Temporary Abdominal Closure
POSITIVE RESULTS
The Challenge

Leaving the abdomen open, during the management of complex abdominal problems, has become common practice. A prolonged open abdomen presents challenges such as:

- Fluid loss
- Infection
- Loss of abdominal domain
- Organ dysfunction and death.\(^1\)

Clinical research has shown removing potentially detrimental peritoneal fluid and achieving primary fascial closure are important goals when managing patients who require an open abdomen for the treatment of critical illness.\(^2\)

The method of temporary abdominal closure chosen may play an important role in patient outcomes.\(^1,3,4\)
ABTHERA™ Open Abdomen Negative Pressure Therapy (ABTHERA™ Therapy) is designed to actively manage the open abdomen by:

- Removing fluid and helping reduce edema
- Providing medial tension, which helps minimize fascial retraction and loss of domain\(^5\)
- Helping protect abdominal contents from external environment
- Providing separation between abdominal wall and viscera, protecting abdominal contents
- Allowing rapid access for re-entry without requiring sutures for placement
- Providing a moist environment
In a twenty-center observational study comparing ABTHERA™ Therapy to Barker’s vacuum-packing technique (BVPT) in trauma and surgical patients, ABTHERA™ OA NPT was associated with a significantly improved 30-day primary fascial closure rate, and a 30-day all cause mortality rate ($p=0.03$ and 0.01 respectively).\(^1\)

### Study design
- Observational, open-label study performed to evaluate two TAC techniques: ABTHERA™ Therapy and the Barker’s vacuum-packing technique.
- 280 patients enrolled from 20 sites in the U.S.

### Key findings

<table>
<thead>
<tr>
<th>30-day primary fascial closure</th>
<th>30-day all-cause mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABTHERA™ Therapy</td>
<td>Barker’s vacuum-packing technique</td>
</tr>
<tr>
<td>$69%$ (77 of 111 patients)</td>
<td>$51%$ (29 of 57 patients)</td>
</tr>
<tr>
<td>$p=0.03$</td>
<td>$p=0.001$</td>
</tr>
</tbody>
</table>

### Other findings
- Patients were both trauma and surgical patients who required TAC following a damage control laparotomy or treatment of either Intra-abdominal hypertension or severe sepsis.
- 168 patients who received at least 48 hours of consistent TAC therapy (111 ABTHERA™ Therapy, 57 BVPT) were evaluated.
- Both groups showed similar patient severity assessment scores (SOFA, APACHE, ISS).

- The median time to primary fascial closure was 9 days for patients treated with ABTHERA™ Therapy and 12 days for those treated with Barker’s vacuum-packing technique ($p=0.12$).
- Patients treated with ABTHERA™ Therapy were 3.2 times more likely to survive up to 30 days than patients treated with Barker’s vacuum-packing technique ($p=0.02$).
ABTHERA™ Therapy has been shown in clinical studies to be associated with positive clinical outcomes.

A STUDY EVALUATED ABTHERA™ THERAPY AND THE AVOIDED COSTS FOR VENTRAL HERNIA REPAIRS

In this study, 33 of 37 (89%) of open abdomen patients achieved midline fascial closure using ABTHERA™ Therapy.6

Study Design

- Comparative retrospective review
- 37 open abdomen patients who had temporary abdominal closure with the ABTHERA™ Open Abdomen Negative Pressure Therapy System from 2010 to 2011
- 37 open abdomen patients who were managed with the Barker’s technique from 2009 to 2010
- The 37 patients managed with the Barker’s technique were the most recent patients treated before the facility transitioned to using the ABTHERA™ System

• Univariate analysis identified only three statistically significant differences between the study populations:
  • BMI was higher in the ABTHERA™ Therapy group (32 kg/m² vs 27 kg/m²) p<0.05
  • Mean age was higher in the ABTHERA™ Therapy group (55 years vs 47 years) p<0.05

According to the authors

- Failure to achieve midline fascial closure leads to large ventral hernias needing subsequent repair
- The cost of a ventral hernia repair may be calculated at $16,000. Reference: HCUP (October 2012) data were used to calculate the cost savings associated with the cost avoidance of ventral hernia repairs
- The difference in closure rates between the techniques may have prevented an estimated 11 ventral hernia repairs, which may have resulted in an overall cost savings of $176,000
During *in vitro* testing, ABTHERA™ Therapy was shown to provide better negative pressure distribution and fluid removal than other TAC techniques.\(^7\)

ABTHERA™ Therapy has been shown to provide rapid fluid removal through enhanced pressure distribution.\(^*\)

ABTHERA™ Therapy and V.A.C.® Abdominal Dressing System demonstrated significantly higher negative pressure distribution \((p<0.05)\) than Barker’s vacuum-packing technique during *in vitro* testing.

ABTHERA™ Therapy has been shown to provide rapid and complete fluid removal through enhanced pressure distribution.\(^*\)

*In vitro test model designed to simulate OA physical condition – Constant -125mmHg negative pressure applied under dynamic conditions.*
KEY FEATURES

ABTHERA™ Therapy is provided via the ABTHERA™ Therapy Unit or an approved KCI V.A.C.® Therapy Unit*

- Provides continuous negative pressure to remove high-volume exudate
- Designed for simplicity, ease-of-use and rapid application

ABTHERA™ Drape
Provides a closed system to help isolate and protect abdominal contents from external environment

ABTHERA™ Perforated Foam
Negative pressure delivered through the foam provides medial tension, which helps minimize fascial retraction and loss of domain

ABTHERA™ Visceral Protective Layer
- Enhances fluid removal from paracolic gutters
- Allows rapid access for re-entry
- No sutures required for placement, minimizing fascial damage
- Provides separation between abdominal wall and viscera, protecting abdominal contents

*Please see Instructions for Use or sterile pouch label provided with the ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing.
ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Quantity</th>
<th>Item number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABTHERA™ Therapy Unit</td>
<td>1 therapy unit</td>
<td>370500</td>
</tr>
<tr>
<td>ABTHERA™ Canister</td>
<td>20 per case</td>
<td>370620</td>
</tr>
<tr>
<td>ABTHERA™ Open Abdomen Tubing Set</td>
<td>5 per case</td>
<td>370642</td>
</tr>
<tr>
<td>ABTHERA™ Open Abdomen Dressing (includes Visceral Protective Layer, Perforated Foam, Drape and Tubing Set)</td>
<td>5 per case</td>
<td>370605</td>
</tr>
<tr>
<td>ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing* (includes Visceral Protective Layer, Perforated Foam, Drape and SENSAT.R.A.C.™ Tubing Set)</td>
<td>5 per case</td>
<td>M8275026/5</td>
</tr>
</tbody>
</table>

*ABTHERA™ Therapy is provided via KCI-approved V.A.C.™ Therapy Units; please see Instructions for Use or sterile pouch label provided with the ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing.

References


Contact KCI today – visit ABTHERA.com or call 800-275-4524

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.

©2016 KCI Licensing, Inc. All Rights Reserved. All trademarks designated herein are proprietary to KCI Licensing, Inc., its affiliates and licensors. DSL#16-0144-US • LIT#29-A-218 • (Rev. 5/16)