solventum

The open abdomen: challenges and choices for success

3M™ AbThera™ Open Abdomen Negative Pressure Therapy

Open abdomen management

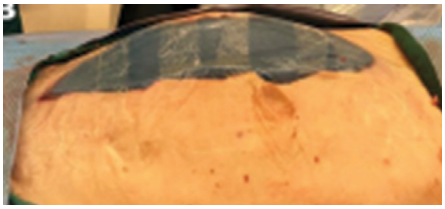
The open abdomen (OA) is a technique in managing complex problems in critically ill patients that has improved patient survival.[1,2] This technique, originally used in trauma care, is now a management strategy for many other non-trauma related illnesses and conditions[1]

Indications and conditions for open abdomen management[1]

Damage control surgery	**Abdominal compartment syndrome** (or inability to achieve closure because of excess fluid or edematous abdominal contents)	**Second-look surgery** (to assess bowel viability or to evaluate and treat continued intra-abdominal contamination)
Damage control surgery in patients in unstable condition with: hypothermia, acidosis, coagulopathy, and unstable hemodynamic status. Prevention of hypothermia and acidosis. Abbreviated operation needed in trauma and non-trauma conditions including: • Penetrating and nonpenetrating trauma • Emergent vascular surgery • Orthotopic liver transplantation • Uncontrolled venous bleeding in pancreatic surgery	Abdominal compartment syndrome due to any cause including: • Necrotizing, infected pancreatitis • Intra-abdominal sepsis • Massive fluid replacement • Retroperitoneal swelling • Bowel obstruction • Toxic megacolon • Tense ascites	• Intra-abdominal sepsis • Bowel obstruction • Intestinal ischemia due to acute mesenteric ischemia or other entity • Necrotizing, infectious acute pancreatitis • Gastrointestinal perforation with peritonitis

Open abdomen consists of[1]

A surgically created entrance into the abdominal cavity in which the fascial edges are intentionally left open (laparostomy) to facilitate healing or prevent complications.



The abdominal contents are exposed but are protected by a temporary covering.

This allows for reentry into the abdominal cavity for multiple operations and eventual completion of the definitive surgical course of treatment.

Patients in whom early definitive primary closure cannot be performed are more likely to experience[1]

- Infectious complications and sepsis
- Increased ICU and hospital LOS
- Increased duration (days) of mechanical ventilation
- Acute kidney injury
- Enteroatmospheric fistula (EAF)
- Fascial retraction with loss of abdominal domain
- Large incisional hernia

20-30%

of OA patients are not able to achieve primary fascial closure.[3]

The septic patient

Sepsis management continues to be a major challenge for healthcare systems worldwide. The cost of sepsis management in US hospitals ranks highest among admissions for all disease states.[4]

Economic impact of sepsis:

Sepsis is the

#1 cause for readmission

to the hospital costing more than **$2 billion** each year.[5-6]

2x

The average cost per hospital stay for sepsis is

$18,600

double the average **cost per stay** across all other conditions.[5-6]

Sepsis is the #1 cost of hospitalization in the U.S. consuming more than

$27 billion each year.[5]

Because sepsis patients stay in the hospital

75% longer than other patients

the increased length of stay (LOS) impacts the ability for hospitals to move patients out of the emergency department and into hospital beds.6

ICU LOS was

3x longer

for septic patients (an average of **6 days [3-13] vs 2 [1-4] for non-septic patients)**, at a cost per case of about $70,000.[7-8]

Prevalence of sepsis:

1.7M

Adults in America develop sepsis annually.[6]

270K Americans die as a result each year.[6]

1:3 Who die in a hospital have sepsis.[6]

An estimated

50%

of open abdomen patients have sepsis.[9]

Intra-abdominal sepsis and NPWT

The negative pressure associated with commercially available temporary abdominal closure (TAC) systems has the benefit of removing fluids thought to be extremely toxic, containing bacteria, cytokines, and other inflammatory mediators and a likely source of continued infection, sepsis, and multiorgan dysfunction.1

"Sadly, septic patients use a huge number of resources, requiring multiple trips to the OR. This is where 3M™ Abthera™ Therapy is ideal—we leave these patients open so we can plan a second look to check our work—to more easily assure we're controlling infection in the bowel."

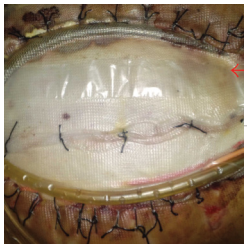
–BT, MD

The evolution of TAC[10]

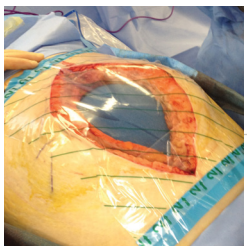
The method of the TAC chosen may play an important role inpatient outcomes.[2]

Skin-Only Closure Techniques (1980s): This technique uses skin to provide some abdominal wall stability and may use a series of towel clips or a rapid monofilament running suture.

Barker's Vacuum-Pack Technique (1995): Developed in the 1990s, this technique paved the way for future commercial negative pressure TAC systems. It is comprised of different component layers to achieve multiple goals of TAC.



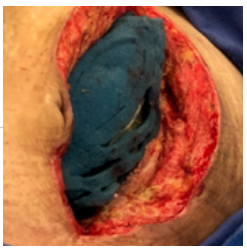
3M™ AbThera™ Open Abdomen Negative Pressure Therapy (2009): AbThera Therapy was developed with the ideal features of a TAC in mind. It offers practical advantages over the "vacuum pack technique" like fluid management and being an all-inclusive system.



Bogota Bag (1984): This technique uses a large intravenous (IV) bag to cover the abdominal viscera stapled or sutured to the skin edges of the wound.

3M™ V.A.C.® Therapy System (2003): The first Negative Pressure Wound Therapy system; provided visceral protective layers to protect abdominal contents.

3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing



3M™ AbThera™ Advance Open Abdomen Dressing (2018): AbThera Advance Dressing builds on the success of AbThera Therapy to actively facilitate drawing wound edges together. (Schmidt SAWC Fall 2018)[15]

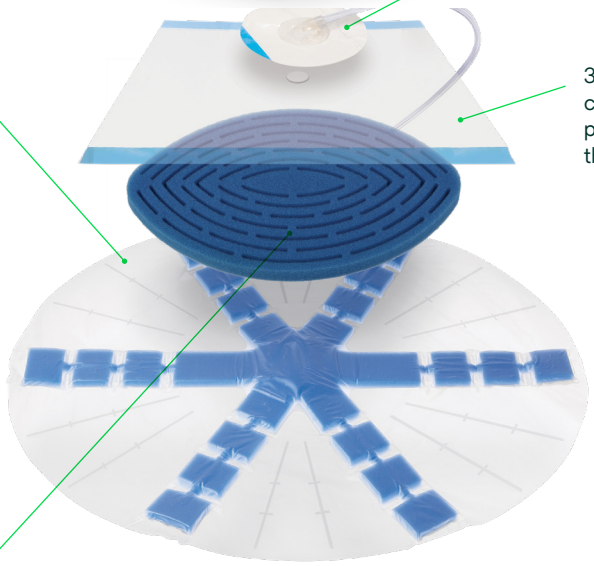
3M™ AbThera™ Open Abdomen Negative Pressure Therapy

3M™ V.A.C.® Ulta Therapy Unit:
V.A.C.® Ulta 4 Therapy Unit provides negative pressure therapy with proprietary technology.

3M™ SensaT.R.A.C.™ Pad/Technology:
Proprietary SensaT.R.A.C.™ Technology provides a real-time pressure feedback system and adjusts and monitors pressure at the abdomen.

3M™ AbThera™ Fenestrated Visceral Protective Layer:

- Provides separation between abdominal wall and viscera, protecting abdominal contents.[11]
- Manifolds negative pressure throughout the open abdomen.
- Fenestrations enable active fluid removal from the paracolic gutters when negative pressure is applied.[11]



3M™ V.A.C.® Drape: Provides a closed system to help isolate and protect abdominal contents from the external environment.[11]

3M™ AbThera™ Advance Perforated Foam

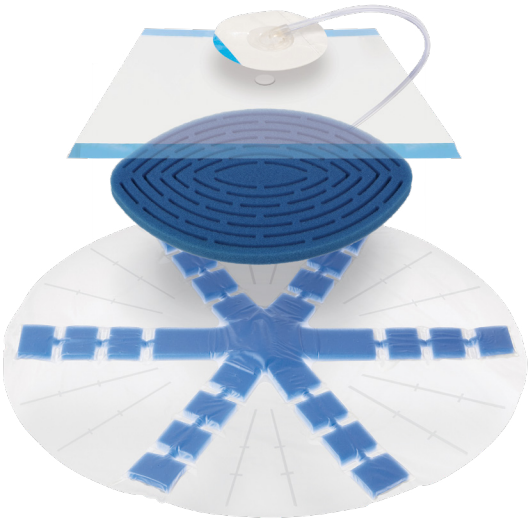
- Provides the same great benefits of 3M™ AbThera SensaT.R.A.C.™ Open Abdomen Dressing
- Under negative pressure, the unique configuration of the AbThera Advance Perforated Foam is designed to collapse medially while maintaining its vertical rigidity[15]
- Actively facilitates drawing the wound edges together[15]

Comparing TAC techniques[1, 10]

Temporary abdominal closure method	No sutures or staples required	Help protect abdominal contents from external environment	Decreases edema	Allows evacuation of fluids	Allows abdominal content to expand	Provides separation between abdominal wall and viscera	Minimizes loss of domain
3M™ AbThera™ Therapy	✓	✓	✓	✓	✓	✓	✓
Barker's Vacuum-Packing Technique	✓	✓	✓	Superficial fluid removal	✓		
Dynamic Wound Closure Systems	✓				✓		✓
Hook-and-Loop Sheets		✓			✓		✓
Bogota Bag		✓			✓		
Skin-only closure							✓

Evidence

Clinical studies have shown that 3M™ AbThera™ Open Abdomen Negative Pressure Therapy compared to BVPT is associated with:



- Decrease in all-cause mortality[2,12]
- Decreased risk of OA complications[11]
- Improved primary fascial closure rates[2,13]
- Lower ICU and ventilator days[2,14]
- Decrease in hospital LOS[2,14]

Level 2

Prospective study examining clinical outcomes associated with a Negative Pressure Wound Therapy (NPWT) System and Barker's Vacuum-Packing Technique (BVPT).[2]

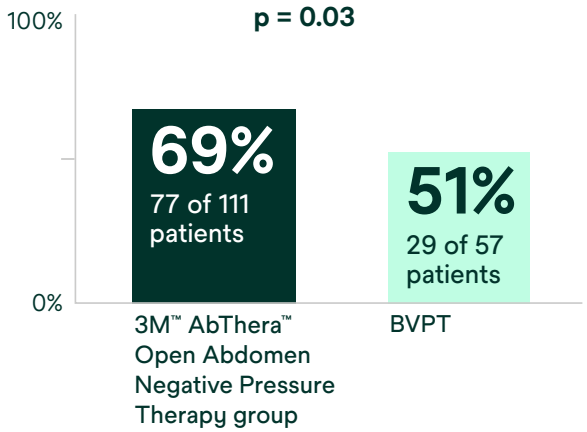
Cheatham ML, et. al.*

20 Study sites

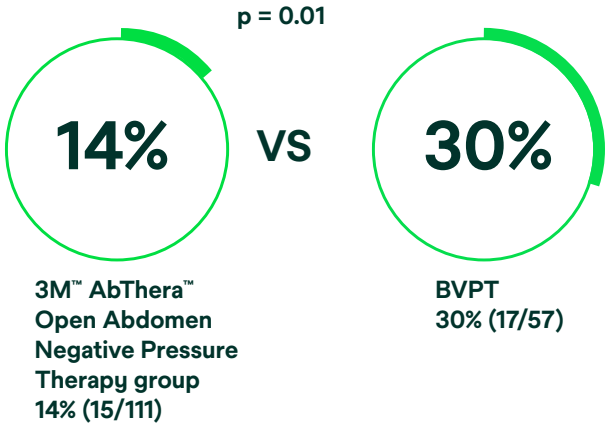
280 Patients enrolled

Among them,168 patients underwent at least 48 hours of consistent TAC therapy (111 NPWT, 57 BVPT).

30-Day primary fascial closure



30-Day all-cause mortality rate



*A prospective, observational, open-label study was performed to evaluate two TAC techniques in surgical and trauma patients requiring open abdomen management: Barker's Vacuum-Packing Technique (BVPT) and the 3M™ AbThera™ Open Abdomen Negative Pressure Therapy (NPWT). Study endpoints were days to and rate of 30-day primary fascial closure (PFC) and 30-day all-cause mortality.

Level 1

Active Negative Pressure Peritoneal Therapy after Abbreviated Laparotomy. The Intraperitoneal Vacuum Randomized Controlled Trial.[12]

Kirkpatrick AW, et. al.*

30-Day primary fascial closure	90-Day all-cause mortality rate

- Cumulative incidence of primary fascial closure at 90 days was similar between groups (hazard ratio, 1.6; 95% confidence interval, 0.82–3.0; p = 0.17).
- No difference in plasma concentration of IL-6 at baseline versus 24 (p = 0.52) or 48 hours (p = 0.82) between the groups.
- No significant intergroup difference in the plasma concentrations of IL-1, –8, –10, or 12 p70 or tumor necrosis factor between these time points.

21%

3M™ AbThera™ Open Abdomen Negative Pressure Therapy
(5/23)

50%

BVPT
(11/22)

Hazard ratio, 0.32; 95% confidence interval 0.11–0.93; p = 0.04.

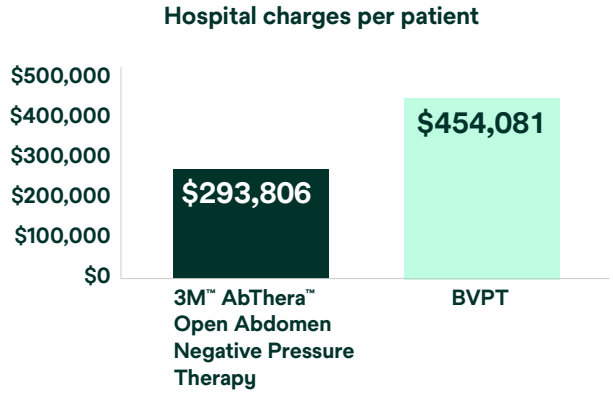
Level 5

Literature Review describing the indications for an open abdomen, methods for temporary abdominal closure, complications of an open abdomen and treatment goals.[14]

Safcsak K, Cheatham ML.†

Compared to Barker's Vacuum-Packing Technique, AbThera Therapy demonstrated a decrease in ICU days, ventilator days, hospital days, days to abdominal closure, and hospital charges. Patients who received AbThera Therapy reduced hospital charges per patient by $160,275.

	3M™ AbThera™ Open Abdomen Negative Pressure Therapy (n = 30)	BVPT (n = 12)
Hospital days (p = 0.17)	20	31
ICU days (p = 0.17)	11	17
Ventilator days (p = 0.17)	9	13
# of dressing changes (p = 0.17)	2	3



Does NPWT in the open abdomen cause fistulas?

An independent systematic review and meta-analysis of the open abdomen and temporary abdominal closure techniques in non-trauma patients was conducted that included 74 studies describing 78 patient series for a total of 4,358 patients, of which 3,461 (79%) had peritonitis and concluded the following:

Open abdomens managed with NPWT were not associated with an increased fistula formation.[3]

*A single-center, randomized controlled trial. Forty-five adults with abdominal injury (46.7%) or intra-abdominal sepsis (52.3%) were randomly allocated to 3M™ AbThera™ Open Abdomen Negative Pressure Therapy (n = 23) or Barker's Vacuum-Packing Technique (n = 22).

†In a 42-patient study AbThera Therapy and Barker's Vacuum-Packing Technique were compared for resource utilization.

Ordering information:

Description	Item number	Qty.
3M™ AbThera™ Advance Open Abdomen Dressing (Includes 3M™ AbThera™ Fenestrated Visceral Protective Layer, (2) 3M™ AbThera™ Advance Perforated Foam (4) 3M™ V.A.C.® Drape, and 3M™ SensaT.R.A.C.™ Pad and Tubing). For use with negative pressure therapy provided by the 3M™ V.A.C.® Ulta Therapy Unit	ABT1055	5 per case
3M™ AbThera™ SensaT.R.A.C. Open Abdomen Dressing (Includes (1) 3M™ AbThera™ Fenestrated Visceral Protective Layer, (2) 3M™ AbThera™ Perforated Foam (4) 3M™ V.A.C.® Drapes, and (1) 3M™ SensaT.R.A.C.™ Pad. For use with negative pressure therapy provided only by the 3M™ V.A.C.® Ulta Therapy Unit	M8275026/5	5 per case

Ready to learn more about 3M™ AbThera™ Open Abdomen Negative Pressure Therapy? Please contact your Solventum Representative.

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3M™ AbThera™ Advance Open Abdomen Negative Pressure Therapy is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. The intended use of this dressing is in open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating room/operating theater.

Follow local institutional protocols for infection control and waste disposal procedures. Local protocols should be based on the applicable federal, state and/or local government environmental regulations.

Note: Specific indications, contraindications, warnings, precautions, and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

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