A Review of Preclinical Time Savings Data
and
A Surgeon Clinical Experience Survey*

Unique design.
Exceptional performance.
Significant results.

Results you can count on.

At BARD, we believe success is measured in every step of the repair. We utilize proven materials that are designed to work together, along with proven surgical techniques. Our goal is to help you achieve a strong, long-term repair for your patients while increasing effectiveness for you and your OR team.

As part of our ongoing commitment to share data, we have undertaken a preclinical porcine study to help demonstrate the advantages of the BARD Echo PS™ Positioning System during a laparoscopic ventral hernia repair when compared to the same procedure using four transfascial positioning sutures.

*All study participants were paid consultants for Davol Inc.
Study Design

- 17 general surgeons
- Preclinical porcine model
- Mesh size: 8” x 10” (20cm x 25cm)

Methods

- Surgeons implanted two pieces of mesh in random order
  - Ventralight™ ST Mesh with four transfascial positioning sutures
  - Ventralight™ ST Mesh with ECHO PS™ Positioning System
- Time from mesh preparation through initial perimeter fixation with SorbaFix™ Absorbable Fixation System was recorded

Statistically Significant Results

Ventralight™ ST Mesh with ECHO PS™ Positioning System demonstrated a 39% time savings vs. mesh alone, placed with four transfascial sutures. When looking at the mesh positioning portion of the procedure in particular, ECHO PS™ Positioning System demonstrated a 61% time savings.

Surgeon Profile

<table>
<thead>
<tr>
<th></th>
<th>Average</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years Post-Residency</td>
<td>12</td>
<td>2-37</td>
</tr>
<tr>
<td>Hernia Repairs / Year</td>
<td>143</td>
<td>25-400</td>
</tr>
<tr>
<td>Ventral Hernia Repairs / Year</td>
<td>40</td>
<td>20-115</td>
</tr>
<tr>
<td>Percent Repaired Laparoscopically</td>
<td>86</td>
<td>35-100</td>
</tr>
<tr>
<td>Clinical Experience (# of cases) with ECHO PS™ Positioning System</td>
<td>18</td>
<td>3-100</td>
</tr>
</tbody>
</table>

Collectively, ECHO PS™ Positioning System experience amongst the study participants represented over 300 clinical uses of the device.

Procedure time variability in the ECHO PS™ Positioning System group was reduced by 84%

A 2007 article in OR Manager suggests that more consistent procedure times may lead to greater operating efficiencies in addition to reduced start time tardiness, fewer excess staffing costs, and better results on patient satisfaction surveys.4

Preclinical results may not correlate to performance in humans.

Davol sponsored and designed in conjunction with:

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*Preclinical results may not correlate to performance in humans.
We asked participating surgeons about their clinical experience with Echo PS™ Positioning System:

- “Saves time in the OR vs. laparoscopic ventral hernia repair without Echo PS™ Positioning System”
  - Agree: 82%
  - Strongly Agree: 6%
  - Disagree: 12%
  - Strongly Disagree: 6%

- “Makes lap ventral hernia repairs easier”
  - Agree: 82%
  - Strongly Agree: 18%
  - Disagree: 12%
  - Strongly Disagree: 6%

- “Allows for more consistency of procedure time which leads to OR efficiencies”
  - Agree: 76%
  - Strongly Agree: 12%
  - Disagree: 12%
  - Don’t Know/Not Sure: 12%

- “Makes mesh placement and positioning more accurate”
  - Agree: 76%
  - Strongly Agree: 24%
  - Disagree: 35%
  - Don’t Know/Not Sure: 6%

- “Is a consistent and reliable technique for lap mesh placement, positioning and fixation”
  - Agree: 65%
  - Strongly Agree: 35%
  - Disagree: 12%
  - Don’t Know/Not Sure: 12%

16 out of 17 surgeons surveyed agreed that less time under anesthesia could be a patient benefit of doing a hernia repair with the Echo PS™ Positioning System.

Literature suggests that shorter anesthesia durations may be associated with:

- Reduced postoperative infection rates
- Reduced length of stay
- Reduced postoperative nausea and vomiting
- Reduced pulmonary complications

Collectively, Echo PS™ Positioning System experience amongst the survey participants represented over 300 clinical uses of the device.

**Echo PS™ Positioning System: Potential Economic Benefits**

**Time Savings**

Survey Question: “How much OR time on average does Echo PS™ Positioning System save you?”

**Average = 25 min. savings (10-60 min. savings)**

**Value**

- If Echo PS™ Positioning System saves an average of 25 minutes, at an average OR cost of $66/min, it could save a hospital $1,650 per patient
- In cases where Echo PS™ Positioning System saves 60 minutes, the OR cost savings may be approximately $4,000

If a hospital averages three large ventral hernia repairs each month, it could save approximately $60,000 annually using the Echo PS™ Positioning System.
VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System is a low profile, bioresorbable, coated, permanent mesh, with a pre-attached removable positioning system, designed for the reconstruction of soft tissue deficiencies during laparoscopic ventral hernia repair.

**Indications**
VENTRALIGHT™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias. The ECHO PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.

**Contraindications**
Literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

**Warnings**
VENTRALIGHT™ ST Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The ECHO PS™ Positioning System (including the balloon, all connectors, and inflation tube) is to be removed from the patient and appropriately discarded as it is not part of the permanent implant.

The ECHO PS™ Positioning System should not be used with any other hernia prosthesis aside from those with which it comes pre-attached/packaged.

**Precautions**
Do not trim the mesh. This will affect the interface between the mesh and positioning system.

**Adverse Reactions**
Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect.

Please consult package insert for more detailed safety information and instructions for use.

1-3 Surgeons were paid consultants for Davol Inc.
4 “Are your operating rooms ‘efficient?’” OR Manager. December 2007; Vol.23, No 12.