AbThera™
Open Abdomen Therapy

3M™ AbThera™ Open Abdomen Negative Pressure Therapy

Product monograph

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Introduction

3M™ AbThera™ Open Abdomen Negative Pressure Therapy is a temporary abdominal closure system, designed to remove fluids from the abdominal cavity and draw wound edges together, helping to achieve primary fascial closure while protecting abdominal contents from external contamination.

This monograph will provide a comprehensive overview of open abdomen management, as well as describe characteristics and features of AbThera Therapy. It will also provide scientific and clinical evidence regarding the efficacy of open abdomen negative pressure therapy.

Background

Historically, surgeons leaving an abdomen open following a laparotomy was uncommon due to the sub-optimal conventional therapy (moist gauze dressings) that typically resulted in bowel desiccation; as a result, fistula formation, infection and sepsis were predictable complications.[1] Due to the associated complications of an open abdomen (OA), the traditional surgical approach to treating abdominal injuries was to assess the trauma, repair the damage and close the abdomen in one definitive procedure.[1] However, the definitive procedure was associated with high rates of morbidity and mortality due to the patient's inability to endure extensive surgery. With advances in medicine, management of the OA when primary closure is inadvisable has evolved to include damage control laparotomies using temporary abdominal closure (TAC) methods. TAC methods are now more acceptable within the medical community[2] and allow for stabilization of the patient to better endure subsequent operations.[3]

OA management is often seen in trauma patients, with the rate of damage control surgery reaching as high as 30%,[4] or used as a treatment for abdominal compartment syndrome (ACS). In non-trauma applications, OA management is used in intra-abdominal hypertension (IAH) treatment and ACS. A decompressive laparotomy is performed to address these conditions in surgical patients. Patients at risk for developing ACS should have intra-abdominal pressure (IAP) monitored (normal IAP range: subatmospheric to 6.5mmHg).[5] Because the abdominal contents are strictly contained, any increase in volume contents results in increased IAP,[5] which can be measured indirectly using pressure readings from the patient's urinary bladder. An increased urinary bladder pressure is associated with an increased IAP, a principal cause of ACS.[6] Furthermore, when IAP is greater than 25mmHg coupled with oliguria, a decompressive laparotomy is performed to reduce the risk of ACS development. Some studies have shown that even lower levels of IAP (10-15mmHg) are clinically relevant, increasing the risk of developing ACS.[4-8] Therefore, managing IAP levels, and subsequently preventing ACS, is critical due to the associated high mortality rate resulting from sepsis and multi-organ failure.[5]

Following damage control laparotomy, the abdomen is left open at the time of operation to facilitate reexploration after trauma, allowing the abdomen to be accessible for washouts, and to stabilize the patient for further surgery.[2] Other indications for maintaining an OA include pancreatitis, bowel edema, acidosis, pelvic inflammatory disease, hypothermia and intra-abdominal bleeding.[1-3,9] Despite these indications, several complications may occur that can result from an OA, including fistula formation, infection, loss of bowel function, ventral hernia, decreased core temperature, and loss of domain.[3] The development of such complications can be minimized by lessening exposure of the bowel and trauma to the abdominal contents, characteristics which an ideal TAC method should address.[1] Over the years, different TAC methods have been developed, providing several options; these are listed in (**Table 1**).

Table 1. Available temporary abdominal closure options

TAC type	Description
Towel clips	• Most basic temporary abdominal closure (TAC) that serves to facilitate skin closure. • Up to 30 surgical clips (1 cm apart from each skin edge) are utilized to perform a skin-only closure.[11] • Advantages: inexpensive, widely available, and quick to perform. • Disadvantages: potential for skin damage, high incidence of abdominal compartment syndrome (ACS) and intra-abdominal hypertension (IAH), and interferes with advanced diagnostic studies.[1,9]
Bogotá bag	• Involves the use of an open intravenous (IV) bag. • Technique involves cutting the pre-gas sterilized IV bag into an open, oval shape and suturing it to the skin.[1,12,13] • Advantages: low-cost, non-adherent, prevention of evisceration, ease of application and availability in the OR.[1,12] • Disadvantages: potential for skin tearing, bowel adherence to the abdominal wall, increased risk of ACS, difficulty reentering the abdomen, having to gas sterilize the bag prior to use, no exudate management, and no preservation of domain.[1,2]
Absorbable mesh closure	• Mesh is placed over abdominal contents, followed by a coat of gauze packing.[11] • Advantages: absorbable, easy placement, and facilitates re-exploration with an increased strength compared to that of the Bogotá bag.[1] • Disadvantages: potential incidence of wound sepsis postoperatively and high rates of fistula and hernia formation when placed over the bowel, with some studies reporting rates as high as 40%.[11,14]
Wittmann Patch™ (Starsurgical, Inc., Burlington, WI)	• A hook and loop prosthetic over the abdomen. • Closure is achieved by overlapping the two hook and loop sheets.[15] • Advantages: allows for easy entrance to abdomen and aids in abdominal closure through gradual fascial approximation.[1,9] • Disadvantages: potential risk for developing IAH and ACS and provides minimal fluid control.[1]
Barker's vacuum packing technique (BVPT)	• Utilizes a fenestrated, non-adherent polyethylene sheet placed over the viscera with moist surgical towels covering it.[1] • Uses two 10-French silicone drains over the towels and an iodoform-impregnated adhesive.[1] • Continuous wall suction is applied to remove fluid. • Advantages: inexpensive, uses readily available materials found in OR, and moderate fluid control. • Disadvantages: potential for bowel adhesion and fascial retractions within 7-10 days of having an OA.[1]
Commercialized Negative Pressure Therapy Systems	• Commercialized device indicated for temporary bridging of abdominal wall openings where primary closure is not possible and / or repeat abdominal entries are necessary.[10] • Kit components include: – A non-adherent layer that protects the bowel and assists with fluid removal. – A wound foam that helps deliver negative pressure to the abdominal cavity. – A transparent film to protect the open abdomen from the external environment. – A tube set that connects the therapy unit to the dressing. • Advantages: provides bowel protection; facilitates fluid removal; facilitates reoperation. • Disadvantages: requires dressing and therapy unit training; premium priced.

The ideal TAC should be easy to use: the components should be easily applied, require limited dressing changes, and be cost-effective. It should also meet the requirements for open abdomen management: allow room for abdominal expansion, protect against contamination, decrease bowel edema, manage fluids and exudate, prevent adhesions, minimize loss of domain, and protect the viscera, fascia, and periwound skin. Lastly, the ideal TAC should reduce the recurrence of ACS, support closure, and reduce the risk of complications and mortality.[10]

Product description

3M™ AbThera™ Open Abdomen Negative Pressure Therapy **(Figure 1)** incorporates all the functional elements of an ideal temporary abdominal closure device. The components form a synergized system designed for simplicity, ease of use, and fast applications. AbThera Therapy dressings contain:

1. The 3M™ AbThera™ Fenestrated Visceral Protective Layer (VPL) is a non-adherent fenestrated polyurethane layer which separates the bowel from the abdominal wall and viscera. It manifolds negative pressure throughout the open abdomen to facilitate removal of fluid deep within the paracolic gutters. It can be cut to size and accommodate tubes and drains.
2. The 3M™ AbThera™ Perforated Foam is a hydrophobic, reticulated foam comprised of an open pore structure (400-600 microns) that transfers uniform distribution of negative pressure to the VPL and helps with exudate removal. When negative pressure is applied, it provides medial tension to minimize fascial retraction and loss of domain. Its flexible design adapts to the contours of an open abdomen, and it can be cut to size to fit varying open abdomen defects. This perforated foam is featured within the AbThera™ SensaT.R.A.C™ Open Abdomen Dressing Kit (seen in **Figure 1**).

   The 3M™ AbThera™ Advance Perforated Foam (**Figure 2**) leverages the predicate foam's composition and benefits, but features a unique configuration designed to collapse medially while maintaining its vertical rigidity when negative pressure is applied. This foam configuration actively facilitates drawing wound edges together. This perforated foam is featured within the 3M™ AbThera™ Advance Open Abdomen Dressing Kit.
3. 3M™ V.A.C.® Drape provides a closed system to help protect the abdominal contents from external contamination.
4. The 3M™ SensaT.R.A.C™ Pad connects the dressing to a compatible therapy unit to deliver negative pressure. It facilitates exudate and fluid removal from the dressing. Featuring the 3M™ SensaT.R.A.C™ Technology, it provides monitoring of negative pressure during therapy.

AbThera Therapy dressings are compatible with the 3M™ V.A.C.® Ulta Therapy Unit which offers continuous negative pressure, allowing for removal of high volumes of exudate. To accommodate the high levels of fluid removal, 1000ml canisters are recommended for use with AbThera Therapy dressings.

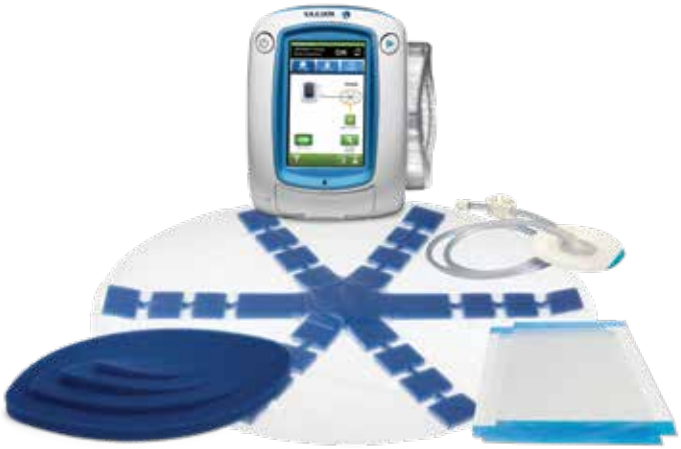


Figure 1. 3M™ AbThera™ SensaT.R.A.C™ Open Abdomen Dressing Kit with the 3M™ V.A.C.® Ulta Therapy Unit.

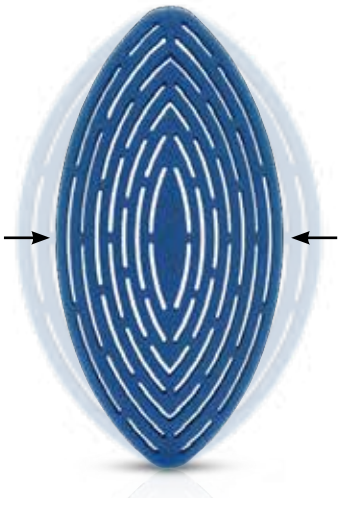


Figure 2. 3M™ AbThera™ Advance Perforated Foam collapses medially when negative pressure is applied to help draw wound edges together.

Mechanism of action overview

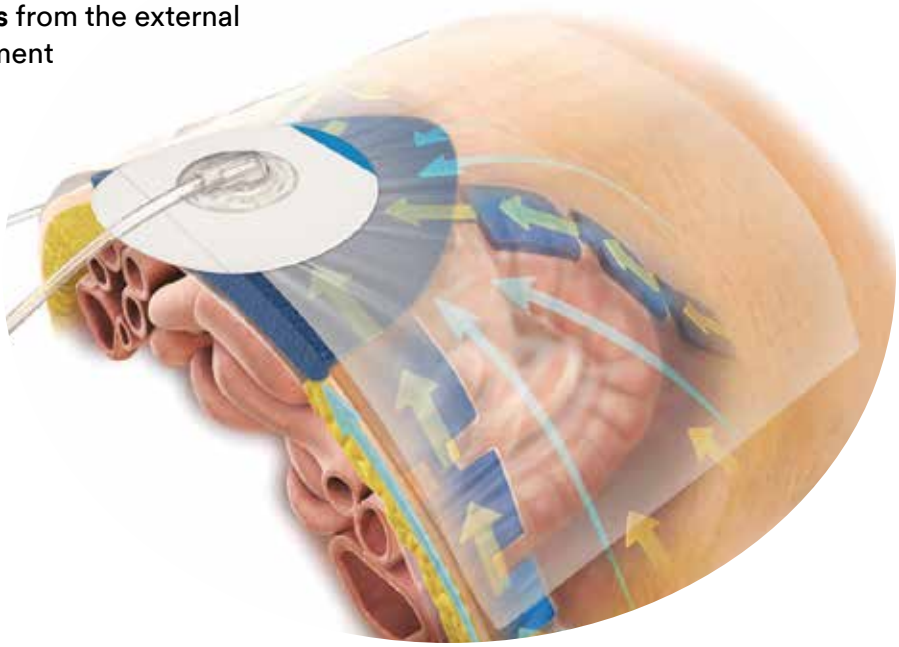
Actively removes fluid and reduce edema[16,17]

Provides medial tension which helps minimize fascial retraction and loss of domain[17-19]

Provides separation between the abdominal wall and viscera, protecting abdominal contents

Allows for **rapid access for re-entry** and does not require sutures for placement

Helps **protect abdominal contents** from the external environment



When used with a compatible therapy unit, continuous negative pressure is transferred from the therapy unit to the perforated foam and to the encapsulated foam within the visceral protective layer. Negative pressure manifolds throughout the open abdomen which facilitates the removal of exudate and infectious material to help reduce edema. At the same time, the perforated foam and the encapsulated foam collapses medially, drawing fascial edges closer together which helps minimize fascial retraction and loss of domain.[16-19]

Indications for use

3M™ AbThera™ 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 system is for use in open abdominal wounds, with exposed viscera, including but not limited to, abdominal compartment syndrome (ACS). 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.

Contraindications

- **Never** place exposed foam material directly in contact with exposed bowel, organs, blood vessels or nerves.
- Protect vital structures with the Visceral Protective Layer at all times during therapy.
- Patients with open abdominal wounds containing non-enteric unexplored fistulas should not be treated with AbThera Therapy.

Warnings

Not for use with Instillation Therapy: Although it is accepted medical practice to flush a contaminated open abdominal cavity with saline or other medical solutions, the 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing and 3M™ AbThera™ Advance Open Abdomen Dressing were not designed for this purpose, and 3M has no studies to support its safe and effective use with instillation therapy. Potential risks of instillation into the open abdomen include:

- Instillation of fluid in the abdomen without sufficient fluid recovery may lead to abdominal compartment syndrome.
- Instillation of fluids in the abdomen that are untested for safety and efficacy with this application could lead to severe hollow viscus and solid organ damage.
- Instillation of unwarmed fluid in large quantities may lead to hypothermia.

Only use the 3M™ SensaT.R.A.C.™ Pad: Substitution with any other tubing, alteration of the SensaT.R.A.C. Pad or breach of the prescribed SensaT.R.A.C. Pad application for the purpose of instilling fluids into the open abdomen is not recommended under any circumstance. This may lead to loss of therapy efficacy or harm to the patient.

Bleeding: Patients with abdominal wounds must be closely monitored for bleeding as these wounds may contain hidden blood vessels which may not be readily apparent. If sudden or increased bleeding is observed in the dressing, tubing or canister, immediately discontinue Negative Pressure Therapy, take appropriate measures to stop bleeding, and contact the physician. Negative Pressure Therapy is not designed to prevent, minimize or stop bleeding.

Warnings *(cont.)*

Hemostasis must be achieved prior to dressing placement.

The following conditions may increase the risk of potentially fatal bleeding.

- Suturing and/or anastomosis
- Trauma
- Radiation
- Inadequate wound hemostasis
- Non-sutured hemostatic agents (for example, bone wax, absorbable gelatin sponge, or spray wound sealant) applied in the abdomen may, if disrupted, increase the risk of bleeding. Protect against dislodging such agents.
- Infection in the abdominal wound may weaken visceral organs and associated vasculature, which may increase susceptibility to bleeding.
- Use of anticoagulants or platelet aggregation inhibitors.
- Bone fragments or sharp edges could puncture vessels or abdominal organs. Beware of possible shifting in the relative position of tissues, vessels or organs within the abdominal wound that might increase the possibility of contact with sharp edges.

Intra-abdominal Pressure Monitoring: Laparotomy with the placement of any temporary abdominal closure does not eliminate the possibility of elevation in intra-abdominal pressure (IAP). When using Negative Pressure Therapy, IAP monitoring (for clinical or diagnostic signs and symptoms of elevated IAP) should continue as indicated by patient condition and in accordance with institutional clinical practice or guidelines. If intra-abdominal hypertension (IAH) or abdominal compartment syndrome (ACS) is observed or suspected, note intraabdominal pressures and turn off power to the Negative Pressure Therapy Unit, discontinuing negative pressure. After full expansion of the perforated foam, obtain a new intra-abdominal pressure measurement. If IAH/ACS persists without negative pressure, discontinue the use of Negative Pressure Therapy and address the underlying condition as medically indicated.

Use of the 3M™ AbThera™ Fenestrated Visceral Protective Layer: When using Negative Pressure Therapy, ensure that the AbThera Fenestrated Visceral Protective Layer completely covers all exposed viscera and completely separates the viscera from contact with the abdominal wall. Place the AbThera Fenestrated Visceral Protective Layer over the omentum or exposed internal organs, and carefully tuck it between the abdominal wall and internal organs, making sure the AbThera Fenestrated Visceral Protective Layer completely separates the abdominal wall from the internal organs.

Adhesions and fistula development: Formation of adhesions of the viscera to the abdominal wall may reduce the likelihood of fascial reapproximation and increase the risk of fistula development which is a common complication in patients with exposed viscera.

Infection: Infected abdominal wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as patient condition, wound condition and treatment goals.

Dressing placement: Always use a dressing from a sterile package that has not been opened or damaged. Do not force any dressing component into the wound, as this may damage underlying tissue.

Dressing removal: The dressing components are not bioabsorbable. Always remove all dressing components from the abdomen at every dressing change.

Warnings *(cont.)*

Keep Negative Pressure on: Never leave the dressing in place without active negative pressure for more than two hours. If negative pressure is off for more than two hours, change dressing. Either apply a new dressing from an unopened sterile package and restart negative pressure or apply an alternative dressing.

Defibrillation: Remove adhesive drape from area of defibrillation to prevent inhibition of electrical energy transmission.

Acrylic Adhesive: The 3M™ V.A.C.® Drape has an acrylic adhesive coating, which may present a risk of adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives. If a patient has a known allergy or hypersensitivity to such adhesives, do not use the dressing. If any signs of allergic reaction or hypersensitivity develop, such as redness, swelling, rash, urticaria or significant pruritus, discontinue use and ensure appropriate emergency medical treatment. If bronchospasm or more serious signs of allergic reaction appear, remove dressing and ensure appropriate emergency medical intervention as indicated.

Magnetic Resonance Imaging (MRI) – Therapy Unit: The 3M™ V.A.C.® Ulta Therapy Unit is MR unsafe. Do not take the device into the MR environment.

Magnetic Resonance Imaging (MRI) – Open Abdomen Dressing: The dressing can remain on the patient with minimal risk in an MR environment, assuming that use of Negative Pressure Therapy is not interrupted for more than two hours.

Hyperbaric Oxygen Therapy (HBO): Do not take the V.A.C.® Ulta Therapy Unit into a hyperbaric oxygen chamber. The therapy unit is not designed for this environment, and should be considered a fire hazard. After disconnecting the therapy unit, either (i) replace the dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the SensaT.R.A.C. Pad Tubing with dry gauze. For HBO therapy, the tubing must not be clamped. Never leave a dressing in place without active negative pressure for more than two hours.

Application setting: Dressing applications and changes should be performed under strict sterile conditions in the operating theater. If dressing change is performed outside the operating theater, it must be performed in an environment equipped to address the onset of critical complications and where strict aseptic technique can be utilized.

Precautions

Standard precautions: To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluids is likely.

Intra-abdominal packing: When using intra-abdominal packing with Negative Pressure Therapy, packing material may be drier than anticipated. Evaluate this material prior to removal and rehydrate if necessary to prevent adherence or damage to adjacent structures.

Monitor fluid output: The dressing is designed to efficiently remove fluid from the abdominal compartment and to evenly distribute negative pressure. When treating patients with Negative Pressure Therapy, the volume of exudate in the canister and tubing should be frequently examined.

Patient size and weight: The size and weight of the patient should be considered when prescribing Negative Pressure Therapy. Initial lower negative pressure should be considered for certain small or elderly patients who are at risk of fluid depletion or dehydration. Monitor fluid output including the volume of exudate in both the tubing and canister. This therapy has the potential to remove and collect large volumes of fluid. Tubing volume is approximately 25ml from 3M™ SensaT.R.A.C.™ Pad to canister.

Spinal cord injury: In the event a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue Negative Pressure Therapy to help minimize sensory stimulation.

Bradycardia: To minimize the risk of bradycardia, the dressing must not be placed in proximity to the vagus nerve.

Enteric fistula or leak: When treating an open abdomen where enteric fistulas are present, clinicians should consider the potential for abdominal contamination if effluent is not appropriately isolated or managed.

Protect periwound skin: Consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile/friable periwound skin with additional drape, hydrocolloid or other transparent film.

- Multiple layers of the drape may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the drape, foam or SensaT.R.A.C. Pad tubing appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the drape over the foam dressing during drape application.

If there are any questions regarding the proper placement or usage of the 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing and 3M™ AbThera™ Advance Open Abdomen Dressing, please contact your local 3M clinical representative.

Science Supporting 3M™ AbThera™ Open Abdomen Negative Pressure Therapy – bench and animal studies

The advantages of applying negative pressure therapy (NPT) for the open abdomen (OA) include providing medial tension, removing abdominal fluids, protecting the OA from external contamination, and helping approximate wound margins. Several studies were conducted to evaluate these negative pressure therapy (NPT) properties. Results have yet to be verified in human trials.

Pressure mapping

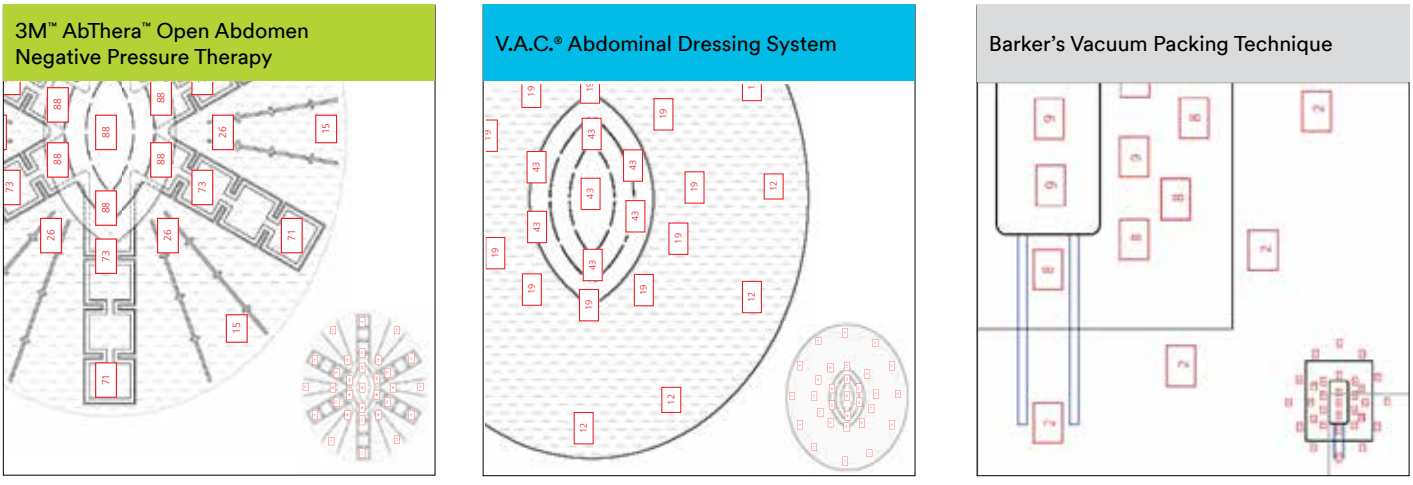
Using a bench top model, Delgado and Sammons[20] compared the performance of AbThera Therapy, V.A.C.® Abdominal Dressing System (VADS)*, and Barker's vacuum packing technique (BVPT).

Methods:

- Constant negative pressure (NP) at -125mmHg was applied to an *in vitro* test model designed to simulate the OA physical conditions in static and dynamic conditions (**Figure 3**).
- A protein solution was used to simulate wound exudates.
- Using pressure sensors, data were collected from 3 concentric zones:
  - Zone 1: closest NP source
  - Zone 2: immediately outside material edge
  - Zone 3: most distal from NP source

Results:

AbThera Therapy and VADS showed significantly higher pressures that were distributed throughout all three zones compared to BVPT ($p<0.05$). Furthermore, compared to VADS, AbThera Therapy showed significantly better pressure distributions in Zones 2 and 3 ($p<0.05$). No significant differences were found in Zone 1 between AbThera Therapy and VADS.



Red boxes with number represent location of pressure sensors and measured mmHg.

Figure 3. Pressure distribution model *in vitro*.
* V.A.C.® Abdominal Dressing System is no longer on the market.

Fluid removal using an in vitro model

Delgado and Sammons[20] also compared 3M™ AbThera™ Open Abdomen Negative Pressure Therapy, V.A.C.® Abodminal Dressing System (VADS)* and Barker's vacuum packing technique (BVPT) in their rate of fluid removed *in vitro*.

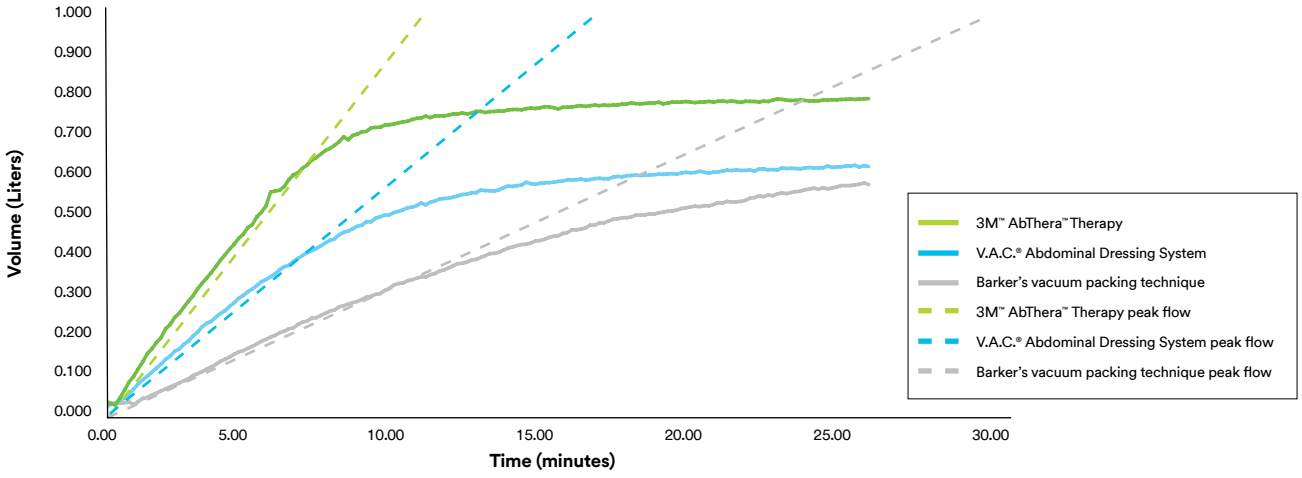
Methods:

- Constant negative pressure at -125mmHg was applied to an *in vitro* test model designed to simulate the open abdomen physical conditions in static and dynamic conditions.
- A protein solution was used to simulate wound exudates.
- Fluid removal was measured by volume (liters) over time.

Results:

AbThera Therapy had the highest rate of fluid removal at 93ml/min compared to 61ml/min for VADS and 34ml/min for BVPT (**Figure 4**). AbThera Therapy also had the highest total volume fluid removal among the three treatment regimens.

Efficient fluid removal



AbThera Therapy provided both rapid and complete fluid removal

Figure 4. Rate of fluid removal of AbThera Therapy, VADS, and BVPT
* V.A.C.® Abdominal Dressing System is no longer on the market.

Blood flow and fluid removal using an *in vivo* model

Lindstedt et al[21] compared changes in porcine microvascular blood flow in small intestinal wall, wound contraction and fluid evacuation with VADS and AbThera Therapy.

Methods:

- Twelve pigs underwent midline incisions and were treated with either VADS or AbThera Therapy.
- Microvascular blood flow was measured using laser Doppler velocimetry before and after application of negative pressure at -50, -75, and -125mmHg.
- Wound contraction and fluid removal rate were also measured.

Results:

Results showed no differences in blood flow between the two products; however, AbThera Therapy afforded significantly better fluid removal and wound contraction compared to VADS ($p<0.05$).

Burst strength testing of anastomoses

Norbury et al[22] evaluated the effect of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy on the integrity of porcine small intestinal anastomoses.

Methods:

- *In situ* burst strength testing was conducted using a domestic pig model; in each pig (n=3), there were 8 anastomoses.
- Four of the anastomosis sites were located in the superficial abdomen in close proximity to negative pressure (NP), and the remaining four sites were located deeper in the abdomen at sites remote to NP.
- In each group of 4 anastomosis sites, 2 were sutured and 2 were stapled.
- Burst strength was measured at each site with NP on or NP off.
- Following 24 hours of AbThera Therapy at -125mmHg continuously, each anastomosis underwent burst strength testing *in situ* (**Figure 5**).
- The relative integrity of each anastomosis condition was calculated by dividing the maximum burst strength pressure value (mmHg) by a baseline intraluminal pressure obtained from untreated, non-anastomosed intestine.

Results:

Stapled anastomoses had lower burst strength than sutured anastomoses, but mean values were still at least 4.6 times greater than baseline (**Figure 6**). Burst strength testing revealed that negative pressure was well tolerated. Results suggest that in a porcine model, negative pressure therapy did not have a negative impact on anastomotic sites when applied during the initial 24 hours post surgery when the sites are weak and not yet healed.

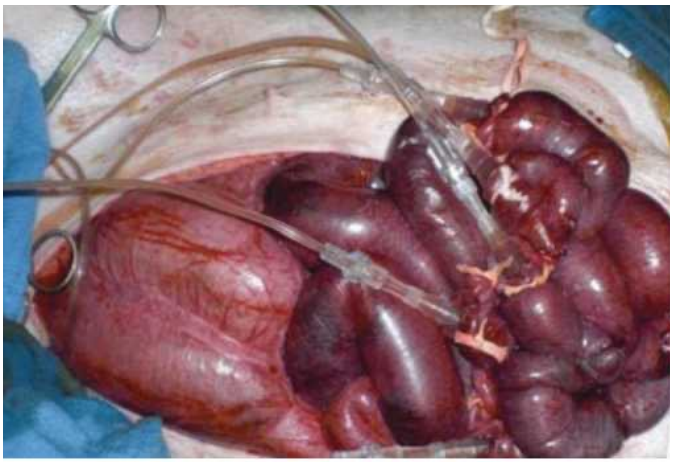


Figure 5. Burst strength testing set-up.

Burst Strength Testing of Porcine Intestinal Anastomoses Treated with 3M™ AbThera™ Open Abdomen Negative Pressure Therapy for 24 hours (Mean±SEM)

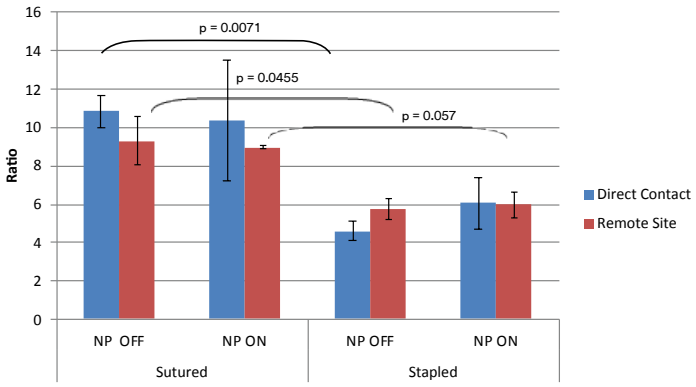


Figure 6. Burst strength testing results (n=4 anastomosis sites per group).

Inflammatory properties and organ damage

Kubiak et al[16,23] used a clinically applicable open abdomen (OA) porcine model of sepsis and ischemia and reperfusion-induced organ injury resulting in abdominal compartment syndrome to compare negative pressure therapy (NPT; V.A.C.® Abdominal Dressing System [VADS]) and passive drainage in reducing systemic inflammation and organ damage.

Methods:

- Twelve pigs were surgically instrumented for hemodynamic monitoring.
- Pigs underwent a laparotomy, and the superior mesenteric artery (SMA) was isolated and clamped for 30 minutes to induce intestinal ischemia/reperfusion.
- Pigs then had an enterotomy made in the cecum, and a fecal clot was created and placed in the abdomen to induce severe sepsis.
- Pigs were divided into two groups of 6, one group receiving a temporary abdominal closure (TAC) via NPT (ie, VADS), while the other group received passive drainage (PD; no NPT).

Results:

Results showed NPT led to increased survival compared to PD group (83% [5/6 pigs] vs 50% [3/6 pigs], respectively; **Figure 7**). A significantly elevated intra-abdominal pressure (measured via the bladder pressure) was seen in the PD group compared to NPT (**Figure 8**). The NPT group had a significantly higher urine output compared to the PD group ($p<0.05$) (**Figure 9**). NPT also significantly removed a greater volume of ascites, reduced systemic inflammation, and showed significant improvement in the lung, kidney, and intestine (**Figure 9**). These results showed that NPT mitigated the systemic inflammatory response that causes injury to other organs (lung and kidney) that can result in multiple organ dysfunction or failure (MODS/MOF) and even death in pigs.

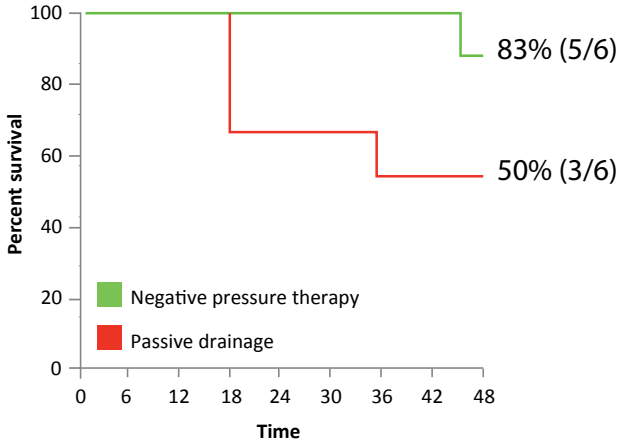


Figure 7. Percent survival over 48 hours.

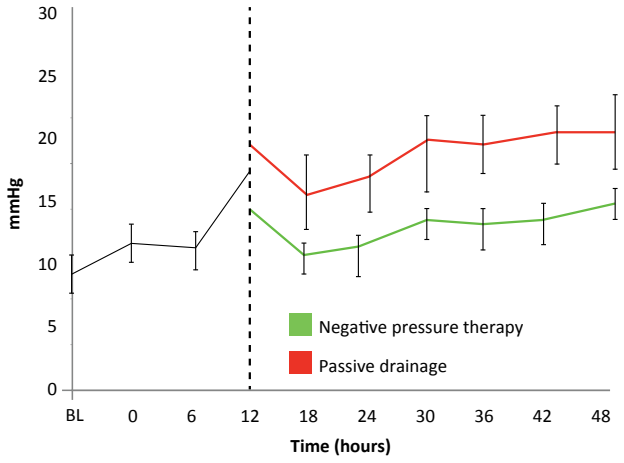
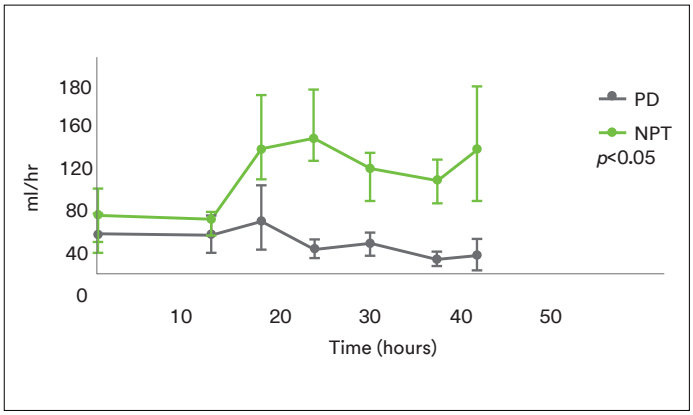


Figure 8. Bladder pressure over time.

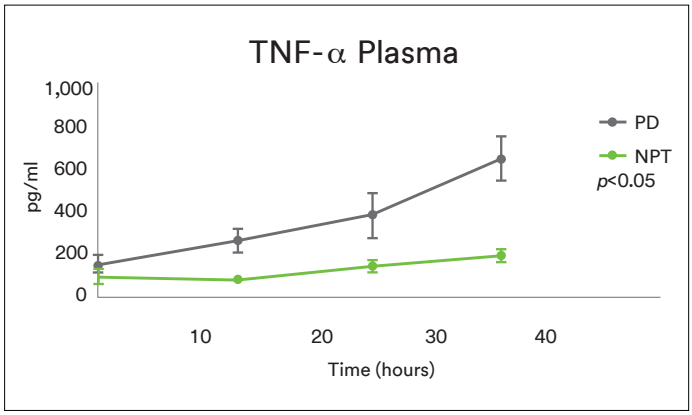
Physiological response

Urine Output (Mean ±SEM) During 36 hr Treatment



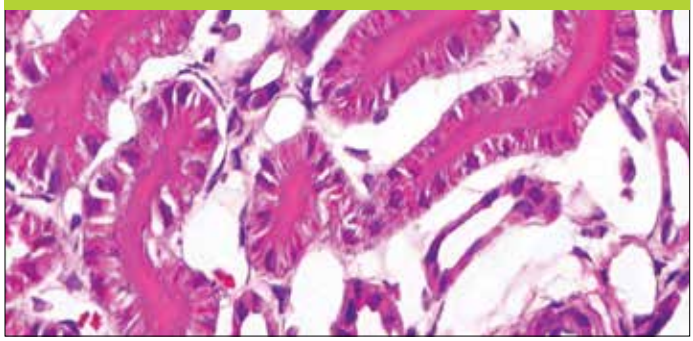
Improved physiological response observed in the kidney.

Inflammatory response



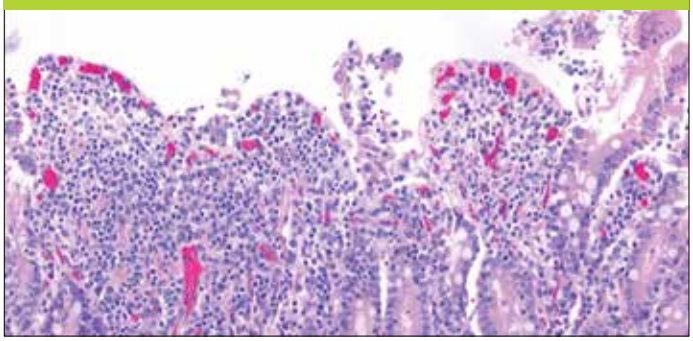
Significant systemic reduction in TNF-α plasma levels was observed.

Kidney histology after passive drainage (400x)



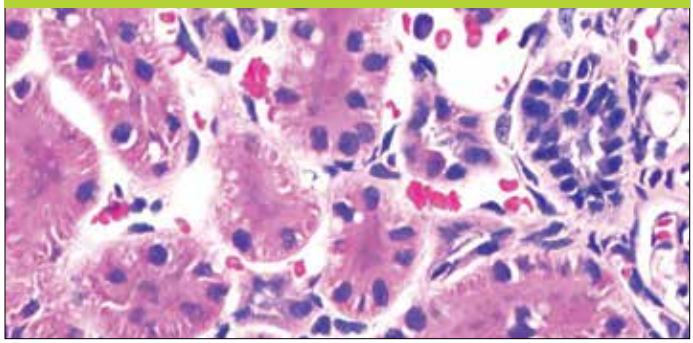
Loss of epitheal barrier, tubular degeneration and noticeable edema present.

Intestinal histology after passive drainage (100x)



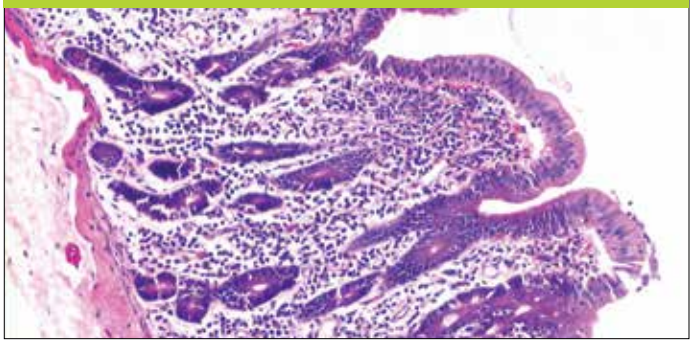
Extensive loss of epithelial layer and congested capillaries, indicative of poor drainage (edema) with heavy infiltration of lymphoid cells (inflammatory response).

Kidney histology after treatment with NPT (400x)



Minimal epithelial barrier damage, less pronounced tubular damage.

Intestinal histology after treatment with NPT (100x)



No obvious cellular damage to surface epithelium is seen and reduced edema. Minimal edema is noted, along with reduced infiltration of lymphoid cells (inflammatory response).

Figure 9. Physiological Response[23] and Inflammatory Response (adapted from Kubiak et al[16]) (Top). Histological imaging[23] (Bottom).

Inflammation, pathophysiological and metabolomic analyses

Norbury[24] evaluated the impact of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy in a closed abdomen septic swine model using pathophysiological and metabolomic analyses.

Methods:

- Ten female swine had intestinal ischemia and reperfusion induced followed by induction of sepsis with a fecal suspension into the peritoneal cavity.
- Negative Pressure Therapy (NPT) was applied to 5 swine, and the remaining 5 received no AbThera Therapy.
- Blood samples taken at hours 10, 18, and 48 were used for biomechanical and metabolomic analyses.
- Proteomic analysis of peritoneal and plasma samples was used to measure inflammatory responses.

Results:

Results showed that swine treated with AbThera Therapy had a reversed effect of injury compared to the control. Metabolomic analysis of plasma samples correlated well with other pathophysiological parameters, suggesting an early indication of injury and therapeutic benefit in terms of mitigating the inflammatory response and recovery from stress-induced septic injury (**Table 2**).

Table 2: Effects of negative pressure therapy on pathophysiological parameters

Organ System	Parameter	Effect of injury	Effect of NPT
Ischemia / Reperfusion	Plasma Lactate	↑	↓
Hemodynamic	CVP	↑	↓
	SvO_2	↓	↑
Pulmonary	PaO_2:FiO_2 & Cstat	↓	↑
	Acute alveolar congestion; interstitial edema and congestion	↓	↑
Renal	Plasma BUN & Creatinine	↑	↓
Inflammatory	Plasma TNF-α	↑	↓
Metabolomic	Myo-inositol (a storage reservoir for pro-inflammatory arachidonic acid)	↑	↓
	Long chain fatty acid biosynthesis	↓	↑

Decompression after ACS

Shah et al[25] evaluated the safety and effects of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy when used as a temporary abdominal closure (TAC) in the immediate post-decompression period after abdominal compartment syndrome (ACS) using a hemorrhagic shock porcine model.

Methods:

- Twelve female Yorkshire swine had ACS physiologically induced.
- Decompressive laparotomy was performed at 0 hours after 3-4 hour induction of ACS.
- Hemorrhagic shock model (blood loss to MAP of 35mmHg) was used.
- At decompression, swine were designated a TAC of either AbThera Therapy (n=6) or Bogotá bag (n=6) lasting 48 hours or until death.
- AbThera Therapy pressure settings were continuous at -125mmHg.

Results:

Results demonstrated that early application of AbThera Therapy did not increase the incidence of post-decompression recurrent intra-abdominal hypertension (IAH; **Figure 10**) or decrease survival time (40.5 ± 4.8 hours versus 29.8 ± 8.2 hours [AbThera Therapy vs Bogotá bag]). AbThera Therapy had no adverse effects on physiological and blood related outcomes. Results suggested that early application AbThera Therapy appears safe with no increased mortality or recurrent IAH.

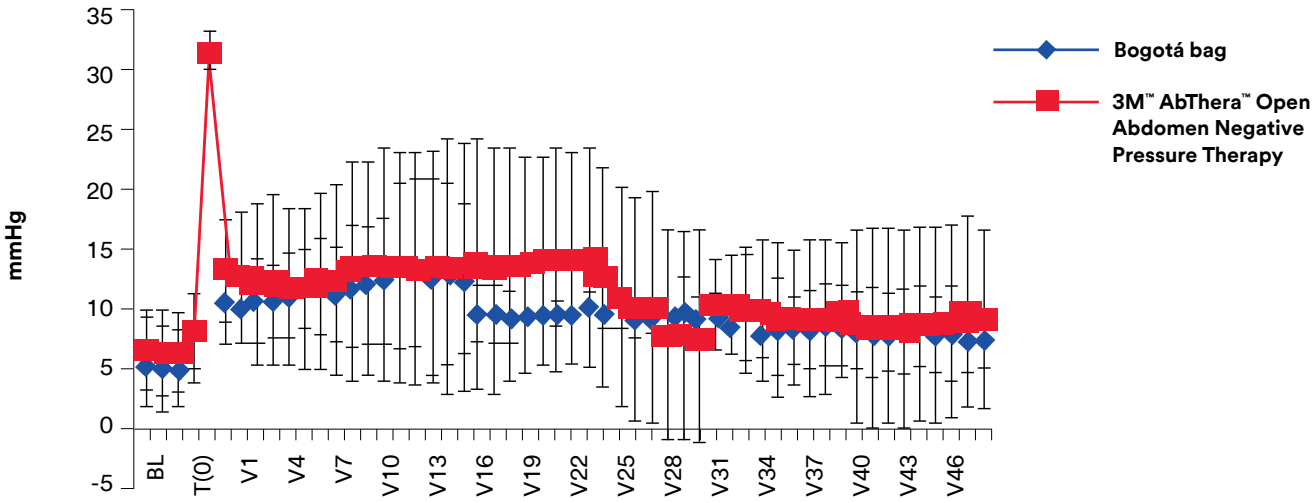


Figure 10. IAP levels of Bogotá bag and 3M™ AbThera™ Open Abdomen Negative Pressure Therapy (n=6 pigs per group)

Inflammatory properties on intestinal microenvironment

Norbury et al[26] evaluated the effect of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy on the inflammatory response of the intestinal microenvironment in a porcine septic model.

Methods:

- Twelve female swine were given intestinal ischemia and reperfusion and had intra-abdominal placement of a fecal clot simulating a septic bowel.
- At 12 hours, a decompressive laparotomy was performed and pigs were subsequently treated with continuous negative pressure at -125mmHg using AbThera Therapy (n=6) or with a Bogotá bag (n=6).
- Treatment with negative pressure lasted up to 35 hours.

Results:

Results showed that swine treated with AbThera Therapy had increased survival with an odds ratio of 4.0 (**Figure 11**). Swine treated with AbThera Therapy also had improved lung function, suggesting that AbThera Therapy reduced the effect of injury to the lung (MODS) (**Figure 12**). More importantly, at a time when immunoparalysis begins to occur (around 12 hours post injury; **Figure 13**), peritoneal fluid (PF) from septic swine treated with AbThera Therapy was better able than PF from Bogotá bag-treated swine to induce human macrophages to produce an inflammatory response as measured by an increase in reactive oxygen species (ROS) *in vitro* (**Figure 14**).

The preliminary findings from this animal study showed that negative pressure therapy appears to modulate the intestinal microenvironment, facilitating an early robust, yet transient, anti-microbial host defense mediated by macrophages to combat sepsis. This may help overcome immunoparalysis that occurs during septic injury without prolonging the inflammatory response. Clinical studies in humans are required to support these findings.

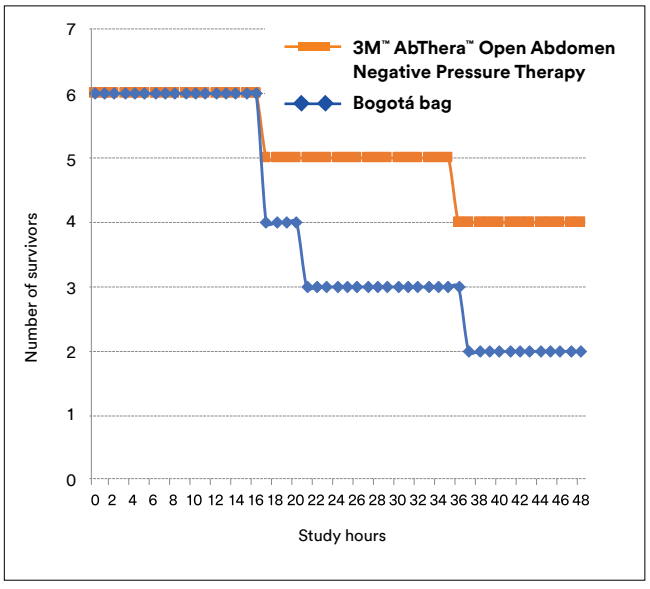


Figure 11. Survival Rate (n=6 swine per group)

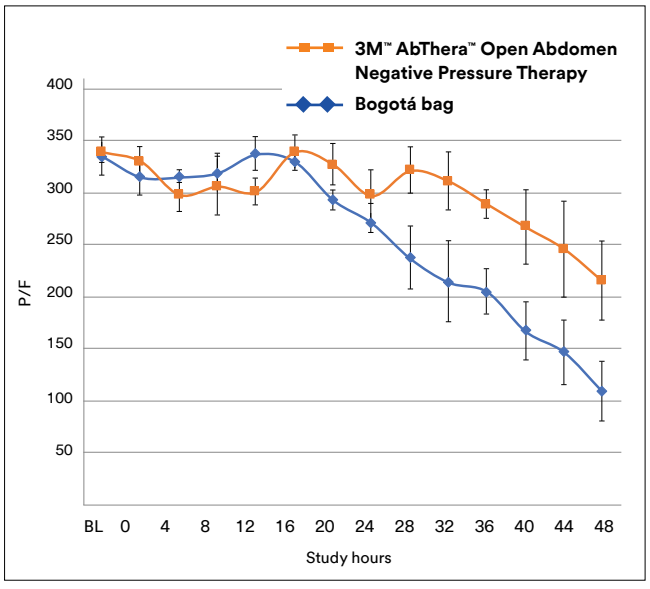
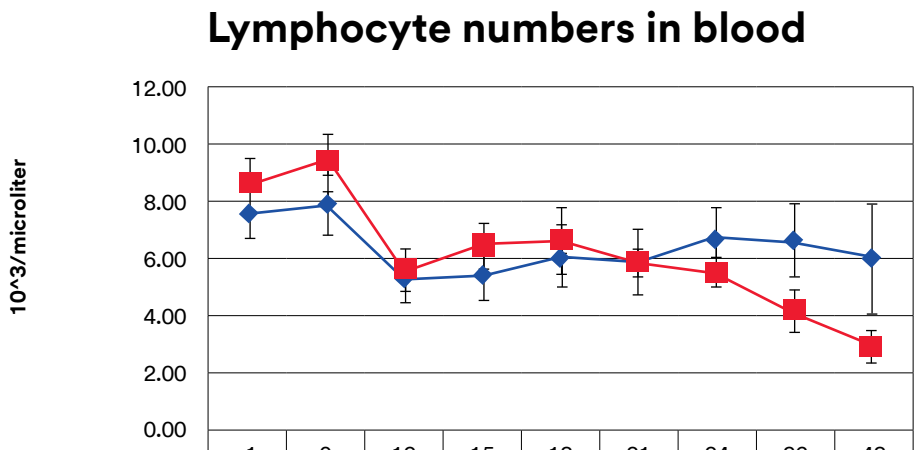
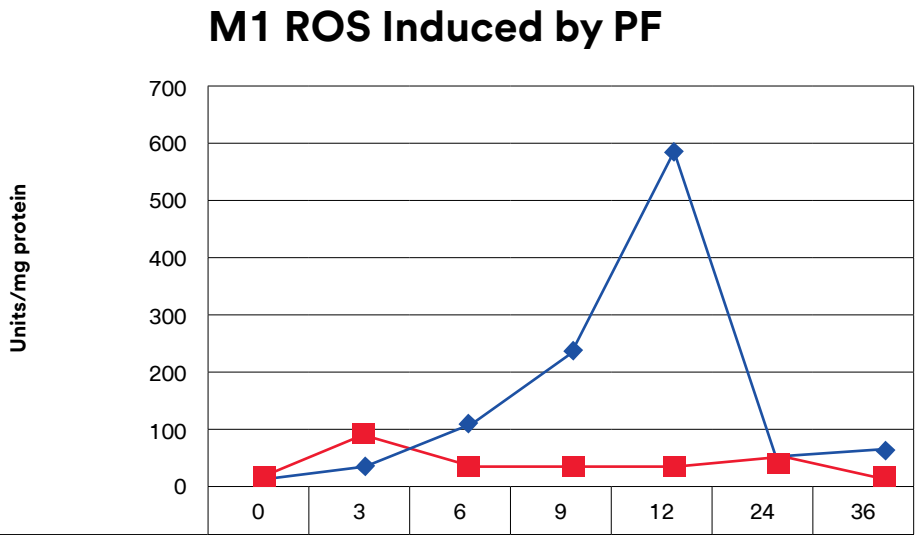


Figure 12. Lung Function (n=6 swine per group)



	-1	0	12	15	18	21	24	36	48
3M™ AbThera™ Open Abdomen Negative Pressure Therapy 7.22	7.60	7.89	5.19	5.34	6.02	5.83	6.65	6.59	5.99
Bogotá bag 8.38	8.65	9.42	5.56	6.41	6.58	5.82	5.46	4.07	2.77

Figure 13. Immunoparalysis in septic swine is reversed by negative pressure therapy.



	0	3	6	9	12	24	36
3M™ AbThera™ Open Abdomen Negative Pressure Therapy	2.5	31	115.8	243.2	576.6	53.9	61.2
Bogotá bag	5.9	98.2	29.1	33.3	32.5	39	13.5

Figure 14. Peritoneal fluid (PF) from 3M™ AbThera™ Open Abdomen Negative Pressure Therapy swine of inducing human macrophages *in vitro* to produce a more robust inflammatory response at a time when immunoparalysis is beginning to compromise the host immune response to septic injury (p=0.02) (n=6 swine per group).

Reapproximation of wound margins

Schmidt et al[27] assessed wound margin movement during application of negative pressure wound therapy using 3M™ AbThera™ SensaT.R.A.C™ Open Abdomen Dressing and 3M™ AbThera™ Advance Open Abdomen Dressing.

Methods:

Bench Test model

- Silicone open abdomen model with transparent, air-filled plastic bladder to simulate intestinal swelling.
- A fenestrated, non-adherent, visceral protective layer (VPL) with encapsulated foam was placed over the air bladder.
- A layer of AbThera SensaT.R.A.C. Dressing (n=30) or AbThera Advance Dressing (n=30) was placed within the margins of the elliptical opening and covered with an adhesive drape to create a seal.
- Negative pressure was applied at -125mmHg, and medial movement was assessed at 6 points on each dressing.

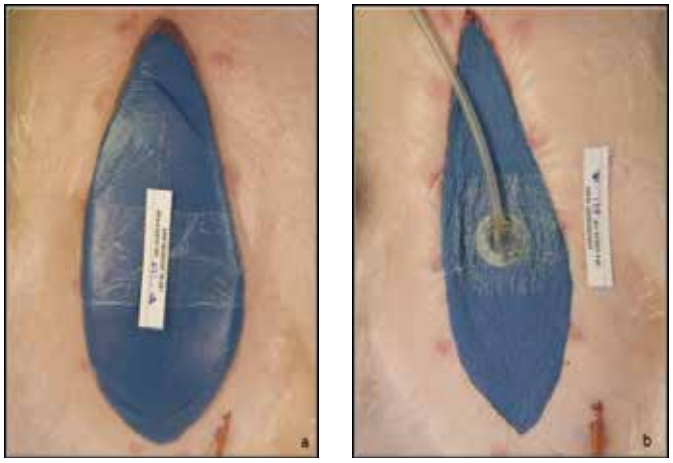


Figure 15. Preclinical testing with 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing, (a) prior to application of negative pressure, and (b) after application of negative pressure.

Preclinical model

- Bowel swelling was induced in a swine model by rapid intravenous infusion of Lactated Ringer's Solution for one hour (3-4% body weight by volume).
- Tissue was excised from either side of the midline of the mammaries creating a large elliptical opening in the abdomen.
- A VPL was placed over the bowel and a layer of AbThera SensaT.R.A.C. Dressing (n=7) or AbThera Advance Dressing (n=7) was placed within the margins of the defect.
- Negative pressure was applied at -125mmHg for 5 minutes, and medial movement was assessed at 6 points on each dressing.

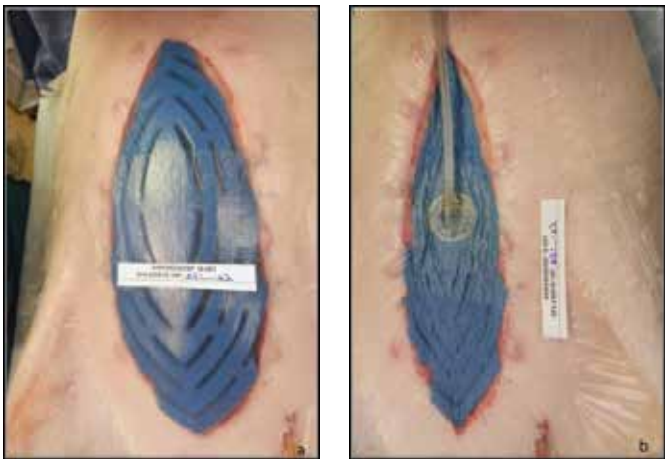


Figure 16. Preclinical testing with 3M™ AbThera™ Advance Open Abdomen Dressing, (a) prior to application of negative pressure, and (b) after application of negative pressure.

Results:

The results of the bench test model show that AbThera Advance Dressing demonstrated an average of 60% more medial movement than AbThera SensaT.R.A.C Dressing. The results were consistent across all samples tested and the prototype foam demonstrated improved results across all measurement points. Preclinical results demonstrated a significant ($p<0.05$) increase of 31% in medial movement compared to control (**Figures 15** and **16**) with no increase in intra-abdominal pressure.

Foam placement configurations and tissue movement

Schmidt et al[28] evaluated the *in vivo* medial tissue movement of 3M™ AbThera™ Advance Open Abdomen Dressing versus 3M™ AbThera™ SensaT.R.A.C™ Open Abdomen Dressing, with dressing in the tucked (a layer of dressing beneath the abdominal fascia) and untucked (a single dressing layer at level with fascia). Changes in intra-abdominal pressure (IAP) would also be monitored in both configurations.

Methods:

- Bowel swelling was induced in a porcine model (n=4) by an intravenous rapid infusion of Lactated Ringer's Solution for 1 hour (3-4% body weight by volume). An elliptical opening approximately 30cm in length was made in the abdomen.
- The visceral protective layer was placed over the bowel, and a layer of AbThera SensaT.R.A.C Dressing (n=7) or AbThera Advance Dressing (n=7) was placed within the margins of the defect in either the tucked or untucked configurations.
- Medial movement was assessed between 6 pairs of staples in each test condition.

Results:

In the tucked configuration, the 23% increase in movement of the AbThera Advance Dressing over the AbThera SensaT.R.A.C Dressing in the tucked configuration was significant ($p<0.05$; **Figure 17**). In the untucked configuration, the 31% increase in movement of the AbThera Advance Dressing over the AbThera SensaT.R.A.C. Dressing in the untucked configuration was significant ($p<0.005$; **Figure 17**).

The average baseline IAP of AbThera SensaT.R.A.C. Dressing was identical for both the tucked and untucked configuration. The average baseline intra-abdominal pressure of the AbThera Advance Dressing was slightly higher for the untucked configuration versus the tucked configuration. There were no significant differences in any of the treatments at baseline. IAP decreased with the application of negative pressure therapy regardless of the treatment (**Figure 18**).

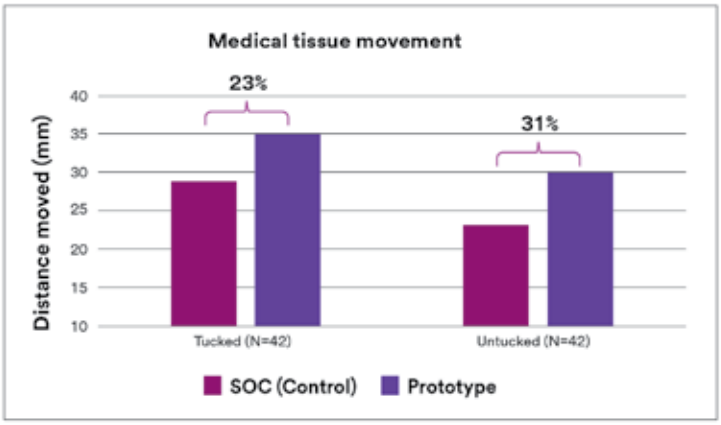


Figure 17. Medial tissue movement after application of negative pressure with 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing (SOC/Control) or 3M™ AbThera™ Advance Open Abdomen Dressing (Prototype).

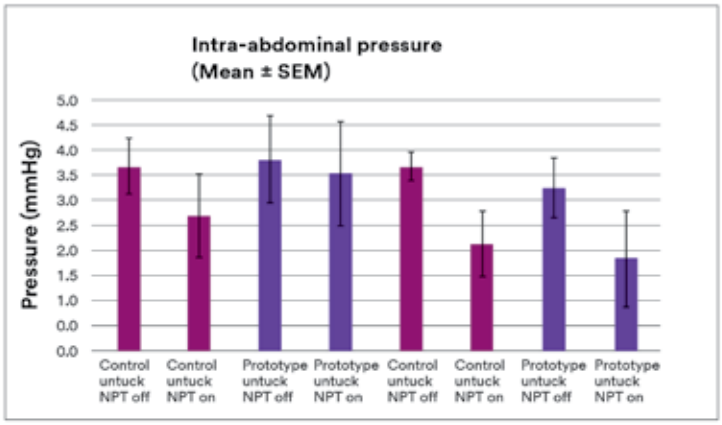


Figure 18. Medial tissue movement after application of negative pressure with 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing (SOC/Control) or 3M™ AbThera™ Advance Open Abdomen Dressing (Prototype).

Fluid removal comparisons

Kieswetter et al[29] used a benchtop model that allowed fluid removal with application of negative pressure to compare 3M™ AbThera™ SensaT.R.A.C™ Open Abdomen Dressing and 3M™ AbThera™ Advance Open Abdomen Dressing.

Methods:

- Nine dressings of each type were placed per the instructions for use in a model designed to simulate a swollen intestine following laparotomy.
- A standardized leak (0.325 ± 0.25L/min) was established using a needle valve and an inline flowmeter.
- 450ml of simulated wound fluid was added to each side of the abdomen model.
- Dressing was placed over the simulated wound, then negative pressure and mass of fluid extracted were measured and followed for 30 minutes.

Results:

There are no differences in the amount or rate of fluid removed between AbThera Advance Dressing and AbThera SensaT.R.A.C. Dressing (**Table 3** and **Figure 19**).

The mean negative pressure provided by AbThera Advance Dressing and AbThera SensaT.R.A.C. Dressing were equivalent (**Table 4** and **Figure 20**).

Table 3. Mean fluid mass against time for each therapy system dressing combination.

Elapsed Time (min)	3M™ AbThera™ Advance Open Abdomen Dressing	3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing	P-value
5	610	623	0.7396
10	706	698	0.5088
15	721	710	0.3189
30	734	721	0.1991

Table 4. Mean negative pressure against time for each therapy system dressing combination.

Elapsed Time (min)	3M™ AbThera™ Advance Open Abdomen Dressing	3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing	P-value
5	60.39	73.48	0.2847
10	93.59	102.0	0.1542
15	101.4	111.4	0.1374
30	109.1	107.7	0.9296

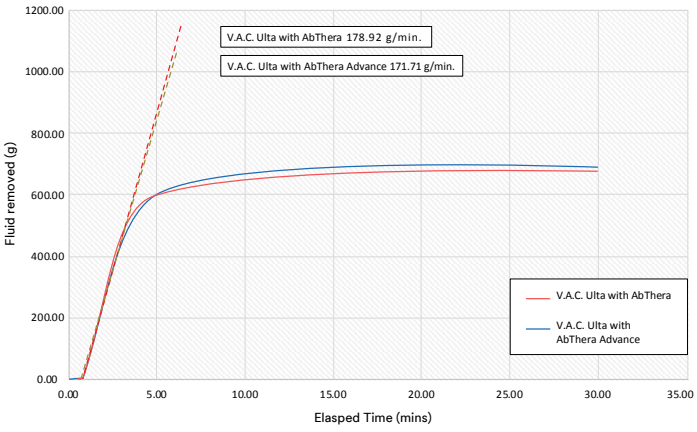


Figure 19. Comparison of average fluid recovery by weight as a function of time with 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing (Current NPT Foam Dressing) and 3M™ AbThera™ Advance Open Abdomen Dressing (Novel Perforated Foam Dressing).

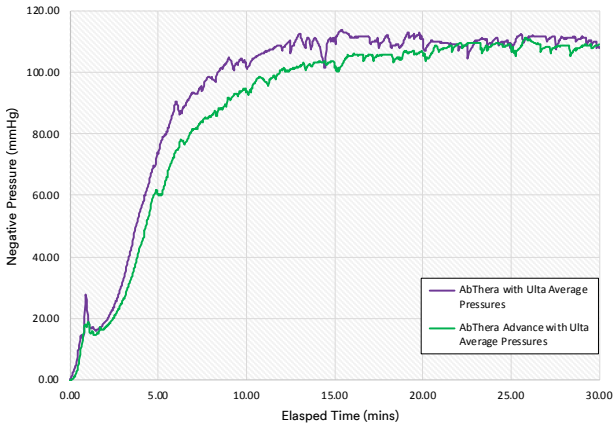


Figure 20. Comparison of average negative pressures as a function of time with 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing (Current NPT Foam Dressing) and 3M™ AbThera™ Advance Open Abdomen Dressing (Novel Perforated Foam Dressing).

Table 5. Summary of supporting science

Property demonstrated	Study description	Results
Pressure mapping[20]	• Performances of 3M™ AbThera™ Open Abdomen Negative Pressure Therapy, V.A.C.® Abdominal Dressing System (VADS) and Barker's vacuum packing technique (BVPT) were compared. • Negative pressure (NP; -125mmHg) was applied to an *in vitro* test model that simulated open abdomen (OA) in static and dynamic physical conditions. • A protein solution was used to simulate wound exudates. • Using pressure sensors, data were collected from Zone 1 (closest NP source), Zone 2 (immediately outside material edge), and Zone 3 (most distal from NP source).	• AbThera Therapy and VADS showed significantly higher pressures that were distributed throughout all 3 zones compared to BVPT ($p<0.05$). • Compared to VADS, AbThera Therapy showed significantly better pressure distributions in Zones 2 and 3 ($p<0.05$).
Fluid removal[20]	• Rate of fluid removed *in vitro* was compared among AbThera Therapy, VADS and BVPT. • NP (-125mmHg) was applied to an *in vitro* test model that simulated the OA in static and dynamic physical conditions. • A protein solution was used to simulate wound exudates. • Fluid removal was measured by volume (liters) over time.	• AbThera Therapy had the highest rate of fluid removal at 93ml/min compared to 61ml/min for VADS and 34ml/min for BVPT.
Blood flow and fluid removal[21]	• Changes in porcine microvascular blood flow in small intestinal wall, wound contraction and fluid evacuation were compared between VADS and AbThera Therapy. • 12 pigs underwent midline incisions and were either treated with VADS or AbThera Therapy. • Microvascular blood flow was measured before and after NP (-50, -75, and -125mmHg). • Wound contraction and fluid removal rate were also measured.	• Results showed that AbThera Therapy afforded significantly better fluid removal and wound contraction compared to VADS ($p<0.05$).
Burst strength of anastomoses[22]	• *In situ* burst strength testing was conducted using a domestic pig model; in each pig (n=3), there were 8 anastomoses per animal. • 4 of the anastomosis sites were located in the superficial abdomen in close proximity to NP and remaining 4 sites were located at sites remote to NP. • In each group of 4 anastomosis sites, 2 were sutured and 2 were stapled. • Following 24 hours of AbThera Therapy (-125mmHg), each anastomosis site underwent burst strength testing *in situ*.	• Stapled anastomoses had lower burst strength than sutured anastomoses, but mean values were still at least 4.6 times greater than baseline. • Burst strength testing revealed that negative pressure was well tolerated. • In this porcine model, negative pressure therapy (NPT) did not have a negative impact on anastomotic sites when applied during the initial 24 hours post surgery when the sites are weak and not yet healed.
Inflammatory properties and organ damage[16,23]	• An OA porcine model of sepsis and ischemia / reperfusion-induced organ injury resulting in abdominal compartment syndrome was induced in 12 pigs. • 6 pigs received NPT [VADS], and the other 6 pigs received passive drainage [PD; no NPT]).	• An elevated intra-abdominal pressure was seen in the PD group compared to NPT. • NPT (VADS) group had a significantly higher urine output compared to the PD group ($p<0.05$). • NPT (VADS) also significantly removed a greater volume of ascites, reduced systemic inflammation, and showed significant improvement in the lung, kidney, and intestine.

Property demonstrated	Study description	Results
Inflammation, pathophysiological and metabolomic analyses[24]	• 10 female swine (5 receiving 3M™ AbThera™ Open Abdomen Negative Pressure Therapy and 5 receiving no negative pressure therapy [NPT]) had intestinal ischemia and reperfusion induced followed by induction of sepsis with a fecal suspension into the peritoneal cavity. • Blood samples taken at 10, 18, and 48 hours were used for biomechanical and metabolomic analyses. • Proteomic analysis of peritoneal and plasma samples were used to measure inflammatory responses.	• Results showed that swine treated with AbThera Therapy had a reversed effect of injury compared to the control.
Decompression after ACS[25]	• 12 female Yorkshire swine had abdominal compartment syndrome (ACS) physiologically induced. • Decompressive laparotomy was performed at 0 hours after 3-4 hour induction of ACS. • At decompression, 6 swine received AbThera Therapy (-125mmHg) and 6 swine received Bogotá bag for 48 hours or until death.	• Early application of AbThera Therapy did not increase the incidence of post-decompression recurrent intra-abdominal hypertension (IAH) or decrease survival time as compared to Bogotá bag (40.5 ± 4.8 hours vs 29.8 ± 8.2 hours, respectively). • AbThera Therapy had no adverse effects on physiological and blood related outcomes.
Inflammatory properties on intestinal microenvironment[26]	• 12 female swine were given intestinal ischemia and reperfusion and had intra-abdominal placement of a fecal clot simulating a septic bowel. • At 12 hours, a decompressive laparotomy was performed and swine were subsequently treated with AbThera Therapy (n=6) or with a Bogotá bag (n=6). • Treatment with NPT lasted up to 35 hours.	• Swine treated with AbThera Therapy had increased survival with an odds ratio of 4.0 and had improved lung function, suggesting that AbThera Therapy reduced the effect of injury to the lung (MODS). • Peritoneal fluid (PF) from septic swine treated with AbThera Therapy was better able than PF from Bogotá bag-treated swine to induce human macrophages to produce an inflammatory response, as measured by an increase in reactive oxygen species *in vitro*.
Reapproximation of wound margins[27]	• **Bench Test Model:** Open abdomen (OA) intestinal swelling model with 3M™ AbThera™ SensaT.R.A.C™ Open Abdomen Dressing (n=30) or 3M™ AbThera™ Advance Open Abdomen Dressing (n=30). Negative pressure was applied at -125mmHg, and medial movement was assessed. • **Preclinical model:** Porcine OA model with AbThera SensaT.R.A.C. Dressing (n=7) or AbThera Advance Dressing (n=7) over OA. Negative pressure was applied at -125mmHg for 5 minutes, and medial movement was assessed.	• Bench test: AbThera Advance Dressing demonstrated an average of 60% more medial movement than AbThera Dressing. • Preclinical model: There was a significant ($p<0.05$) increase of 31% in medial movement with AbThera Advance Dressing compared to AbThera SensaT.R.A.C Dressing with no increase in intra-abdominal pressure.
Foam placement configurations and tissue movement[28]	• Porcine ACS model (n=4) with AbThera SensaT.R.A.C Dressing (n=7) or AbThera Advance Dressing (n=7) placed in either the tucked or untucked configurations. • Medial movement was assessed between 6 pairs of staples in each test condition.	• Tucked configuration: 23% increase in movement with AbThera Advance Dressing over the AbThera SensaT.R.A.C Dressing ($p<0.05$). • Untucked configuration: the 31% increase in movement with AbThera Advance Dressing over AbThera SensaT.R.A.C Dressing ($p<0.005$). • IAP decreased with the application of negative pressure in all dressing configurations.
Fluid removal[29]	• OA intestinal swelling model with simulated exudate covered with AbThera SensaT.R.A.C Dressing (n=9) or AbThera Advance Dressing (n=9). • Negative pressure and mass of fluid extracted were measured and followed for 30 minutes.	• The average negative pressure or the amount of fluid extracted were equivalent with both dressings.

Literature review – clinical and economics

Clinical evidence demonstrates that 3M™ AbThera™ Open Abdomen Negative Pressure Therapy is associated with improved clinical outcomes like increased patient survival, improved primary fascial closure rates, decreased hospital charges, decreased surgeries, and decreased resource utilization. The key studies that follow are also summarized in (**Table 8**) along with other publications supporting the use of AbThera Therapy.

Prospective study examining clinical outcomes associated with a negative pressure wound therapy system and Barker's vacuum packing technique.

In an open-label, prospective observational study, Cheatham et al[17] evaluated two temporary abdominal closure (TAC) techniques in surgical and trauma patients who required open abdomen management.

Methods:

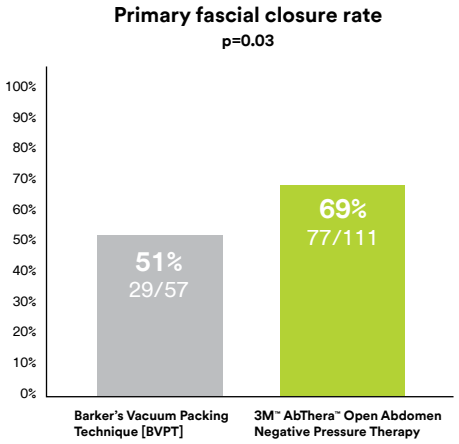
- A total of 168 patients received **at least 48 hours of consistent TAC therapy**. 111 patients received AbThera Therapy, and 57 received Barker's vacuum packing technique (BVPT).

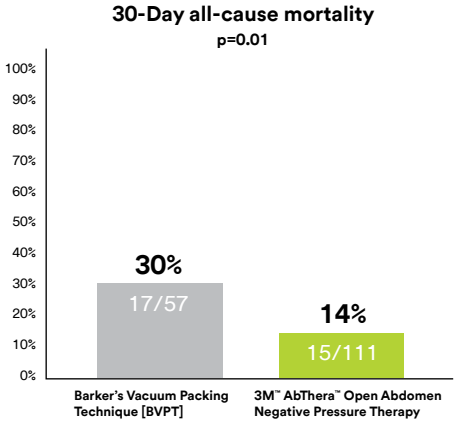
Results:

- AbThera Therapy patients had **significantly higher rates of 30-day primary fascial closure** when compared to BVPT (69% AbThera Therapy versus 51% BVPT, p=0.03).
- Patients in this study who received AbThera Therapy had a **significantly lower rate of 30-day all-cause mortality** when compared to those who received BVPT (14% AbThera Therapy versus 30% BVPT, p=0.01).
- AbThera Therapy resulted in a **significant reduction in length of stay** (27 ± 17 days AbThera Therapy, versus 33 ± 23 days BVPT, (p=0.02).
- Statistical analysis controlling for potential confounding factors found that patients treated with AbThera Therapy were **significantly more likely to survive** compared to BVPT patients (OR 3.17, p=0.02).

Limitations

- TAC techniques were not randomized or evenly distributed across the 20 participating trauma centers.
- No between group differences were observed in patients receiving TAC therapy for less than 48 hours. Because these patients had significantly less severe illness than patients treated for 48 hours or longer, they were not used in the assessment of TAC technique benefit.
- The large number of sites and observational nature of the study limited collection of uniform data and may have obscured factors independently predictive of primary fascial closure.





Are commercial negative pressure systems worth the cost in open abdomen management?

In this comparative retrospective review, Frazee et al[18] compared 3M™ AbThera™ Open Abdomen Negative Pressure Therapy with the Barker's vacuum packing technique (BVPT) for temporary closure in open abdomen management.

Methods:

- 37 patients were managed with AbThera Therapy and 37 patients were managed with BVPT.

Results:

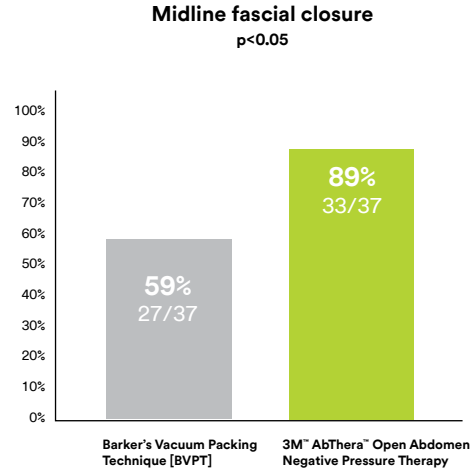
- AbThera Therapy patients had significantly higher rates of primary fascial closure than BVPT (89% AbThera Therapy versus 59% BVPT; p<0.05).

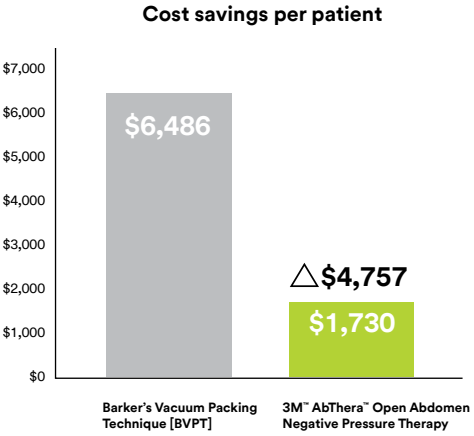
Discussions

- The authors estimated that the difference in closure rates between techniques indicated an estimated 11 ventral hernias could have been prevented with AbThera Therapy, for a cost savings of $176,000 (at $16,000 per ventral hernia in 2006).

Limitations

- Study design was limited as a retrospective review of 2 consecutive patient populations.
- The AbThera Therapy group was significantly older and had a higher BMI than the BVPT group.





3M™ AbThera™ Open Abdomen Negative Pressure Therapy demonstrated a greater reduction in 90-day all-cause mortality among open abdomen patients.

In a single-center, parallel-group randomized controlled trial, Kirkpatrick et al[30] examined whether 3M™ AbThera™ Open Abdomen Negative Pressure Therapy reduces systemic inflammation after abbreviated laparotomy.

Methods:

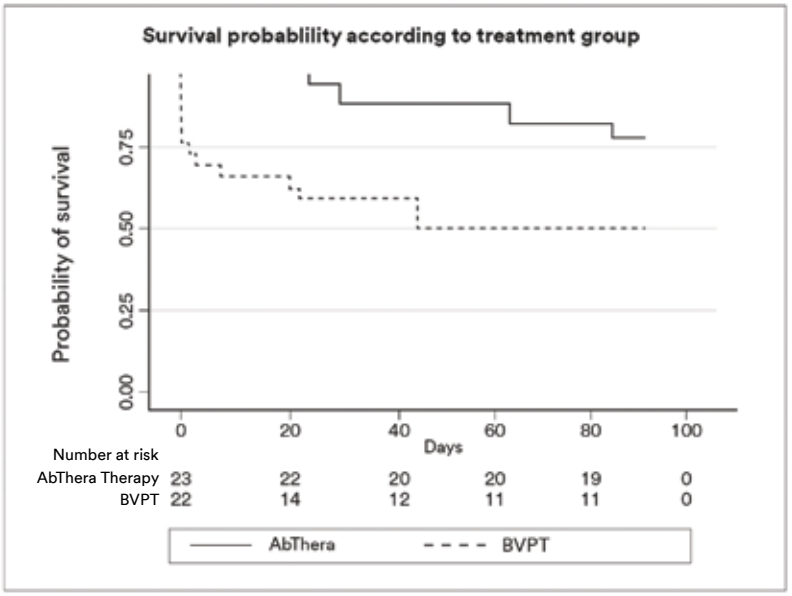
- Patients were treated with either AbThera Therapy (n=23) or Barker's vacuum packing technique BVPT (n=22). Inflammatory cytokines were collected and analyzed at 24 and 48 hours.

Results:

- Primary Endpoint: There was no significant difference in plasma concentration of interleukin-6 at 24 and 48 hours after application.
- Secondary Endpoint: 90-day all-cause mortality was significantly lower in the AbThera Therapy group (21.7% AbThera Therapy versus 50.0% BVPT, p=0.04).

Limitations

- The allocated temporary abdominal closure was required to be utilized for only 24 hours in per-protocol analyses.
- The AbThera Therapy group had significantly higher Charlson Comorbidity Index scores, indicating higher baseline disease burden.
- Improved survival in the AbThera Therapy cohort may be due to covariate imbalance at baseline given the small sample size of the study.



3M™ AbThera™ Open Abdomen Negative Pressure Therapy versus Barker's vacuum packing technique: Analysis of resource utilization

Cheatham et al[31] conducted a retrospective, observational study of 42 patients undergoing temporary abdominal closure (TAC) with AbThera Therapy or Barker's vacuum packing technique (BVPT).

Methods:

- Patients received TAC using AbThera Therapy (n=32) or BVPT (n=12).
- Information regarding complications and resource utilization were collected and analyzed.

Results:

- There were no significant differences in overall survival, ICU days, ventilator days, hospital days, days to abdominal closure, or complication rates.
- On average, AbThera Therapy patients required fewer dressing changes than the BVPT group (2 versus 3, respectively; p=0.047).
- Hospital charges were on average $454,081 in the BVPT group, versus $293,806 in the AbThera Therapy group (p=0.11).

Limitations

- The small sample size limits the statistical power of the comparative analyses.
- Patients who died or achieved closure within 48 hours were excluded from analysis.

Table 6. Summary of clinical outcomes

	3M™ AbThera™ Open Abdomen Negative Pressure Therapy	BVPT	P-value
Hospital days	20	31	0.17
ICU days	11	17	0.1
Ventilator days	9	13	0.19
# of dressing changes	2	3	0.047
Wound dehiscence	3%	8%	0.5
Fistula development	3%	8%	0.5
Recurrent ACS	7%	17%	0.56

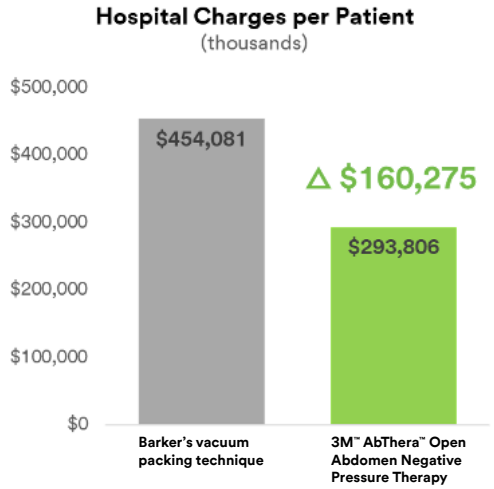


Table 7. Summary of literature review

Author	Study type and patients	Products evaluated	Results
Kirkpatrick et al 2015[30]	• Single-center, parallel-group randomized controlled trial comparing temporary abdominal closure (TAC) methods for patients after abbreviated laparotomy for injury or sepsis. • 45 patients with abdominal injury orsepsis received TAC therapy for 48 hours. – 23 received 3M™ AbThera™ Open Abdomen Negative Pressure Therapy. – 22 received Barker's vacuum packing technique (BVPT).	• AbThera Therapy • Barker's vacuum packing technique (BVPT)	• No difference in inflammatory cytokines. • No difference in sequential organ failure assessment. • Significantly improved 90-day mortality rate with AbThera Therapy (21.7%) vs BVPT (50%, p=0.04). • Non-significant increase in median days alive without open abdomen (OA) in AbThera Therapy group (27 vs 18 days, p=0.08).
Cheatham et al 2013[17]	• 280 patients were enrolled in this 20-site, prospective observational study comparing the method of TAC to the out comes of trauma and surgical patients. • Of the 280 patients, 168 patients underwent consistent TAC therapy for at least 48 hours. – 111 patients received AbThera Therapy. – 57 patients received BVPT.	• AbThera Therapy • Barker's vacuum packing technique (BVPT)	• Patients in the AbThera Therapy group had a higher primary fascial closure rate at 30 days compared to BVPT group, (69% vs 51% respectively, p=0.03). • 30-day all cause mortality rate was significantly lower in AbThera Therapy patients (14%) compared to BVPT patients (30%, p=0.01). • After controlling for severity of illness, age, and cumulative fluid administration, multivariate logistic regression analysis showed that patients treated with AbThera Therapy were 3.17 times more likely to survive than BVPT patients (95% confidence interval, 1.22-8.26, p=0.02).
Carlson et al 2013[32]	• 578 patients treated with an open abdomen following laparotomy were included in this prospective observational study between 01-Jan-2010 and 30-Jun-2011. • Patients were from 105 different hospitals in the UK. – N=355 patients were treated with negative pressure therapy (NPT). – Bogotá bag (n=127). – Prosthetic mesh (n=39). – Dynamic retention sutures (n=8). – Simple packing/stoma bag (n=19). – No data were available for 27 patients. • Primary endpoints: development of intestinal fistula, death, bleeding, acute intestinal failure, delayed primary closure, prosthetic replacement of abdominal wall.	• Unspecified NPT system • Bogotá bag • Prosthetic mesh • Dynamic retention sutures • Stoma bag	• Intestinal fistulation, death, bleeding, and intestinal failure were no more common in patients treated with NPWT than other treatments. • Rate of delayed primary closure when NPWT was used was significantly lower (Relative Risk=0.74, 95% CI: 0.60-0.90, p=0.002).

Author	Study type and patients	Products evaluated	Results
Plaudis et al 2012[33]	• 22 patients with intra-abdominal infection with severe sepsis due to purulent peritonitis and/or abdominal compartment syndrome (ACS) were included in this prospective study. • All patients were treated with 3M™ AbThera™ Open Abdomen Negative Pressure Therapy. • 18 patients were treated for intra-abdominal infection. • 4 patients were treated for ACS due to severe acute pancreatitis, secondary ileus and damage control in polytrauma.	• AbThera Therapy	• A median of 2 dressing changes (range 1-6) were done in the time interval of 4 days (range 1-5). • Complete fascial closure was achieved in a median of 7 days (range 4-18 days) following initial application of AbThera Therapy. • After removal of negative pressure therapy (NPT), no repeated operations were required. • Permanent abdominal closure was achieved in all patients.
Jensen et al 2017[34]	• Prospective multicenter study of 74 patients treated with AbThera Therapy in Southern Denmark. • Primary endpoints: secondary fascia closure rate, fistula formation, incisional hernia formation, self-assessed quality of life, mortality.	• AbThera Therapy • Barker's vacuum packing technique (BVPT)	• Treatment outcomes: – 4/74 (5%) patients died prior to closure – 11/74 (15%) died within 3 months of discharge. – Complete secondary closure of the fascia without mesh was successfully achieved in 59/74 (84%) patients. • Patients that were successfully treated with AbThera Therapy reported a higher physical score (p=0.006). • There was no difference in mental score (p=0.319).
Frazee et al 2013[18]	• Charts from 74 patients were retrospectively reviewed. – 37 patients were treated with AbThera Therapy. – 37 patients were treated with BVPT.	• AbThera Therapy • Barker's vacuum packing technique (BVPT)	• Patients in the AbThera Therapy had a higher mean age and higher BMI compared to BVPT patients. • 33/37 patients in the AbThera Therapy group reached ultimate midline fascial closure more frequently than 22/37 patients in the BVPT group (89% vs 59%, p<0.05).
Seternes et al 2016[35]	• Retrospective review of 98 patients treated with AbThera Therapy. • 42/98 had all dressing changes completed in the OR (VAC-OR). • 22/98 all in the ICU (VAC-ICU). • 34/98 had changes done in both (VAC-OR/ICU).	• AbThera Therapy	• The mean total time for dressing change. – 63.4 min in the ICU. – 98.2 min in the OR. • Average per-change cost: – €226 for VAC-ICU. – €908 for VAC-OR. • Median days with OA: – 12.5 days for VAC-ICU related to the placement of AbThera Therapy. – 10.5 days for VAC-OR. – 18.5 for VAC-OR/ICU. • No significant between-group difference in 30-, 60-, and 90-day survival rates.

Author	Study type and patients	Products evaluated	Results
Hougaard et al 2014[36]	• Retrospective review of patients over 5-year period. • 115 patients treated with open abdomen (OA) and 3M™ AbThera™ Advance Open Abdomen Negative Pressure Therapy.	• AbThera Therapy	• The median length of hospital stay was 25 days. • The median stay in the ICU was 3 days. • The mortality rate was 17%. • Secondary closure was obtained in 92% of the patients.
Franklin et al 2012[3]	• 19 consecutive patients undergoing abdominal exploration were included in this prospective case series. • All patients received AbThera Therapy placed in the OR. • Pressure settings were continuous -125mmHg.	• AbThera Therapy	• 17/19 patients (89.5%) achieved fascial closure in a median time of 6 days (Kaplan-Meier). • Of these 17 patients, 5 had AbThera Therapy in place for less than 3 days until fascial closure was achieved. • Dressing changes occurred every 2-3 days in most patients until fascia had negative cultures or was free of drainage. • Five patients died throughout their hospitalization; however, this was not related to the placement of AbThera Therapy.
Demetriades 2012[9]	• Literature Review describing the indications for an OA, methods for temporary abdominal closure (TAC), complications of an OA and treatment goals.	• V.A.C.® Abdominal Dressing System (VADS) • AbThera Therapy • Barker's vacuum packing technique (BVPT)	• Negative pressure therapy on an OA promoted early abdominal wall closure and reduced complications seen in patients with chronic OAs. • AbThera Therapy uniformly distributed negative pressure throughout the abdomen whereas BVPT had uneven pressure distribution. • Use of AbThera Therapy may help reduce adhesion formation, prevent loss of abdominal domain, and promote approximation of fascial edges towards the midline.
Fitzgerald et al 2012[38]	• A 44-year-old male patient initially presented with severe, constant epigastric pain and associated vomiting. • Elevated amylase levels led to admittance to the hospital for management of pancreatitis followed by severe systemic inflammatory syndrome. • Patient developed intra-abdominal hypertension (IAH) for management of pancreatitis later developing IAH with renal and respiratory failure. • Patient underwent a decompressive laparostomy following diagnosis of abdominal compartment syndrome (ACS) secondary to acute pancreatitis.	• AbThera Therapy • VADS	• VADS was initially applied over laparostomy. • A dressing change occurred four days later and an AbThera Therapy dressing was applied with pressure setting at -125mmHg. • Patient experienced several complications throughout treatment including spontaneous bleeding at laparostomy site, tear in the muscularis layer of the descending colon, discharge of fecal material, and septic episodes. • Restoration of gastrointestinal continuity was achieved 383 days after admission • Patient was successfully managed through a laparostomy and placement of AbThera Therapy.
Fernandez et al 2011[11]	• This review describes reasons for TAC, prevention and treatment of ACS, types of TAC, and implications for OA.	• Towel clips • Wittmann Patch™ • Synthetic mesh • Bogotá bag • VADS	• This review concluded that use of the Wittmann Patch™ and VADS functioned as both a temporary closure and assisted in permanent fascial closure, potentially reducing costs associated with planned ventral hernia repair that would otherwise be required.

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