ABThera™ Open Abdomen Negative Pressure Therapy

Monograph
Table of Contents

Preface ................................................................. 3
Introduction ......................................................... 3
ABThera™ OA NPT System ................................. 6
Science Supporting NPT for the OA (Preclinical Studies) ...... 10
Literature Review .................................................... 21
Clinical Case Studies ............................................... 25

Preface

The ABThera™ Open Abdomen Negative Pressure Therapy System (ABThera™ OA NPT) 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 document will provide a comprehensive overview of the ABThera™ OA NPT System, including:

- Introduction to temporary abdominal closure methods (e.g., Barker’s Vacuum Pack Technique, Wittmann Patch™, etc) and ABThera™ OA NPT
- Description of the ABThera™ OA NPT System
- Science supporting NPT using V.A.C.® Abdominal Dressing System (VADS; first generation) or ABThera™ OA NPT
- Literature review of VADS and ABThera™ OA NPT System
- Case studies using ABThera™ OA NPT

Introduction

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. 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. 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 and allow for stabilization of the patient to better endure subsequent operations.

OA management is often seen in trauma patients, with the rate of damage control surgery reaching as high as 30%, 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) measured (normal IAP range: subatmospheric to 6.5 mmHg). Because the abdominal contents are strictly contained, any increase in volume contents results in increased IAP, 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. Furthermore, when IAP is greater than 25 mmHg, a decompressive laparotomy is performed to reduce the risk of ACS development. Some studies have shown that even lower levels of IAP (10-15 mmHg) are clinically relevant, increasing the risk of developing ACS. Therefore, managing IAP levels, and subsequently preventing ACS, is critical due to the associated high mortality rate resulting from sepsis and multi-organ failure.

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. Other indications for maintaining an OA include pancreatitis, bowel edema, acidosis, pelvic inflammatory disease, hypothermia and intra-abdominal bleeding. 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. 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 should address. Over the years, different TAC methods have been developed, providing several options; these are listed in Table 1.
The ABThera™ OA NPT System (Figure 1A) is the second generation design of the KCI negative pressure system for use in the OA. Developed for the management of an OA (Figure 1B) and to facilitate fascial closure, it provides design features that facilitate the delivery of negative pressure and removal of abdominal fluids. This system consists of:

- A non-adherent fenestrated polyurethane visceral protective layer (VPL), which separates the bowel from the abdominal wall and manifolds negative pressure through the OA and facilitates the removal of fluid.
- The ABThera™ Perforated Foam, which delivers negative pressure, providing medial tension, to help minimize fascial retraction and loss of domain. 
- An occlusive dressing that protects the abdominal contents from external contamination.
- A SensaT.R.A.C.™ Pad with tubing that is placed over the foam and connected to a KCI negative pressure therapy unit.
- The recommended negative pressure is continuous at -125 mmHg. Pressures below -125 mmHg are not recommended.

### Table 1. Available TAC options

<table>
<thead>
<tr>
<th>TAC Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Towel Clips</strong></td>
<td>• Most basic TAC that serves to facilitate skin closure&lt;br&gt;• Up to 30 surgical clips (1 cm apart from each skin edge) are utilized to perform a skin-only closure&lt;br&gt;• Advantages: inexpensive, widely available, and quick to perform&lt;br&gt;• Disadvantages: potential for skin damage, high incidence of ACS and IAH, and interferes with advanced diagnostic studies.</td>
</tr>
<tr>
<td><strong>Bogotá bag</strong></td>
<td>• Involves the use of an open intravenous (IV) bag&lt;br&gt;• Technique involves cutting the pre-gas sterilized IV bag into an open, oval shape and suturing it to the skin&lt;br&gt;• Advantages: low-cost, non-adherent, prevention of evisceration, ease of application and availability in the OR&lt;br&gt;• Disadvantages: potential risk for developing IAH and ACS and provides minimal fluid control</td>
</tr>
<tr>
<td><strong>Absorbable mesh closure</strong></td>
<td>• Mesh is placed over abdominal contents, followed by a coat of gauze packing&lt;br&gt;• Advantages: absorbable, easy placement, and facilitates re-exploration with an increased strength compared to that of the Bogotá bag&lt;br&gt;• 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%</td>
</tr>
<tr>
<td><strong>Wittmann Patch™</strong> (StarSurgical, Inc., Burlington, WI)</td>
<td>• A hook and loop prosthetic over the abdomen&lt;br&gt;• Closure is achieved by overlapping the two hook and loop sheets&lt;br&gt;• Advantages: allows for easy entrance to abdomen and aids in abdominal closure through gradual fascial approximation&lt;br&gt;• Disadvantages: potential risk for developing IAH and ACS and provides minimal fluid control</td>
</tr>
<tr>
<td><strong>Barber’s vacuum packing technique (BVPT)</strong></td>
<td>• Utilizes a fenestrated, non-adherent polyethylene sheet placed over the viscera with moist surgical towels covering it&lt;br&gt;• Uses two 10-French silicone drains over the towels and an iodoform-impregnated adhesive&lt;br&gt;• Continuous wall suction is applied to remove fluid&lt;br&gt;• Advantages: inexpensive, uses readily available materials found in OR, and moderate fluid control&lt;br&gt;• Disadvantages: potential for bowel adhesion and fascial retractions within 7-10 days of having an OA</td>
</tr>
<tr>
<td><strong>V.A.C.® Abdominal Dressing System (VADS)</strong></td>
<td>• First generation negative pressure therapy system for the OA introduced to the market in 2003, replaced by ABThera™ OA NPT System&lt;br&gt;• Constructed of:&lt;br&gt;  - A fenestrated non-adherent layer with encapsulated foam that is placed on the wound surface&lt;br&gt;  - V.A.C.® Perforated GranuFoam Dressing that is placed over the covered wound surface&lt;br&gt;  - Drape, which is applied over the abdomen&lt;br&gt;  - The SensaT.R.A.C.™ Tubing that is placed over a hole cut in the drape to have direct contact with the GranuFoam™ Dressing&lt;br&gt;  - Continuous negative pressure at -125 mmHg is applied&lt;br&gt;• Advantages: provides medial tension, removes abdominal fluids, protects the OA from external contamination, and helps approximate wound margins&lt;br&gt;• Disadvantages: less efficient fluid removal than ABThera™ Therapy Dressing; non-adherent layer tends to retract</td>
</tr>
</tbody>
</table>
| **ABThera™ OA NPT System** | • Second generation negative pressure therapy system for the OA; has been on the market since 2009<br>• Similar in design to the VADS dressing except for the visceral protective layer (VPL) that contains six foam extensions and provides for improved fluid removal<br>• Uses a non-adherent fenestrated polyurethane, which separates bowel from abdominal wall and removes fluid<br>• The ABThera™ Perforated Foam, which delivers negative pressure, provides medial tension to help minimize fascial retraction and loss of domain<br>• Continuous negative pressure (<125 mmHg) is recommended. Pressures below -125 mmHg are not recommended<br>• Advantages: Same as VADS plus enhanced fluid removal and ease of use

---

**Figure 1.** A. ABThera™ OA NPT System and V.A.C.® NPT Therapy Units that can be used with the ABThera™ Dressing. ABThera™ Dressing is not for use with instillation therapy provided by the V.A.C.® Ultra™ Therapy Unit. B. Schematic of ABThera™ OA NPT.
ABThera™ OA NPT System

The ABThera™ OA NPT System is the KCI NPT platform for OA management. The ABThera™ OA NPT System is a replacement of the previous VADS.

Two dressings for multiple units give clinicians the flexibility to provide OA management utilizing negative pressure with any one of the following units they have available:

- ABThera™ Dressing is used with the ABThera™ Therapy Unit
- ABThera™ SensaT.R.A.C.™ Dressing is used with the InfoV.A.C.® and V.A.C.Ulta™ Therapy Units (when used in V.A.C.® Therapy mode only; not for use with instillation).

All of the above therapy units offer continuous negative pressure, allowing for removal of high volume of exudates. To accommodate the high levels of fluid removal, 1000 mL canisters are recommended for use with the ABThera™ OA NPT Dressing.

ABThera™ OA NPT Technology

The ABThera™ OA NPT System is intended for patients with open abdominal wounds with exposed viscera, including, but not limited to, ACS. There are several system accessories designed for use with ABThera™ OA NPT (Table 2).

- The large 1000mL canisters are appropriate for the high levels of exudate from an OA. These canisters can fit into the therapy units listed above.
- The SensaT.R.A.C.™ Pad facilitates exudate/fluid removal from the dressings. It is a part of the SensaT.R.A.C.™ Technology that provides monitoring of negative pressure during therapy.
- The ABThera™ Visceral Protective Layer protects the abdominal contents by separating the abdominal wall and viscera. It also enhances fluid removal from paracolic gutters. Re-entry into the abdomen is easily accessible, and no sutures are required for placement.
- The negative pressure is delivered through the ABThera™ Perforated Foam. By manifolding negative pressure from the therapy unit, the ABThera™ Perforated Foam provides medial tension, which helps minimize fascial retraction and loss of domain.
- The ABThera™ Drape covers the ABThera™ Perforated Foam and OA, providing a closed system to help isolate abdominal contents.

Table 2. ABThera™ OA NPT Components

<table>
<thead>
<tr>
<th>Name/Description</th>
<th>Picture/Diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABThera™ OA NPT System</td>
<td>ABThera™ OA NPT System</td>
</tr>
<tr>
<td>• ABThera™ Dressing is used with ABThera™ Therapy Unit</td>
<td></td>
</tr>
<tr>
<td>• ABThera™ SensaT.R.A.C.™ Dressing is used with InfoV.A.C.® and V.A.C.Ulta™ Therapy Units (when used in V.A.C.® Therapy mode only; not for use with instillation)</td>
<td></td>
</tr>
</tbody>
</table>

Therapy Units: Negative Pressure Sources

- ABThera™ Negative Pressure Therapy Unit (for use with the ABThera™ Dressing)
- InfoV.A.C.® and V.A.C.Ulta™ Therapy Units (*Not for use with instillation) (*Not for use with instillation)

Exudate Canisters: Single-patient use, disposable canisters

- ABThera™ 1000mL Canister
Table 2. ABThera™ OA NPT Components (continued)

<table>
<thead>
<tr>
<th>Name/Description</th>
<th>Picture/Diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubing Set: Single-patient use disposable tube set; tube delivers negative pressure and monitors pressure setting at the wound site; this is applied over the wound via the SensaT.R.A.C.™ Pad</td>
<td><img src="image1" alt="Tubing Set" /></td>
</tr>
<tr>
<td>ABThera™ Tubing Set (for use with the ABThera™ Therapy Unit)</td>
<td><img src="image2" alt="Tubing Set" /></td>
</tr>
<tr>
<td>SensaT.R.A.C.™ Pad and Tubing (for use with the InfoV.A.C.® and V.A.C. ULTA™ Therapy* Units) (*Not for use with instillation)</td>
<td><img src="image3" alt="SensaT.R.A.C. Pad and Tubing" /></td>
</tr>
<tr>
<td>ABThera™ Dressing</td>
<td><img src="image4" alt="ABThera Dressing" /></td>
</tr>
<tr>
<td>• ABThera™ Drape</td>
<td>Provides a closed system to help isolate and protect abdominal contents from external environment</td>
</tr>
<tr>
<td>• ABThera™ Perforated Foam</td>
<td>Negative pressure delivered through the foam provides medial tension, which helps minimize fascial retraction and loss of domain **</td>
</tr>
</tbody>
</table>
| • ABThera™ Visceral Protective Layer | - Enhances fluid removal
- Allows for re-entry
- No sutures required for placement
- Provides separation between abdominal wall and viscera, protecting abdominal contents |

## Indications for Use
The ABThera™ OA NPT System is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. This system is intended for use in open abdominal wounds, with exposed viscera, including but not limited to, 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
Patients with open abdominal wounds containing non-enteric unexplored fistulas should not be treated with the ABThera™ OA NPT System. Vital structures should be protected with the ABThera™ Visceral Protective Layer (VPL) at all times during therapy. Exposed foam material should never be placed directly in contact with exposed bowel, organs, blood vessels, or nerves.

## Warnings and Precautions
Table 3 lists the warnings and precautions for ABThera™ OA NPT. It is important to read and follow all instructions and safety information prior to use for any NPWT device. Please refer to the KCI e-labeling link (http://www.kci1.com/KCI1/elabeling) for detailed safety information.

### Table 3. Warnings and Precautions

<table>
<thead>
<tr>
<th>Warnings</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not for use with Instillation Therapy:</strong> Although the practice is common to flush a contaminated OA cavity with saline or other medical solutions, the ABThera™ Open Abdomen Dressing was not designed for this purpose.</td>
<td>Standard precautions for infection should be followed, regardless of diagnosis or presumed infection status.</td>
</tr>
<tr>
<td><strong>Use of tubing set:</strong> Substitution with any other tubing or alteration of the tubing system is not recommended. This may lead to loss of system efficacy or harm to the patient.</td>
<td>Intra-abdominal packing material may be drier than anticipated. Rehydrate if necessary to prevent adherence to adjacent structures.</td>
</tr>
<tr>
<td><strong>Bleeding:</strong> Patients with abdominal wounds must be closely monitored for bleeding as these wounds may contain hidden blood vessels. Immediately discontinue NPT if there is a sudden increase in bleeding observed in the dressing, tubing, or canister.</td>
<td>Frequently examine the volume of exudates in the canister and tubing.</td>
</tr>
<tr>
<td><strong>Intra-abdominal Pressure (IAP) Monitoring:</strong> IAP monitoring should continue as outlined by institutional clinical practice and guidelines.</td>
<td>If enteric fistulas are present, consider the possibility of abdominal contamination if effluent is not appropriately isolated or managed.</td>
</tr>
<tr>
<td><strong>Use of Visceral Protective Layer (VPL):</strong> The VPL should completely cover all exposed viscera and completely separate the viscera from contact with the abdominal wall.</td>
<td></td>
</tr>
<tr>
<td><strong>Adhesions and Fistula Development:</strong> Adhesion formation of the viscera to the abdominal wall may reduce the likelihood of fascial reapproximation and increase the risk of fistula development.</td>
<td></td>
</tr>
<tr>
<td><strong>Infection:</strong> 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.</td>
<td></td>
</tr>
</tbody>
</table>

For detailed warning and precaution information, please see KCI e-labeling link (http://www.kci1.com/KCI1/elabeling).
Science Supporting NPT for the OA (Preclinical Studies)

The advantages of applying NPT for the 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 NPT properties. Results have yet to be verified in human trials.

Pressure mapping

Using a bench top model, Sammons et al. compared the performance of ABThera™ OA NPT, VADS and BVPT.

Methods:

- Constant negative pressure (NP) at -125 mmHg was applied to an in vitro test model designed to simulate the OA physical conditions in static and dynamic conditions (Figure 2).
- 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™ OA NPT and VADS showed significantly higher pressures that were distributed throughout all three zones compared to BVPT (p<0.05). Furthermore, compared to VADS, ABThera™ OA NPT showed significantly better pressure distributions in Zones 2 and 3 (p<0.05). No significant differences were found in Zone 1 between ABThera™ OA NPT and VADS.

Fluid Removal Using an in vitro Model

Sammons et al. also compared ABThera™ OA NPT System, VADS and BVPT in their rate of fluid removed in vitro.

Methods:

- Constant negative pressure at -125 mmHg was applied to an in vitro test model designed to simulate the OA 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™ OA NPT had the highest rate of fluid removal at 93 mL/min compared to 61 mL/min for VADS and 34 mL/min for BVPT (Figure 3). ABThera™ OA NPT also had the highest total volume fluid removal among the three treatment regimens.

Efficient Fluid Removal

Blood Flow and Fluid Removal Using an in vivo Model

Lindstedt et al. 2013 compared changes in porcine microvascular blood flow in small intestinal wall, wound contraction and fluid evacuation with VADS and ABThera™ OA NPT System.

Methods:

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

Results:

Results showed no differences in blood flow between the two products; however, ABThera™ OA NPT afforded significantly better fluid removal and wound contraction compared to VADS (p<0.05).
Burst Strength Testing of Anastomoses

Norbury et al evaluated the effect of ABThera™ OA NPT 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™ OA NPT at -125 mmHg continuously, each anastomosis underwent burst strength testing in situ (Figure 4).
- 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 5). Burst strength testing revealed that negative pressure was well tolerated. Results suggest that in a porcine model, 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.

Figure 4. Burst strength testing set-up.

Figure 5. Burst strength testing results (n=4 anastomosis sites per group).

Inflammatory Properties and Organ Damage

Kubiak et al used a clinically applicable OA porcine model of sepsis and IR-induced organ injury resulting in ACS to compare NPT (ie, 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 TAC via NPT (ie, VADS), while the other group received passive drainage (PD; no NPT).

Results:
Results showed that NPT led to increased survival compared to PD group (83% [5/6 pigs] vs 50% [3/6 pigs], respectively; Figure 6). A significantly elevated intra-abdominal pressure (measured via the bladder pressure) was seen in the PD group compared to NPT (Figure 7). The NPT group had a significantly higher urine output compared to the PD group (p<0.05) (Figure 8). NPT also significantly removed a greater volume of ascites, reduced systemic inflammation, and showed significant improvement in the lung, kidney, and intestine (Figure 8). 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 6. Percent survival over 48 hours.

Figure 7. Bladder pressure over time.
Inflammation, Pathophysiological and Metabolomic Analyses

Norbury evaluated the impact of ABThera™ OA NPT 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.
- NPT was applied to 5 swine, and the remaining 5 received no ABThera™ OA NPT.
- 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™ OA NPT 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 4).

Table 4. Effects of NPT on pathophysiological parameters

<table>
<thead>
<tr>
<th>Organ System</th>
<th>Parameter</th>
<th>Effect of Injury</th>
<th>Effect of NPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>I/R</td>
<td>Plasma Lactate</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>Hemodynamic</td>
<td>CVP</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td></td>
<td>SvO₂</td>
<td>↓</td>
<td>↑</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>PaO₂,FiO₂ &amp; Cstat</td>
<td>↓</td>
<td>↑</td>
</tr>
<tr>
<td></td>
<td>Acute alveolar congestion; interstitial edema and congestion</td>
<td>↓</td>
<td>↑</td>
</tr>
<tr>
<td>Renal</td>
<td>Plasma BUN &amp; Creatinine</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>Inflammatory</td>
<td>Plasma TNF-α</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>Metabolomic</td>
<td>Myo-inositol (a storage reservoir for pro-inflammatory arachidonic acid)</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td></td>
<td>Long chain fatty acid biosynthesis</td>
<td>↓</td>
<td>↑</td>
</tr>
</tbody>
</table>
Decompression after ACS

Shah et al\(^2\) evaluated the safety and effects of ABThera™ OA NPT when used as a TAC in the immediate post-decompression period after ACS using a hemorrhagic shock porcine model.

Methods:

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

Results:

Results demonstrated that early application of ABThera™ OA NPT did not increase the incidence of post-decompression recurrent IAH (Figure 9) or decrease survival time (40.5 ± 4.8 hours versus 29.8 ± 8.2 hours [NPT vs Bogotá]). ABThera™ OA NPT had no adverse effects on physiological and blood related outcomes. Results suggested that early application of ABThera™ OA NPT appears safe with no increased mortality or recurrent IAH.

Inflammatory Properties on Intestinal Microenvironment

Norbury et al\(^3\) evaluated the effect of ABThera™ OA NPT 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 -125 mmHg using ABThera™ OA NPT System (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™ OA NPT System had increased survival with an odds ratio of 4.0 (Figure 10). Swine treated with ABThera™ OA NPT also had improved lung function, suggesting that ABThera™ OA NPT reduced the effect of injury to the lung (MODS) (Figure 11). More importantly, at a time when immunoparalysis begins to occur (around 12 hours post injury; Figure 12), peritoneal fluid (PF) from septic swine treated with ABThera™ OA NPT 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 13).

The preliminary findings from this animal study showed that NPT 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.
Table 5. Summary of Science Supporting NPT for the OA

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Mapping⁷⁷</td>
<td>• Performances of ABThera™ OA NPT, VADS and BVPT were compared. • Negative pressure (NP: -125 mmHg) was applied to an in vitro test model that simulated 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).</td>
<td>• ABThera™ OA NPT and VADS showed significantly higher pressures that were distributed throughout all 3 zones compared to BVPT (p&lt; 0.05). • Compared to VADS, ABThera™ OA NPT showed significantly better pressure distributions in Zones 2 and 3 (p&lt; 0.05).</td>
</tr>
<tr>
<td>Fluid Removal⁷⁷</td>
<td>• Rate of fluid removed in vitro was compared among ABThera™ OA NPT System, VADS and BVPT. • NP (-125 mmHg) 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.</td>
<td>• ABThera™ OA NPT had the highest rate of fluid removal at 93 mL/min compared to 61 mL/min for VADS and 34 mL/min for BVPT.</td>
</tr>
<tr>
<td>Blood Flow and Fluid Removal⁷⁷</td>
<td>• Changes in porcine microvascular blood flow in small intestinal wall, wound contraction and fluid evacuation were compared between VADS and ABThera™ OA NPT. • 12 pigs underwent midline incisions and were either treated with VADS or ABThera™ OA NPT. • Microvascular blood flow was measured before and after NP (-50, -75, and 125 mmHg). • Wound contraction and fluid removal rate were also measured.</td>
<td>• Results showed that ABThera™ OA NPT afforded significantly better fluid removal and wound contraction compared to VADS (p&lt;0.05).</td>
</tr>
<tr>
<td>Burst Strength of Anastomoses¹⁸</td>
<td>• 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™ OA NPT (-125 mmHg), each anastomosis site underwent burst strength testing in situ.</td>
<td>• 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, NPT did not have a negative impact on anastomotic sites when applied during the initial 24 hrs post surgery when the sites are weak and not yet healed.</td>
</tr>
</tbody>
</table>

Figure 12. Immunoparalysis in septic swine is reversed by NPT.

Figure 13. Peritoneal fluid (PF) from ABThera™ OA NPT-treated septic swine was more capable than PF from Bogotá bag treated 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).
Table 5. Summary of Science Supporting NPT for the OA

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Results</th>
</tr>
</thead>
</table>
| Inflammatory Properties and Organ Damage\(23\) | • An OA porcine model of sepsis and IR-induced organ injury resulting in ACS was induced in 12 pigs.  
• 6 pigs received NPT (VADS), and the other 6 pigs received passive drainage (PD; no NPT). | • An elevated IAP 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. |
| Inflammation, pathophysiological and metabolomic analyses \(24\) | • 10 female swine (5 receiving ABThera™ OA NPT and 5 receiving no NPT) had intestinal ischemia and reperfusion induced following by induction of sepsis with a fecal suspension into the peritoneal cavity.  
• Blood samples taken at 10, 18, and 48 hrs were used for biomechanical and metabolic analyses.  
• Proteomic analysis of peritoneal and plasma samples were used to measure inflammatory responses. | • Results showed that swine treated with ABThera™ OA NPT had a reversed effect of injury compared to the control. |
| Decompression after ACS \(25\) | • 12 female Yorkshire swine had ACS 5 physiologically induced.  
• Decompressive laparotomy was performed at 0 hrs after 3-4 hr induction of ACS.  
• At decompression, 6 swine received ABThera™ OA NPT (1-125 mmHg) and 6 swine received Bogotá bag for 48 hours or until death. | • Early application of ABThera™ OA NPT did not increase the incidence of post-decompression recurrent IAH or decrease survival time as compared to Bogotá bag (40.5 ± 4.8 hours vs 29.8 ± 8.2 hours, respectively).  
• ABThera™ OA NPT did not have 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™ OA NPT (n=6) or with a Bogotá bag (n=6).  
• Treatment with NP lasted up to 35 hours. | • Swine treated with ABThera™ OA NPT System had increased survival with an odds ratio of 4.0 and had improved lung function, suggesting that ABThera™ OA NPT reduced the effect of injury to the lung (MOPS).  
• Peritoneal fluid (PF) from septic swine treated with ABThera™ OA NPT 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. |

Literature Review

The use of NPT on the OA is well-documented in the literature. Below are summaries of key publications supporting the use of ABThera™ OA NPT as a TAC method.

- In a study published in 2013, Cheatham et al\(27\) prospectively compared the clinical outcomes of patients treated with ABThera™ OA NPT and patients treated with Barker’s Vacuum Packing Technique (BVPT). Endpoints included days to primary fascial closure (PFC), rate of 30-day PFC and 30-day mortality rate. A total of 168 patients who received at least 48 hours of consistent TAC therapy were included in the study; 111 were ABThera™ OA NPT patients and 57 patients were treated with BVPT. Patients in the ABThera™ OA NPT group achieved PFC in less time (median 9 days ABThera™ OA NPT vs 12 days BVPT, p= 0.12) and at a higher rate of 30-day PFC than those treated with BVPT (69% vs 51% respectively; p= 0.03). A lower overall 30-day mortality rate for patients treated with ABThera™ OA NPT (14% vs 30% respectively, p= 0.01) was observed. In this study, the authors concluded that ABThera™ OA NPT resulted in significant benefits in patient outcomes.

- In addition, Fraze et al\(28\) (2013) retrospectively evaluated the ABThera™ OA NPT patient outcomes compared to outcomes seen on patients treated with BVPT (control). The study included 74 patients, with 37 treated by ABThera™ OA NPT (from 2010-2011) and the remaining 37 with BVPT (from 2009-2010). Patients in the ABThera™ OA NPT group had a higher mean age and a higher BMI compared to control. Midline fascial closure was achieved in 89% (33/37) of patients treated with ABThera™ OA NPT compared to 59% (22/37) of patients treated with BVPT (p<0.05). Results suggested that the increased upfront cost of using ABThera™ OA NPT was offset by improved patient results and cost savings from successful closure.

- In Plaudis et al\(29\) (2012), 22 patients with intra-abdominal infection with severe sepsis due to purulent peritonitis and/ or ACS were prospectively evaluated. A total of 18 patients were treated for intra-abdominal infection and 4 patients were treated for ACS due to severe acute pancreatitis, secondary ileus and damage control in polytrauma. ABThera™ OA NPT was applied following decompressive laparotomy. Dressing changes occurred in a median of 2 days (range 1-5 days). Fascial closure was achieved in a median of 7 days (range 4-18 days) following initial application of ABThera™ OA NPT System. After removal of ABThera™ OA NPT, no repeated operations were required. Permanent abdominal closure was achieved in all patients.

- In a prospective case series of 19 consecutive patients undergoing abdominal explorations, Franklin et al\(30\) (2012) evaluated the use of ABThera™ OA NPT. Out of the 19 patients, only two were programmed operations. The remaining operations were considered emergency operations due to perforation, incarcerated hernia or cancer obstruction/invasion. ABThera™ OA NPT was placed with dressing changes occurring every 2 to 3 days until negative cultures or free of drainage. Results showed an 89.5% (17/19 pts) fascial closure rate. Of the 17 patients who achieved fascial closure, five patients had the ABThera™ OA NPT System in place for less than 3 days before the fascia was closed. Five patients died while hospitalized; however, this was unrelated to the placement of ABThera™ OA NPT.

The key studies outlined above are summarized in Table 6 along with other publications supporting the use of NPT for temporary abdominal closure. Pyramids display the evidence level of each publication (Figure 14).
Study Type
• 22 patients with intra-abdominal infection with severe sepsis due to purulent peritonitis and/or ACS were included in this prospective study.
• All patients were treated with ABThera™ OA NPT
  - 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

Results/Conclusions
• Authors suggested that NPWT for open abdomen management was not associated with a reduced rate of delayed primary closure.
• After controlling for severity of illness, age, and cumulative fluid administration, multivariate logistic regression analysis showed that patients treated with ABThera™ OA NPT were 3.17 times more likely to survive 30 days compared to BVPT group, (69% vs 30%, p=0.01).
• Authors suggested the increased upfront cost of using ABThera™ OA NPT was offset by improved patient results and cost savings from successful closure.
• Use of ABThera™ OA NPT on an OA promoted early abdominal wall closure and reduced complications seen in patients with chronic OAs.
• ABThera™ OA NPT uniformly distributed negative pressure throughout the abdomen whereas BVPT had uneven pressure distribution.
• Use of ABThera™ OA NPT may help reduce adhesion formation, prevent loss of abdominal domain, and promote approximation of fascial edges towards the midline.

Table 6. Literature Review

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type and Patients</th>
<th>Products Evaluated</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheatham et al 2013</td>
<td>• 280 patients were enrolled in this 20-site, prospective observational study comparing the method of TAC to the outcomes of trauma and surgical patients.</td>
<td>• ABThera™ OA NPT • BVPT</td>
<td>• Patients in the ABThera™ OA NPT 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™ OA NPT pts (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™ OA NPT were 3.17 times more likely to survive than BVPT patients (95% confidence interval, 1.22-8.26, p=0.02).</td>
</tr>
</tbody>
</table>
| Carlson et al 2013 | • 578 patients treated with an open abdomen following laparotomy were included in this prospective study between 01-Jan-2010 and 30-Jun-2011. Patients were from 105 different hospitals in the UK. n=355 patients were treated with NPWT
  - Bogota 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 | • Unspecified NPWT system • Bogota 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). • Authors suggested that NPWT for open abdomen management was not associated with an increased risk of mortality or intestinal fistulation. However, NPWT was associated with a reduced rate of delayed primary closure. |

Table 14. ASPS Evidence Rating Scale for Therapeutic Studies

<table>
<thead>
<tr>
<th>Grade</th>
<th>Evidence Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Level I Evidence</td>
</tr>
<tr>
<td>2</td>
<td>Level II Evidence</td>
</tr>
<tr>
<td>3</td>
<td>Level III Evidence</td>
</tr>
<tr>
<td>4</td>
<td>Level IV Evidence</td>
</tr>
<tr>
<td>5</td>
<td>Level V Evidence</td>
</tr>
</tbody>
</table>

Table 6. Literature Review

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type and Patients</th>
<th>Products Evaluated</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaids et al 2012</td>
<td>• 22 patients with intra-abdominal infection with severe sepsis due to purulent peritonitis and/or ACS were included in this prospective study.</td>
<td>• ABThera™ OA NPT • BVPT</td>
<td>• 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™ OA NPT System. • After removal of NPT, no repeated operations were required. • Permanent abdominal closure was achieved in all patients.</td>
</tr>
<tr>
<td>Frazee et al 2013</td>
<td>• Charts from 74 patients were retrospectively reviewed.</td>
<td>• ABThera™ OA NPT • BVPT</td>
<td>• Patients in the ABThera™ OA NPT had a higher mean age and higher BMI compared to BVPT patients. • 33/37 patients in the ABThera™ OA NPT group reached ultimate midline fascial closure more frequently than 22/37 patients in the BVPT group (99% vs 59%, p=0.05). • Authors suggested the increased upfront cost of using ABThera™ OA NPT was offset by improved patient results and cost savings from successful closure.</td>
</tr>
<tr>
<td>Franklin et al 2013</td>
<td>• 19 consecutive patients undergoing abdominal exploration were included in this prospective case series.</td>
<td>• ABThera™ OA NPT</td>
<td>• 17/19 patients (89.5%) achieved fascial closure in a median time of 6 days (Kaplan-Meier). • Of these 17 pts, 5 had ABThera™ OA NPT 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™ OA NPT.</td>
</tr>
<tr>
<td>Demetriades 2011</td>
<td></td>
<td>• VADS • ABThera™ OA NPT • BVPT</td>
<td>• NPT on an OA promoted early abdominal wall closure and reduced complications seen in patients with chronic OAs. • ABThera™ OA NPT uniformly distributed negative pressure throughout the abdomen whereas BVPT had uneven pressure distribution. • Use of ABThera™ OA NPT may help reduce adhesion formation, prevent loss of abdominal domain, and promote approximation of fascial edges towards the midline.</td>
</tr>
</tbody>
</table>
Table 6. Literature Review

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type and Patients</th>
<th>Products Evaluated</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fitzgerald et al 2012&lt;sup&gt;29&lt;/sup&gt;</td>
<td>A 44-year-old male patient initially presented with severe, constant epigastric pain and associated vomiting. Elevated amylase levels led to admission to the hospital for management of pancreatitis followed by severe systemic inflammatory syndrome. Patient developed intra-abdominal hypertension 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.</td>
<td>ABThera™ OA NPT</td>
<td>V.A.C.™ Abdominal Dressing was initially applied over laparostomy. A dressing change occurred four days later and an ABThera™ Dressing was applied with pressure setting at -125 mmHg. 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™ OA NPT System.</td>
</tr>
<tr>
<td>Fernandez et al 2011&lt;sup&gt;10&lt;/sup&gt;</td>
<td>This review describes reasons for TAC, prevention and treatment of ACS, types of TAC, and implications for OA.</td>
<td>Towel Clips, Wittmann Patch™, Synthetic Mesh, Bogotá Bag, VADS</td>
<td>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.</td>
</tr>
</tbody>
</table>

Clinical Case Studies

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient’s circumstances and condition.

Case Study 1: Severe peritonitis following colonic anastomotic leak

A 65-year-old male with a history of recurrent diverticulitis underwent an elective open left colectomy and primary anastomosis 6 days prior to presentation with peritonitis and fascial dehiscence (Figure 15A). An emergency reoperation revealed an anastomotic leak and severe peritonitis (Figure 15B). The affected segment of the colon was resected (Figure 15C) and primary re-anastomosis was performed. The peritoneal cavity was washed out with copious saline, and the abdomen was left open for re-evaluation and to prevent abdominal compartment syndrome. Temporary abdominal wall closure was performed using the ABThera™ OA NPT System. The ABThera™ fenestrated Visceral Protective Layer (VPL) was trimmed to size and tucked inside the abdominal wall under the peritoneum to completely cover the viscera and protect abdominal contents. The ABThera™ Perforated Foam was measured and cut to fit inside the exposed abdominal cavity. The ABThera™ Drape and tubing were placed over the dressing to create a seal, and negative pressure was set at -125 mmHg (Figure 15D). The patient received standard ICU treatment, including fluid resuscitation and antibiotics. Dressing changes and washouts were performed on days 1, 2 and 4. By hospital Day 4, the patient’s condition was stable, and there was no evidence of residual abdominal sepsis (Figure 15E). On hospital Day 6, the ABThera™ OA Dressing was removed, and the abdomen was primarily closed. The patient had an uneventful recovery and was discharged on post-operative Day 9. There were no complications at subsequent outpatient follow-up.

Figure 15. Temporary abdominal wall closure following severe peritonitis and colonic anastomotic leak.

A. Dehisced, acute open abdomen at presentation
B. Anastomotic colonic leak
C. Diseased section of colon excised during emergency resection
D. ABThera™ OA Dressing applied as temporary abdominal closure
E. Open abdomen on 4th post-operative day after removal of ABThera™ OA Dressing looks clean and free of infection

Patient data and photos courtesy of Demetrios Demetriades, MD, PhD
Case Study 2: Hemorrhagic pancreatitis with ACS

A 75-year-old Caucasian female presented with an acute onset of epigastric pain radiating to both shoulders. There was no associated nausea, vomiting, diarrhea, fever, or chills. Patient had a medical history of hypertension, hyperlipidemia, and hypothyroidism. Previous surgeries included a cholecystectomy (10 years prior) and a remote hysterectomy. There was no history of tobacco or alcohol use. Initial CBC and chemistries were within normal limits. Lipase level was at 104. An initial CT of the abdomen revealed peripancreatic edema (Figure 16A). At 48 hours post admission, CT/CAP revealed a hemorrhagic pancreatitis and hemoperitoneum (Figure 16B). Patient had elevated amylase/lipase levels, acute blood loss anemia, thrombocytopenia, coagulopathy, hypotension, AKI, metabolic acidosis, acute respiratory distress syndrome (ARDS) and ACS. Damage control surgery was performed (Figure 16C) and ABThera™ OA NPT was applied. An ABThera™ OA dressing was placed intraoperatively into the open abdomen. The ABThera™ Visceral Protective Layer (VPL) was trimmed to fit the size of the defect and tucked inside the abdominal wall to completely cover the viscera and protect abdominal contents (Figure 16D). The ABThera™ Perforated Foam was measured and cut to fit inside the exposed abdominal cavity. The ABThera™ Drape (Figure 16E) and tubing were placed over the dressing to create a seal. Continuous pressure was initiated at -125 mmHg to remove exudate and decrease edema. Dressing changes and washouts occurred at 48 and 72 hours. Component separation closure was performed at 72 hours. A Prevena™ Incision Management System was applied over the clean, closed surgical incision for 3 days (Figure 16F). After 20 days in the SICU/acute care hospital, the patient was transferred to a long-term acute care facility. Patient continued to improve and was placed in rehabilitation. Patient subsequently returned home, but died a year later from urosepsis that was unrelated to surgery.

Figure 16. Hemorrhagic pancreatitis with ACS.

A. Edematous pancreas at CT on admission
B. CT/CAP 48 hours post admission
C. Damage control surgery
D. Application of VPL
E. Application of ABThera™ Drape
F. Application of Prevena™ Therapy after component separation closure

Case Study 3: Necrotizing soft tissue infection with multiple enteroatmospheric fistula

A 42-year-old male with prior medical history of necrotizing soft tissue infection of the abdomen following a liposuction procedure required numerous operations resulting in full-thickness loss of most of the anterior abdominal wall. A split-thickness skin graft was applied on the exposed intestines. Unfortunately, patient developed multiple high-output enteroatmospheric fistulas and was referred to higher level care. A complex operative procedure (duration 8 hours) included a difficult entry into the abdomen through the side of the wound (Figure 17A). The bowel was mobilized, and the loops with the fistulas were isolated (Figure 17B). A matted mass of bowel with multiple fistulas was excised (Figure 17C), and an anastomosis performed. There was extensive peritoneal contamination with intestinal contents, and the bowel was edematous. Copious lavage with saline was performed. Routine postoperative care was carried out with antibiotics and TPN. An ABThera™ OA Dressing was placed intraperitoneally into the open abdomen, and negative pressure was initiated at -125 mmHg (Figure 17D). Dressing changes occurred every 24-48 hours for 4 days. On postoperative Day 4, the method of TAC was switched to traditional NPWT with V.A.C.® WhiteFoam Dressings applied over a layer of vaseline gauze, as there was no plan for fascial closure due to the extensive tissue loss. The abdominal wound was skin grafted on post-operative day 8. On postoperative day 16, patient was discharged with no complications. Subsequent follow-up showed good healing without any problems.

Figure 17. Necrotizing soft tissue infection with multiple enteroatmospheric fistula.

A. Prior necrotizing soft tissue infection of the abdomen, requiring a complex operative procedure
B. Intraoperative appearance of matted loops of small bowel with multiple fistulas
C. Excised matted mass of bowel with multiple fistulas
D. Application of ABThera™ OA NPT

Patient data and photos courtesy of Demetrios Demetriades, MD, PhD
Case Study 4: Damage control following motor vehicle accident

A 37-year-old male presented with systolic blood pressure of 70 mmHg and a heart rate at 118 beats per minute after being struck by an automobile. Following a positive result with the abdominal FAST (Focused Assessment with Sonography for Trauma), an emergency laparotomy was performed. Laparotomy revealed massive bleeding from a grade IV liver injury. Midline laparotomy and a right subcostal incision for exposure of the posterior liver were performed. Right lobe liver resection was also performed (Figure 18A). Patient remained hypertensive throughout the operation, with a pH of 7.02 and a temperature of 34.4°C. Patient received massive transfusion consisting of 22 units of packed red blood cells, 15 units of FFP and 3 units of platelets. Patient developed severe bowel edema (Figure 18B). Treatment included closure of the right subcostal incision, damage control with perihpatic packing (9 perihpatic packs) and temporary closure of the laparotomy wound with ABThera™ OA NPT. The ABThera™ Visceral Protective Layer (VPL) was tucked under the peritoneum to completely cover the viscera and protect abdominal contents (Figure 18C). The ABThera™ Perforated Foam was cut into size and shape and was placed over the protective foam (Figure 18D). The ABThera™ Drape and tubing were placed over the dressing to create a seal, and the tubing was connected to the negative pressure therapy unit at -125 mmHg (Figure 18E). The patient received standard ICU care, including mechanical ventilation and fluid resuscitation. Dressing changes were performed on Days 2, 4, and 7 with definitive closure on Day 9 (Figure 18F). The post-operative recovery was uneventful.

Figure 18. Temporary closure following motor vehicle accident.

Case Study 5: Laparotomy following gunshot wound

A 32-year-old male presented with a gunshot wound to the right thoracoabdominal area. Upon admission, patient had severe hypotension with systolic blood pressure of 60 mmHg. A FAST (Focused Assessment with Sonography for Trauma) exam was positive for intraperitoneal bleeding. Emergency laparotomy revealed a massive hemoperitoneum due to a grade V liver injury that included a right hepatic venous injury. A subcostal incision was added to the midline laparotomy for improved exposure. The right hepatic vein was ligated, and a right lobectomy was performed. An intraoperative liver angio-embolization was also performed, and the patient received a massive transfusion of 28 units of packed red blood cells. During surgery, patient was hypotensive, hypothermic (34.0°C), acidic with pH of 6.9, and coagulopathic and developed massive bowel edema. Damage control with perihpatic packing and temporary abdominal wall closure was performed using the ABThera™ OA NPT System. The ABThera™ fenestrated Visceral Protective Layer (VPL) was tucked inside the abdominal wall to completely cover the viscera and protect abdominal contents. The ABThera™ Perforated Foam was measured and cut to fit inside the exposed abdominal cavity. The ABThera™ Drape and tubing were placed over the dressing to create a seal and were connected to the negative pressure therapy unit set at -125 mmHg. The patient was transferred to the surgical intensive care unit where he was stabilized after 8 hours with blood product transfusions and ventilator support. ABThera™ OA Dressing changes were performed at 36 hours and on postoperative Days 3, 5, and 7. Definitive closure was performed on Day 8 (Figure 19). The post-operative course was uneventful.

Figure 19. Temporary abdominal wall closure following penetrating trauma.
Important Note: Specific indications, contraindications, warnings, precautions and safety information exist for KCI products and therapies. Please consult a physician and product instructions for use prior to application. Rx only.

©2013 KCI Licensing, Inc. All rights reserved. Unless otherwise specified, all trademarks designated herein are proprietary to KCI Licensing, Inc., its affiliates and/or licensors. DSL#13-0652.US (12/13)LIT#29-A-238