



ABThera™ Open Abdomen Negative Pressure Therapy for Active Abdominal Therapy

Case Series

Summary of Cases:

USER EXPERIENCE

The ABThera™ OA NPT system was found by surgeons to be a convenient and effective method of temporary abdominal closure (TAC) in all 3 cases of application. The dressing was well-tolerated by the patients and allowed quick and easy access for abdominal re-exploration. The abdomen appeared adequately perfused at each dressing change. The ABThera™ Visceral Protective Layer adequately protected the bowel. No adherence of the visceral protective layer to the bowel upon dressing removal was reported. No fistula formation was observed, and in Case #3, neither fistula formation nor hernia formation was observed after 4 months. There were no complications related to the ABThera™ OA NPT System placement in the 3 cases presented here. In the opinion of the surgeons, use of the dressing allowed for primary fascial closure to be achieved.

ECONOMIC VALUE

In all 3 cases, potential abdominal compartment syndrome was avoided. In Case #1, the wound remained completely closed without signs of infection during the 3-month follow-up period. In Case #2, the patient has experienced no further abdominal complications such as fistula formation or infection. Secondary ventral hernia repairs was not required. In the experiences of the surgeons, the technology allowed for earlier fascial closure in all 3 instances compared with other TAC methods used previously.

CLINICAL OUTCOMES/CONCLUSION

In Case #1, the ABThera™ OA NPT System appeared to provide efficient removal and isolation of the abdominal wound fluid, resulting in a clean wound within 48 hours. The closed wound dressing functioned as a barrier against outside contaminants. As a secondary dressing following fascial closure, the NPWT with V.A.C.® GranuFoam™ Dressing stimulated granulation tissue formation, which may have allowed for early hospital discharge. In Case #2, the ABThera™ OA Dressing helped facilitate definitive fascial closure in 8 days in this critically ill patient. In Case #3, the closed dressing protected the open abdomen from environmental contaminants and provided a noticeable reduction in intestinal edema. In all 3 instances, the compressed top foam layer functioned as a dynamic closure device and prevented fascial retraction.

REFERENCE:

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Drs. Franklin and Russek have been consultants for KCI USA, Inc.

NOTE: As with any case study, the results and outcomes of these patients 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: Temporary Abdominal Closure of Laparostomy Wound Following Inguinal Hernia Repair

PATIENT

An 81-year-old male presented with a permanent gastrostomy tube. Patient's prior medical history included fascial trauma and several hernia repairs with a history of recurrence.

DIAGNOSIS

Patient was admitted with painful left inguinal hernia. Labs revealed low hemoglobin, hematocrit, and albumin levels, and elevated creatinine, glucose and hepatic enzyme values.

INITIAL TREATMENT/APPLICATION OF ABTHERA™ OPEN ABDOMEN (OA) NEGATIVE PRESSURE THERAPY

On hospital day 3, the patient was taken to the operating room for laparoscopic repair of a left inguinal hernia. The following day (hospital day 4), a relaparotomy revealed massive intra-abdominal loss of 4,000 ml of blood. Diffuse intraperitoneal bleeding was uncovered, largely in the omentum. The patient was intubated and antibiotics were administered. The omentum was excised, and no specific area of bleeding was identified in the omentum vasculature. Abdominal lavage was performed, and the abdomen was left open for reexploration and to prevent potential abdominal compartment syndrome.

An ABThera™ NPT Dressing was placed intraoperatively into the open abdomen. The ABThera™ Visceral Protective Layer (A) was tucked deep around the small pelvis, subdiaphragm and paracolic gutters to create a barrier between viscera and the abdominal wall. The ABThera™ Perforated Foam was measured and cut to fit inside the abdominal incision. The ABThera™ Drape and tubing set were placed over the dressing (B) to create a seal. Pressure was initiated at -125mmHg to begin exudate removal and decrease edema, which were the primary goals of initiating therapy. The patient remained closely monitored in the intensive care unit.

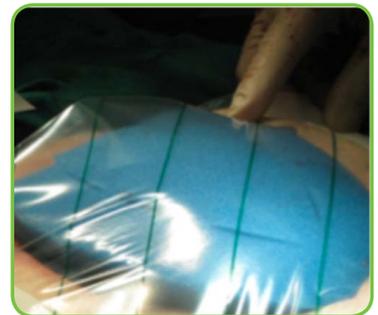
On open abdomen day 3, the ABThera™ OA NPT dressing was removed and the wound appeared clean. Exudate was clear, no signs of fistula formation, and the fascia was closed primarily (C). The patient was extubated. V.A.C.® negative pressure wound therapy (NPWT) with a standard V.A.C.® GranuFoam™ Dressing was initiated over the fascia at -125mmHg (D) with dressing changes every 48 hours until hospital discharge 8 days later.

DISCHARGE AND FOLLOW-UP

The patient was discharged on hospital day 15 with weekly follow-up. Stable cutaneous coverage was achieved by secondary intention at home. At his 3 month follow-up appointment, the patient was doing well and the wound was completely closed.



A. ABThera™ Visceral Protective Layer



B. ABThera™ Drape placed over perforated foam layer



C. Fascia primarily closed post ABThera™ OA Dressing use



D. V.A.C.® Therapy dressing compressed over fascia

Case Study 2: Open Abdominal Wound Following Repair of Parastomal Hernia with Large Necrotic Colon

PATIENT

A 67-year-old obese female presented with colostomy from previous transverse colon resection, chronic obstructive pulmonary disease, gastroesophageal reflux disease, sleep apnea, and a history of multiple hernia repairs.

DIAGNOSIS

The patient was admitted with abdominal pain and clinical signs of peritonitis. Leukocyte count was $17.3 \times 10^3/\text{mm}^3$ and hemoglobin was 10.1 g/dL. A laparoscopy performed upon admission revealed multiple adhesions, wire mesh from a prior incisional hernia repair, and a right parastomal hernia with small bowel incarceration (two-thirds).

INITIAL TREATMENT/APPLICATION OF ABTHERA™ OPEN ABDOMEN (OA) NEGATIVE PRESSURE THERAPY

Surgeons performed lysis of adhesions, resection of right colon, creation of end ileostomy, reduction of the right parastomal hernia, and excision of the previously placed wire mesh. The abdomen was left open for re-exploration and to prevent potential abdominal compartment syndrome.

An ABThera™ Dressing was placed intraoperatively into the open abdomen. The ABThera™ Visceral Protective Layer was trimmed to fit the size of the defect (A) and 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 abdominal incision (B). Additional foam was used to fill the parastomal hernia wound and create a bridge to the OA wound site (C). The ABThera™ Drape and tubing set were placed over the dressing to create a seal (C), and negative pressure was initiated at -125mmHg . Dressing changes and washouts were performed every 2-3 days for a total of 3 dressing changes.

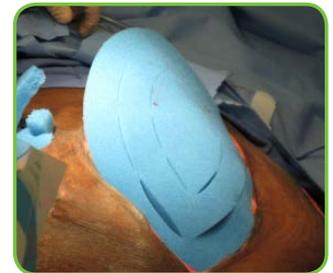
At the first dressing change on hospital day 4, an abdominal washout was performed along with debridement of the necrotic hernia sac. At the second dressing change on hospital day 8, the patient was taken to the operating room for a washout and removal of the ABThera™ OA Dressing (D), and primary fascial closure was achieved. The patient was extubated and V.A.C.® Therapy with a standard V.A.C.® GranuFoam™ Dressing was initiated over the fascia to stimulate granulation tissue formation (E). Dressings were changed every 48 hours until discharge 11 days later.

DISCHARGE AND FOLLOW-UP

The patient was discharged on hospital day 19 with weekly follow-up. Stable cutaneous coverage was achieved by secondary intention at home. At 5 weeks post discharge, the patient was readmitted due to subacute bacterial endocarditis, acidosis, anemia and diabetes. Her abdominal wound remained closed. The patient was subsequently diagnosed with renal failure, but her abdomen remained closed at the 3-month follow-up.



A. ABThera™ Visceral Protective Layer trimmed according to size of patient and to fit underneath abdominal wall



B. ABThera™ Perforated Foam Dressing sized to fit over the abdominal cavity opening



C. ABThera™ Drape and Interface Pad are sealed over the dressing



D. Clean wound ready for fascial closure



E. Fascia closed primarily using V.A.C.® Therapy with standard V.A.C.® GranuFoam™ dressing

Case Study 3: Open Abdominal Wound Following Intestinal Resection

PATIENT

A 68-year-old male presented with status epilepticus and respiratory and renal failure. The patient had a history of type 2 diabetes, seizures, dyslipidemia, hypothyroidism, congestive heart failure, and chronic renal failure.

DIAGNOSIS

A laparoscopy performed upon admission revealed an intestinal obstruction.

INITIAL TREATMENT/APPLICATION OF ABThera™ OPEN ABDOMEN (OA) NEGATIVE PRESSURE THERAPY

After the laparoscopy, the patient was converted to an open abdomen following a culture and lavage. The surgeons found small intestine necrosis, which required a small bowel resection. The abdomen was left open for re-exploration.

An ABThera™ Dressing was placed intraoperatively into the open abdomen. The ABThera™ Visceral Protective Layer was trimmed to fit the size of the defect (A) and tucked inside the abdominal wall to completely cover the viscera. The ABThera™ Perforated Foam was measured and cut to fit inside the abdominal cavity (B). The ABThera™ Drape and tubing set were placed over the dressing to create a seal (C and D), and negative pressure was initiated at -125mmHg .

The open abdomen was closed by primary intention 48 hours later. During this time, there were no complications. V.A.C.® Therapy with a standard V.A.C.® GranuFoam™ dressing was initiated over the fascia to stimulate granulation tissue formation.

DISCHARGE AND FOLLOW-UP

The patient was discharged on hospital day 20 to a home care facility. At 3 weeks post discharge, the patient was readmitted due to seizures, but his abdominal wound remained clean and he remained on V.A.C.® Therapy. At his 5-week office visit, the patient's wound was healing with good granulation tissue formation. At his 4-month follow-up visit, the wound was completely healed with no signs of hernia.



A. ABThera™ Visceral Protective Layer trimmed according to size of patient and to fit underneath abdominal wall



B. ABThera™ Perforated Foam dressing sized to fit over the abdominal cavity opening



C. Drape placed over perforated foam layer



D. ABThera™ Drape and Interface Pad are sealed over the dressing

ABThera™ Open Abdomen Negative Pressure Therapy System for Active Abdominal Therapy

INDICATIONS FOR USE

- The ABThera™ Open Abdomen Negative Pressure Therapy (NPT) System is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeated 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.
- The ABThera™ NPT System is intended for use in the acute hospital setting: in trauma, general and plastic surgery wards. The abdominal dressing will most often be applied in the operating room.

ABThera™ Open Abdomen Negative Pressure Therapy consists of the following components:



*ABThera™ Negative Pressure Therapy Unit, V.A.C.Ultra™ or InfoV.A.C.® Therapy Units

Only for use with the negative pressure therapy provided by the V.A.C.Ultra™ Therapy Unit; not for use with V.A.C. VeraFlo™ Instillation Therapy.

NOTE: Specific indications, contraindications, precautions and safety tips exist for this product and therapy. Please consult a physician, product instructions, and safety tips prior to application. Rx only.