: Related NICE guidance for negative pressure wound therapy for the open abdomen

Guidance	Recommendations
Interventional procedures	**Negative pressure wound therapy for the open abdomen. NICE interventional procedures guidance 322 (2009) (current guidance)** 1.1 Current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen is inadequate in quality and quantity. There has been concern about the occurrence of intestinal fistulae associated with this procedure but there is currently no evidence about whether NPWT is the cause. Therefore clinicians should make special arrangements for audit of the management of all patients with an open abdominal wound, as recommended below. 1.2 Clinicians managing any patient with an open abdomen (laparostomy) should: • Inform the clinical governance leads in their Trusts with the aim of ensuring that audit support is available for collecting data for each patient, whether treated by NPWT or by other means, specifically to document the development of intestinal fistulae. • Use the NICE audit tool to collect data on outcomes for each patient, including those treated by NPWT for the open abdomen (see section 3.1). Anonymised data collected using the audit tool should be submitted to the Review Body for Interventional Procedures from 1 January 2010 to 30 June 2011 only. • Whenever possible, ensure that patients and their families or carers understand the uncertainty about the safety and efficacy of NPWT and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 NPWT for the open abdomen should only be carried out by staff with specific training in the procedure and in accordance with manufacturer's instructions when commercial products are used. 1.4 NICE encourages further research into the role of NPWT for the open abdomen. This should include a clear description of the patients and indications, and of the type of NPWT systems used. Research should include documentation of efficacy outcomes such as ease of wound care, healing rates and duration of intensive or high-dependency care, and safety outcomes including development of fistulae. Details of patients involved in research studies should also be included in the audit described in section 1.2. NICE will review the procedure when sufficient audit data and other published evidence are available.

Medical technology	**The MIST Therapy system for the promotion of wound healing. NICE medical technology guidance 5 (2011).** 1.1 The MIST Therapy system shows potential to enhance the healing of chronic, 'hard-to-heal', complex wounds, compared with standard methods of wound management. If this potential is substantiated then MIST could offer advantages to both patients and the NHS. 1.2 The amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient, at the time of writing, to support the case for routine adoption of the MIST Therapy system in the NHS. 1.3 Comparative research is recommended in the UK to reduce uncertainty about the outcomes of patients with chronic, 'hard-to-heal', complex wounds treated by the MIST Therapy system compared with those treated by standard methods of wound care. This research should define the types and chronicity of wounds being treated and the details of other treatments being used. It should report healing rates, durations of treatment (including debridement) needed to achieve healing, and quality of life measures (including quality of life if wounds heal only partially). It is recommended that centres using the MIST Therapy system take part in research that delivers these outcomes. Current users of the MIST Therapy system who are unable to join research studies should use NICE's audit criteria to collect further information on healing rates, duration of treatment and quality of life and publish their results. 1.4 NICE will review this guidance when new and substantive evidence becomes available.

Appendix C: Literature search for negative pressure wound therapy for the open abdomen

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	20/02/2013	Issue 1 of 12, Jan 2013
Database of Abstracts of Reviews of Effects – DARE (CRD website)	20/02/2013	Issue 1 of 12, Jan 2013
HTA database (CRD website)	20/02/2013	Issue 1 of 12, Jan 2013
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	20/02/2013	Issue 1 of 12, Jan 2013
MEDLINE (Ovid)	20/02/2013	1946 to February Week 1 2013
MEDLINE In-Process (Ovid)	20/02/2013	February 19, 2013
EMBASE (Ovid)	20/02/2013	1974 to 2013 Week 07
CINAHL (NLH Search 2.0/EBSCOhost)	20/02/2013	-

Trial sources searched on 21/09/2012

- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database

Websites searched

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference search
- Evidence Updates (NHS Evidence)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 exp Abdominal Injuries/
2 (Abdom* adj3 (surg* or trauma* or wound* or injury* or open* or cut* or incis* or break*)).tw.

3	(bowel adj3 (surg* or trauma* or wound* or injury* or open* or cut* or incis* or break*)).tw.
4	or/1-3
5	Wound Healing/
6	(wound* adj3 (heal* or mend*)).tw.
7	or/5-6
8	exp Abdomen/
9	Abdom*.tw.
10	Bowel*.tw.
11	or/8-10
12	7 and 11
13	Compartment Syndromes/
14	(Compartment* adj3 syndrom*).tw.
15	or/13-14
16	11 and 15
17	(Open adj3 (wound* or injury* or trauma* or surg*)).tw.
18	11 and 17
19	laparostom*.tw.
20	4 or 12 or 16 or 18 or 19
21	Negative-Pressure Wound Therapy/
22	Negative* Pressure* Wound* Therap*.tw.
23	Negative*- Pressure* Wound therap*.tw.
24	Negative* Pressure* Therap*.tw.
25	NPWT.tw.
26	Topic* negative* pressure* therap*.tw.
27	TNPT.tw. (6)
28	negative* pressure* dress*.tw.
29	Subatmospher* pressur* dress*.tw.
30	Vacuum assist* closu*.tw.
31	VAC.tw.
32	VAFC.tw.
33	vacuum* assist* fascial* closu*.tw.
34	Suction/
35	suction*.tw.
36	(vacuum* adj3 (therap* or seal* or closu*)).tw.
37	or/21-36
38	20 and 37
39	Activac.tw.
40	Engenex.tw.
41	Exusdex.tw.
42	EZCARE.tw.
43	EZ-Care.tw.

44	extricare.tw.
45	Infovac.tw.
46	Invia.tw.
47	Chariker-jeter.tw.
48	mini vac.tw.
49	NPD 1000.tw.
50	Renasys.tw.
51	Svedman.tw.
52	V1STA.tw.
53	Venturi avanti.tw.
54	Vac via.tw.
55	Vac ats.tw.
56	Prospera PRO.tw.
57	Versatile_1.tw.
58	or/39-55
59	38 or 58
60	Animals/ not Humans/
61	59 not 60
62	limit 61 to ed=20120901-20130228